

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 417, 422, 423, 455, and 460

Office of the Secretary

45 CFR Part 170

[CMS–4205–P]

RIN 0938–AV24

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

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: Proposed rule.

SUMMARY: This proposed rule would 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 proposed rule also includes proposals to codify existing sub-regulatory guidance in the Part C and Part D programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 5, 2024.

ADDRESSES: In commenting, please refer to file code CMS–4205–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following

address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4205–P, P.O. Box 8013, Baltimore, MD 21244.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4205–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT:

Carly Medosch, (410) 786–8633—General Questions.

Naseem Tarmohamed, (410) 786–0814—Part C and Cost Plan Issues.

Lucia Patrone, (410) 786–8621—Part D Issues.

Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeal Issues.

Kelley Ordonio, (410) 786–3453—Parts C and D Payment Issues.

Hunter Coohill, (720) 853–2804—Enforcement Issues.

Lauren Brandow, (410) 786–9765—PACE Issues.

Sara Klotz, (410) 786–1984—D–SNP Issues.

Joe Strazzire, (410) 786–2775—RADV Audit Appeals Issues.

Alexander Baker, (202) 260–2048—Health IT Standards.

PartCandDStarRatings@cms.hhs.gov—Parts C and D Star Ratings Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is

identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at <https://www.regulations.gov/>.

I. Executive Summary

A. Purpose

The primary purpose of this proposed 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 proposed rule includes a number of new policies that would improve these programs beginning with contract year 2025 and proposes to codify existing Part C and Part D sub-regulatory guidance. Please note that the new marketing and communications policies in this rule are proposed to be applicable for all contract year 2025 marketing and communications, beginning September 30, 2024. This proposed rule also includes revisions to existing regulations in the Risk Adjustment Data Validation (RADV) audit appeals process and the appeals process for quality bonus payment determination that would take effect and apply 60 days after publication of a final rule. Revisions to existing regulations for the use and release of risk adjustment data would also take effect and apply 60 days after publication of a final rule. A limited number of the provisions in this rule are proposed to be applicable beginning with coverage on and after January 1, 2026.

Additionally, this proposed 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.
- The Consolidated Appropriations Act (CAA), 2023.

B. Summary of the Major Provisions

1. Improving Access to Behavioral Health Care Providers

We propose regulatory changes that would improve access to behavioral health care by adding certain behavioral health provider specialties to our MA network adequacy standards. Specifically, we propose to add a new facility-specialty type to the existing list of facility-specialty types evaluated as part of our network adequacy reviews. The new facility-specialty type, “Outpatient Behavioral Health,” would be included in network adequacy

evaluations and 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. MFTs and MHCs will be eligible to enroll in Medicare and start billing for services beginning January 1, 2024, 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 requirements for MA organizations.

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

We are proposing regulatory changes that would help ensure that SSBCI items and services offered are appropriate and improve or maintain the health or overall function of chronically ill enrollees. First, we are proposing to require that an MA organization must be able to demonstrate through 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, and must, by the date on which it submits its bid to CMS, establish a bibliography of this evidence. Second, we are proposing to clarify 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 proposing to require that the MA plan document its denials of SSBCI eligibility rather than its approvals. Additionally, we are proposing to codify 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 propose to codify CMS's authority to review SSBCI offerings annually for compliance, considering the evidence available at the time. These proposals, if implemented, would better ensure that the benefits offered as SSBCI are reasonably expected to improve 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 evidence.

In addition, we are proposing 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 propose to modify and strengthen the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned. Specifically, we propose 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. We propose 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 other coverage criteria also apply. We also propose to establish 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 propose to clarify that MA organizations must 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.

3. 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. It is not clear whether MA plans are actively encouraging utilization of these benefits by their enrollees. We propose requiring MA plans to notify enrollees mid-year of the unused supplemental benefits available to them. The notice would list any supplemental benefits not utilized by the beneficiary during the first 6 months of the year (1/1 to 6/30). Currently, MA plans are not required to send any communication specific to an enrollee's usage of supplemental benefits which could be an important part of a plan's overall care coordination efforts. This policy aims to 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.

4. Enhance Guardrails for Agent and Broker Compensation

Section 1851(j) of the Act requires that CMS develop guidelines to ensure that compensation to agents and brokers creates incentives to enroll individuals in MA plans that are 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 have the effect of circumventing compensation caps. We also note that that these additional payments appear to be increasing. In this rule, we are proposing to generally prohibit contract terms between MA organizations and agents, brokers or other third party marketing organizations (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 compensation rate for all plans; 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 proposing to make conforming edits to the Part D agent broker compensation rules at § 423.2274. Collectively, we believe the impact of these proposed changes will better align with statutory requirements and intent: 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.

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

We are proposing regulatory changes to the composition and responsibilities of the Utilization Management (UM) committee. We propose to require that a member of the UM committee have expertise in health equity. We also propose that the UM committee conduct an annual health equity analysis of the use of prior authorization. The proposed

analysis would 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, 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. Finally, we propose to require MA organizations to make the results of the analysis publicly available on their website in a manner that is easily accessible and without barriers.

6. Amendments to Part C and Part D Reporting Requirements

We are proposing to affirm 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 Medicare Advantage and Part D. This proposal would lay the groundwork for new data collection to be established through the Paperwork Reduction Act (PRA) process, which would 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.

7. 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. We are proposing 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 provision requiring the

forfeiture of an enrollee's right to appeal a termination of services decision when they leave the facility. These proposals would 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.

8. Additional Changes to an Approved Formulary—Substituting Biosimilar Biological Products

Under current policy, Part D sponsors must 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. 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 can remain on the reference product until the end of the plan year without having to obtain an exception. To increase access to biosimilar biological products, including interchangeable biological products, in the Part D program, 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 previously proposed to permit Part D sponsors either to immediately substitute interchangeable biological products for their reference products and/or to treat such substitutions as changes applicable to all enrollees following 30 days' notice.¹ As we continue to consider comments received on that proposal, we are now also proposing 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. This proposed policy regarding formulary substitution of biosimilar biological products would parallel our

¹ See section III.Q., Changes to an Approved Formulary, of 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** (87 FR 79452) (hereinafter referred to as the December 2022 proposed rule).

current notice policy for formulary changes that cannot take place immediately. Under current § 423.120(b)(5)(i), Part D sponsors must give 30 days' advance notice to affected enrollees before removing or changing the tiered cost-sharing status of a Part D drug, unless, for instance, the formulary change qualifies for an immediate substitution. This proposal would not permit immediate formulary substitution of biosimilar biological products other than interchangeable biological products.

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

We are proposing 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, its parent organization, or entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO. This proposed rule would increase the percentage of dually eligible MA enrollees who are in plans that 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 would also reduce the number of 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.

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

We are proposing to limit out-of-network cost sharing for D-SNP preferred provider organizations (PPOs) for specific services. The proposed rule would 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.

11. 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 proposing to lower the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026. This proposal would 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.

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

We propose 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 proposal would 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 proposing 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 also propose several other revisions to our regulatory appeals process to conform with these proposed changes to our procedures.

C. Summary of Costs and Benefits

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TABLE A1

Provision	Description	Financial Impact
1. Improving Access to Behavioral Health Care Providers	We propose 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 would be evaluated using time and distance and minimum number standards proposed here. The new facility type would include MFTs, MHCs, OTP or other behavioral health and addiction medicine specialists and facilities.	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.
2. Special Supplemental Benefits for the Chronically Ill (SSBCI)	We propose 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 would 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 proposing 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 propose to modify and strengthen the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned.	The proposed requirements for SSBCI are not expected to have any economic impact on the Medicare Trust Fund.
3. Mid-Year Enrollee Notification of Available Supplemental Benefits	We propose to require MA plans to issue notices to enrollees who, by June 30 th 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 the intent is to increase 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.

Provision	Description	Financial Impact
4. Enhance Guardrails for Agent/Broker Compensation	We propose modifications to 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.	There is a paperwork burden of about \$31 million annually. Other effects cannot be analyzed at this time because of uncertainty; however, we expect any impact would be minimal. See the Regulatory Impact Analysis for further discussion.
5. Annual Health Equity Analysis of Utilization Management Policies and Procedures	We propose 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.
6. Amendments to Part C and Part D Reporting Requirements	We propose to affirm our authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements.	We do not expect any cost impact to the Medicare Trust Fund.
7. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services	We propose 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.	We do not expect any cost impact to the Medicare Trust Fund.
8. Additional Changes to an Approved Formulary—Substituting Biosimilar Biological Products	We propose to permit biosimilar biological products ² to be substituted for their reference products without requiring that enrollees currently taking the reference product be exempt from the change for the remainder of the contract year.	We do not expect any cost impact to the Medicare Trust Fund.
9. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization	We propose to (a) replace the current dual/LIS quarterly SEP, (b) create a new integrated care SEP, (c) limit enrollment in certain D-SNPs to those 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.
10. For D-SNP PPOs, Limit Out-of-Network Cost Sharing	We propose to limit 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.

Provision	Description	Financial Impact
<p>11. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes</p>	<p>We propose to lower the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026.</p>	<p>We estimate this provision would 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 would 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.</p>
<p>12. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process</p>	<p>Revising when a medical record review determination and a payment error calculation appeal can be requested and adjudicated is necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations. We are also proposing other revisions to our regulatory appeals process to conform with these proposed changes. The proposed changes could reduce burden on some MA organizations that, absent these revisions, would 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 and execution of the appeals process pursuant to these changes. 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 proposed policies on MA organization behavior is further unquantifiable. The proposed changes do not impose any new information collection requirements.</p>	<p>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.</p>

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

We established at §§ 422.502(b) and 423.503(b) that we may deny an

² We previously proposed that would provide Part D sponsors (choosing not to or unable to qualify to make immediate substitutions as proposed) the option to treat substitutions of interchangeable biological products for their reference products as changes applicable to all enrollees requiring 30 days' notice for those currently taking a related reference product. See

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 are proposing 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

section III.Q. of the December 2022 proposed rule. These and other proposals discussed in section III.Q. of the December 2022 proposed rule have not been finalized and remain under consideration.

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 propose to

change “Was subject to the imposition of an intermediate sanction” to “Was under an intermediate sanction.” We are proposing 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 filed 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,” final rule 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 propose 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 program or the beneficiaries they serve. This concern is equally applicable to both Federal and State bankruptcy, so we propose 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 are also proposing to correct two technical issues identified since the final rule was published in May 2022. At § 422.502(b)(1)(i)(B), we propose 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 propose to remove the duplication of § 422.502(b)(1)(i)(A) and (B).

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

A. 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 are proposing 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 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(III) of the Act)

and MHC services (as defined in section 1861(III) 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(III)(2) of the Act, and MHCs, as defined in section 1861(III)(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 would 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) waived 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 is proposing 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 would be possible under a combined behavioral health specialty

CMS is committed to improving access to behavioral health care services for enrollees in the MA program. The CMS Behavioral Health Strategy,³ aims to improve access and quality of mental health care and services, including, access to substance use disorder prevention and treatment services. We propose 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 are proposing 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(III) of the Act), MHCs (as defined in section 1861(III) 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 are proposing to add this combined facility-specialty type instead

³ <https://www.cms.gov/cms-behavioral-health-strategy>.

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.^{4,5} 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 (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 list⁶ 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 would be best evaluated separately for MFTs, MHCs, or OTPs instead of under the one facility-specialty type we are proposing in this rule. Any related changes would be proposed in future rulemaking. At this time, we are proposing that MA organizations are allowed to include on their facility HSD tables the following: contracted individual practitioners, group practices, or facilities that are applicable under this specialty type. Under this proposal, MA organizations may not submit a single provider, for purposes of meeting more than one of our provider network requirements, for example, they cannot submit a single provider as a psychiatry, clinical social work, or clinical psychologist provider specialty and also 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 are proposing base time and distance standards in each county type for the new specialty type as follows:

TABLE CA-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 paragraphs (b)(2)(ii) through (xiv) and are proposing to add Outpatient Behavioral Health as a facility type at paragraph (b)(2)(xiv), we are not proposing any revisions to paragraph (e)(2)(iii). We followed the analysis and methodology described in the February 2020 proposed rule to

⁴ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Marriage and Family Therapists, at <https://www.bls.gov/ooh/marriage-and-social-service/marriage-and-family-therapists.htm> (visited July 03, 2023).

⁵ 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-](https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm)

[disorder-and-mental-health-counselors.htm](https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm) (visited July 06, 2023).

⁶ <https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers>.

develop the time and distance standards that we propose 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 propose to add the new Outpatient Behavioral Health facility-specialty type to the list at § 422.116(d)(5) of the specialty types that 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 welcome comment on this proposal.

B. Standards for Electronic Prescribing (§ 423.160)

1. Legislative Background

Section 1860D–4(e) of the Act requires the adoption of Part D e-prescribing standards. Part D sponsors are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. For a further discussion of the statutory requirements at section 1860D–4(e) of the Act, refer to the proposed rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” which appeared in the February 4, 2005 **Federal Register** (70 FR 6255). Section 6062 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271),

hereinafter referred to as the SUPPORT Act, amended section 1860D–4(e)(2) of the Act to require the electronic transmission of ePA requests and responses for the Part D e-prescribing program to ensure secure ePA request and response transactions between prescribers and Part D sponsors for covered Part D drugs prescribed to Part D-eligible individuals. Such electronic transmissions must comply with technical standards adopted by the Secretary. There is generally no requirement that Part D prescribers or dispensers implement e-prescribing, with the exception of required electronic prescribing of Schedule II, III, IV, and V controlled substances that are Part D drugs, consistent with section 2003 of the SUPPORT Act and as specified at § 423.160(a)(5). However, prescribers and dispensers who electronically transmit and receive prescription and certain other information regarding covered Part D drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

2. Regulatory History

As specified at § 423.160(a)(1), Part D sponsors are required to support the Part D e-prescribing program transaction standards as part of their electronic prescription drug programs. Likewise, as specified at § 423.160(a)(2), prescribers and dispensers that conduct electronic transactions for covered Part D drugs for Part D eligible individuals for which a program standard has been adopted must do so using the adopted standard. Transaction standards are periodically updated to take new knowledge, technology, and other considerations into account. As CMS adopted specific versions of the standards when it initially adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the healthcare industry. CMS discussed these processes in the final rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” (hereinafter referred to as “the November 2005 final rule”) which appeared in the November 7, 2005 **Federal Register** (70 FR 67579). An account of successive adoption of new and retirement of previous versions of various e-prescribing standards is described in the final rule titled “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee

Schedule & Other Revisions to Part B for CY 2014,” which appeared in the December 10, 2013 **Federal Register** (78 FR 74229); the proposed rule titled “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program,” which appeared in the November 28, 2017 **Federal Register** (82 FR 56336); and the corresponding final rule (83 FR 16440), which appeared in the April 16, 2018 **Federal Register**. The final rule titled “Medicare Program; Secure Electronic Prior Authorization For Medicare Part D,” which appeared in the December 31, 2020 **Federal Register** (85 FR 86824), codified the requirement that Part D sponsors support the use of NCPDP SCRIPT standard version 2017071 for certain ePA transactions (85 FR 86832).

The final rule titled “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses,” which appeared in the May 23, 2019 **Federal Register** (84 FR 23832), codified at § 423.160(b)(7) the requirement that Part D sponsors adopt an electronic RTBT capable of integrating with at least one prescriber's electronic prescribing or electronic health record (EHR) system, but did not name a standard since no standard had been identified as the industry standard at the time (84 FR 23851). The electronic standards for eligibility transactions were codified in the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 **Federal Register** (77 FR 29001), to align with the applicable Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards.

The Part D program has historically adopted electronic prescribing standards independently of other HHS components that may adopt electronic prescribing standards under separate authorities; however, past experience has demonstrated that duplicative adoption of health IT standards by other agencies within HHS under separate authorities can create significant burden on the healthcare industry as well as HHS when those standards impact the same technology systems. Notably, independent adoption of the NCPDP SCRIPT standard version 2017071 by CMS in various subsections of § 423.160 (83 FR 16638) in 2018, which required use of the standard beginning in 2020, led to a period where ONC had to exercise special enforcement discretion

in its Health Information Technology (IT) Certification Program until the same version was incorporated into regulation at 45 CFR 170.205(b)(1) through the final rule titled “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,” which appeared in the May 1, 2020 **Federal Register** (85 FR 25679). This resulted in significant impact on both ONC and CMS program resources. See section III.C. of this proposed rule for additional discussion of ONC’s proposal and authority. Similarly, the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 **Federal Register** (77 FR 29002), noted that, in instances in which an e-prescribing standard has also been adopted as a HIPAA transaction standard in 45 CFR part 162, the process for updating the e-prescribing standard would have to be coordinated with the maintenance and modification of the applicable HIPAA transaction standard (77 FR 29018).

3. Withdrawal of Previous Proposals and Summary of New Proposals

CMS published a 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” (hereinafter referred to as “the December 2022 proposed rule”), which appeared in the **Federal Register** December 27, 2022 (87 FR 79452), in which we proposed updates to the standards to be used by Medicare Part D prescription drug plans for electronic prescribing (e-prescribing). The proposals in the December 2022 proposed rule included a novel approach to updating e-prescribing standards by proposing to cross-reference Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards adopted by HHS for electronic transactions under HIPAA⁷ rather than

the historical approach of adopting e-prescribing standards in the Part D regulations independently or making conforming amendments to the Part D regulations in response to updated HIPAA standards for eligibility transactions. We proposed this approach in concert with ONC in order to mitigate potential compliance challenges for the healthcare industry and enforcement challenges for HHS that could result from independent adoption of such standards.⁸

In summary, the proposals in the December 2022 proposed rule included the following:

- Requiring the National Council for Prescription Drug Plans (NCPDP) SCRIPT standard version 2022011, proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for transmitting prescriptions and prescription-related information, medication history, and electronic prior authorization (ePA) transactions using electronic media for covered Part D drugs for Part D eligible individuals. This proposal included a transition period from July 1, 2023 up to January 1, 2025, when either version of the NCPDP SCRIPT standard could be used. The cross citation to 45 CFR 170.205(b) included an expiration date of January 1, 2025 for NCPDP SCRIPT standard version 2017071 meaning that this version would expire for the purposes of HHS use and entities named at § 423.160(a)(1) and (2) could use only NCPDP SCRIPT standard version 2022011 as of that date;
- Requiring the NCPDP Real-Time Prescription Benefit (RTPB) standard version 12, proposed for adoption at 45 CFR 170.205(c), as the standard for prescriber real-time benefit tools (RTBTs) supported by Part D sponsors beginning January 1, 2025; and
- Revising regulatory text referring to standards for eligibility transactions (87 FR 79548) to cross reference standards adopted for electronic eligibility transactions in the HIPAA regulations at 45 CFR 162.1202.

We received 24 comments related to these proposals by the close of the comment period on February 13, 2023. Commenters largely supported the proposals; however, several commenters, including NCPDP, recommended that CMS require use of

NCPDP SCRIPT standard version 2023011, rather than NCPDP SCRIPT standard version 2022011. Similarly, NCPDP and other commenters recommended that CMS require NCPDP RTPB standard version 13, rather than NCPDP RTPB standard version 12.

Several commenters expressed concerns about being able to successfully transition to NCPDP SCRIPT standard version 2022011 by January 1, 2025, and requested at least 2 years from publication of a final rule to sunset NCPDP SCRIPT standard version 2017071. Several commenters noted that if the implementation of NCPDP SCRIPT standard version 2022011 (or NCPDP SCRIPT standard version 2023011, as recommended by some commenters) is delayed, the January 1, 2025 compliance deadline for electronic prescribing of controlled substances (EPCS) in long-term care (LTC) facilities, as codified at § 423.160(a)(5), should also be delayed accordingly, since the new versions of the NCPDP SCRIPT standard permit 3-way communication between the prescriber, LTC pharmacy, and LTC facility, enabling EPCS to occur reliably in the LTC setting.

A commenter expressed concern that requiring use of the NCPDP SCRIPT standard imposes a financial barrier for independent pharmacies since NCPDP membership is required to access standards. CMS’s requirements at § 423.160(a)(2) do not require that all pharmacies transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media for Part D drugs for Part D-eligible individuals, but (subject to exemptions in § 423.160(a)(3)) § 423.160(a)(2) does require that when pharmacies do so, they must comply with the Part D electronic prescribing standards. CMS’s understanding is that a pharmacy management system vendor or software developer is the entity that incurs the direct costs associated with accessing the code and implementation guide associated with updating standards, not the pharmacy itself. We acknowledge that these costs may be passed on through license fees that the vendor charges to the pharmacy as normal costs of doing business. We are not aware of any open-source standards that could replace the NCPDP standards in the Part D program, but we invite comments on this topic. We also note in section III.C.10. of this proposed rule that interested parties may view materials proposed for incorporation by reference for free by following the instructions provided.

CMS has considered these comments, reviewed NCPDP SCRIPT standard

⁷ HIPAA mandated the adoption of standards for electronically conducting certain health care administrative transactions between certain entities. HIPAA administrative requirements are codified at 45 CFR part 162. See also: <https://www.cms.gov/about-cms/what-we-do/administrative-simplification>.

⁸ Due to discrepancies between prior regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program. See section III.C.5. for additional discussion.

version 2023011 and NCPDP RTPB standard version 13, and identified areas where we can reorganize the regulatory text in § 423.160.

Consequently, CMS is withdrawing all proposals contained in section III.S. Standards for Electronic Prescribing (87 FR 79548) of the December 2022 proposed rule. This approach will allow CMS to incorporate the feedback we received on prior proposals, seek comment on concerns raised in response to prior proposals, add new proposals, reorganize and make technical changes to the electronic prescribing regulations at § 423.160, and allow the public to comment on all Medicare Part D electronic prescribing-related proposals simultaneously.

In sections III.B.4. through III.B.9. of this proposed rule, the new proposals related to standards for electronic prescribing that we are putting forth encompass the following:

- Requiring use of NCPDP SCRIPT standard version 2023011, proposed for adoption at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071 for communication of a prescription or prescription-related information supported by Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule during which either version of the NCPDP SCRIPT standard may be used. The transition period would end on January 1, 2027, which is the date that ONC has proposed that NCPDP SCRIPT standard version 2017071 would expire for the purposes of HHS use, as described in section III.C.8.a. of this proposed rule. If finalized as proposed, starting January 1, 2027, NCPDP SCRIPT standard version 2023011 would be the only version of the NCPDP SCRIPT standard available for HHS use and for purposes of the Medicare Part D electronic prescribing program;

- Requiring use of NCPDP RTPB standard version 13 for prescriber RTBTs implemented by Part D sponsors beginning January 1, 2027;

- Requiring use of NCPDP Formulary and Benefit (F&B) standard version 60, proposed for adoption at 45 CFR 170.205(u), and retiring use of NCPDP F&B version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule and ending January 1, 2027, during which entities would be permitted to use either NCPDP F&B version 3.0 (currently named in regulation at § 423.160(b)(5)(iii) and proposed to be named at § 423.160(b)(3) consistent with

the proposed technical changes in this rule) or NCPDP F&B standard version 60, proposed for adoption at 45 CFR 170.205(u). If finalized as proposed, starting January 1, 2027, only a version of the standard adopted for HHS use at 45 CFR 170.205(u) would be permitted for use in Part D electronic prescription drug program, which would be NCPDP F&B standard version 60 if the proposal in section III.C.8.c. of this rule is finalized as proposed;

- Cross-referencing standards adopted for eligibility transactions in HIPAA regulations at 45 CFR 162.1202 for requirements related to eligibility inquiries; and
- Making multiple technical changes to the regulation text throughout § 423.160 by removing requirements and incorporations by reference that are no longer applicable, re-organizing existing requirements, and correcting a technical error.

In these proposals, we propose a novel approach to updating e-prescribing standards by cross-referencing Part D e-prescribing requirements with standards, including any expiration dates, adopted by ONC, as discussed in section III.C.5. of this proposed rule, and the standards adopted by HHS for electronic transactions under HIPAA. This approach differs from our historical approach of adopting e-prescribing standards in the Part D regulations independently or undertaking rulemaking to make conforming amendments to the Part D regulations in response to updated HIPAA standards for eligibility transactions.⁹ As ONC notes in section III.C.5., independent adoption of the NCPDP SCRIPT standard version 2017071 in different rules¹⁰ led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT

⁹ HIPAA eligibility transaction standards were updated in final rule titled “Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards,” which appeared in the January 16, 2009 *Federal Register* (74 FR 3296). Conforming amendments to the Part D regulation were made in the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 *Federal Register* (77 FR 29002).

¹⁰ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, which appeared in the May 1, 2020 *Federal Register* (85 FR 25642), and 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* (83 FR 16440).

Certification Program. We believe the proposed approach would mitigate potential compliance challenges for the healthcare industry and enforcement challenges for HHS that could result from independent adoption of such standards or asynchronous rulemaking cycles across programs. CMS invites comment on all aspects of these proposals. We also solicit comment on our proposals to cross-reference ONC regulations adopting NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60. We solicit comment on the effect of the proposals that, taken together, would require use of these standards by January 1, 2027, as a result of ONC’s proposals to adopt these standards and retire previous versions, as well as our proposal to require use NCPDP F&B standard version 60 by that date.

The NCPDP SCRIPT standards are used to exchange information among prescribers, dispensers, intermediaries, and Medicare prescription drug plans (PDPs). NCPDP has requested that CMS adopt NCPDP SCRIPT standard version 2023011 because this version provides a number of enhancements to support electronic prescribing and transmission of prescription-related information.¹¹ Accordingly, we propose to update § 423.160 to specify where transactions for electronic prescribing, medication history, and ePA are required to utilize the NCPDP SCRIPT standard. The proposal, in conjunction with ONC’s proposal as described in section III.C.8.a. of this proposed rule, will allow for a transition period where either NCPDP SCRIPT standard version 2017071 or 2023011 can be used, with exclusive use of NCPDP SCRIPT standard version 2023011 required by January 1, 2027. As described in section III.B.7., we solicit comment on the date by which use of the updated version of this and other standards proposed in this proposed rule would be required, if finalized as proposed.

The NCPDP RTPB standard enables the real-time exchange of patient-specific eligibility, product coverage (including any restrictions and alternatives), and estimated cost sharing so prescribers have access to this information through a RTBT application

¹¹ National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdpd.org. The NCPDP SCRIPT standard version 2023011 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

at the point-of-prescribing.^{12 13} As discussed in section III.B.5. of this proposed rule, as currently codified at § 423.160(b)(7), CMS requires that Part D sponsors implement one or more electronic RTBTs that are capable of integrating with at least one prescriber's electronic prescribing system or electronic health record, as of January 1, 2021; however, at the time CMS established this requirement, no single industry RTPB standard was available. NCPDP has since developed an RTPB standard. We propose to require the most current version, NCPDP RTPB standard version 13, as the standard for prescriber RTBTs at § 423.160(b)(5) starting January 1, 2027.

The NCPDP F&B standard is a batch standard that provides formulary and benefit information at the plan level rather than at the patient level. The NCPDP F&B standard complements other standards utilized for electronic prescribing, electronic prior authorization, and real-time prescription benefit applications.^{14 15} We propose to require use of NCPDP F&B standard version 60, and retire NCPDP F&B standard version 3.0, beginning January 1, 2027, and after a transition period during which either version may be used.

Eligibility inquiries utilize the NCPDP Telecommunication standard or Accredited Standards Committee X12N 270/271 inquiry and response transaction for pharmacy or other health benefits, respectively. The Part D program has adopted standards based on the HIPAA electronic transaction

standards, which have not been updated for more than a decade. HHS has proposed updates to the HIPAA electronic transaction standards for retail pharmacies (87 FR 67638) in the proposed rule titled “Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard.” (hereinafter referred to as “the November 2022 Administrative Simplification proposed rule”), which appeared in the **Federal Register** November 9, 2022 (87 FR 67634). We propose to update the Part D regulation at § 423.160(b)(3) to require that eligibility transactions utilize the applicable standard named as the HIPAA standard for electronic eligibility transactions at 45 CFR 162.1202. Since 45 CFR 162.1202 currently identifies the same standards that are named at § 423.160(b)(3)(i) and (ii), we anticipate no immediate impact from this proposed change in regulatory language. Our proposal, however, would ensure that Part D electronic prescribing requirements for eligibility transactions align with the HIPAA standard for electronic eligibility transactions should a newer version of the NCPDP Telecommunication (or other) standards be adopted as the HIPAA standard for these types of electronic transactions, if HHS' proposals in the November 2022 Administrative Simplification proposed rule are finalized or as a result of any future HHS rules.

4. Requiring NCPDP SCRIPT Standard Version 2023011 as the Part D Electronic Prescribing Standard, Retirement of NCPDP SCRIPT Standard Version 2017071, and Related Conforming Changes in § 423.160

The NCPDP SCRIPT standard has been the adopted electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals since foundation standards were named in the final rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” which appeared in the November 7, 2005 **Federal Register** (70 FR 67568), at the start of the Part D program. The NCPDP SCRIPT standard is used to exchange information among prescribers, dispensers, intermediaries, and Medicare prescription drug plans. In addition to electronic prescribing, the NCPDP SCRIPT standard is used in electronic prior authorization (ePA) and medication history transactions.

Although electronic prescribing is optional for physicians, except as to Schedule II, III, IV, and V controlled substances that are Part D drugs prescribed under Part D, and pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit prescriptions and related communications electronically must utilize the adopted standards except in limited circumstances, as codified at § 423.160(a)(3).

NCPDP's standards development process involves a consensus-based approach to solve emerging needs of the pharmacy industry or to adapt NCPDP standards to changes made by other standards development organizations.¹⁶ Emerging needs of the pharmacy industry may be the result of legislative or regulatory changes, health IT innovations, patient safety issues, claims processing issues, or electronic prescribing-related process automation.¹⁷ Changes to standards are consensus-based and driven by the NCPDP membership, which includes broad representation from pharmacies, insurers, pharmacy benefit managers, Federal and State government agencies, and vendors serving all the stakeholders.^{18 19}

In a letter to CMS dated January 14, 2022, NCPDP requested that CMS adopt NCPDP SCRIPT standard version 2022011, given the number of updates and enhancements that had been added to the standard since NCPDP SCRIPT standard version 2017071 was adopted.²⁰ NCPDP summarized the major enhancements in NCPDP SCRIPT standard version 2022011 relative to the currently required NCPDP SCRIPT standard version 2017071. Those summarized enhancements include—

- General extensibility;²¹
- Redesign of the Product/Drug groupings requiring National Drug Code

¹⁶ <https://standards.ncdp.org/Our-Process.aspx>.

¹⁷ NCPDP University. How Industry Needs Drive Changes in Standards. Accessed August 15, 2023, from <https://member.ncdp.org> (member-only content).

¹⁸ NCPDP University. Voting: The Life Cycle of Standards Approval. Accessed August 15, 2023, from <https://member.ncdp.org> (member-only content).

¹⁹ <https://www.ncdp.org/Membership-diversity.aspx>.

²⁰ <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf>.

²¹ Extensibility is a term in software engineering that is defined as the quality of being designed to allow the addition of new capabilities or functionality. See: Ashaolu B. What is Extensibility? Converged. February 17, 2021. Available from: <https://converged.propelsoftware.com/blogs/what-is-extensibility>.

¹² National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, July 2023. NCPDP RTPB standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdp.org. The NCPDP RTPB standard version 13 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

¹³ Bhardwaj S, Miller SD, Bertram A, Smith K, Merrey J, Davison A. Implementation and cost validation of a real-time benefit tool. *Am J Manag Care*. 2022 Oct 1;28(10):e363–e369. doi: 10.37765/ajmc.2022.89254.

¹⁴ National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard, Implementation Guide, Version 60, April 2023. NCPDP F&B standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdp.org. The NCPDP F&B standard version 60 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

¹⁵ Babbrah P, Solomon MR, Stember L, Hill JW, Weiker M. Formulary & Benefit and Real-Time Pharmacy Benefit: Electronic standards delivering value to prescribers and pharmacists. *J Am Pharm Assoc*. 2023 May–June;63(3):725–730. <https://doi.org/10.1016/j.japh.2023.01.016>.

(NDC) for DrugCoded element, but not for NonDrugCoded element;

- Addition of Observation elements to Risk Evaluation and Mitigation Strategies (REMS) transactions;

- Addition of

ProhibitRenewalRequest to RxChangeResponse and RxRenewalResponse;

- Modification of Structured and Codified Sig Structure format; and

- Additional support related to dental procedure codes, RxBarCode, PatientConditions, patient gender and pronouns, TherapeuticSubstitutionIndicator, multi-party communications, and withdrawal/retracting of a previous sent message using the MessageIndicatorFlag.

Subsequently, in the December 2022 proposed rule, CMS proposed to require NCPDP SCRIPT standard version 2022011 and retire NCPDP SCRIPT standard version 2017071, after a transition period, by cross referencing the standards as proposed for adoption by ONC. In response to this proposal, NCPDP and many other commenters recommended that CMS instead adopt the more current NCPDP SCRIPT standard version 2023011. NCPDP SCRIPT standard version 2023011, like NCPDP SCRIPT standard version 2022011, includes the functionality that supports a 3-way transaction (that is, multi-party communication) among prescriber, facility, and pharmacy, which will enable EPCS in the LTC setting.²² In its comments on the December 2022 proposed rule,²³ NCPDP highlighted specific enhancements within NCPDP SCRIPT standard version 2023011 that are not present in NCPDP SCRIPT standard version 2022011, which include:

- Addition of an optional element in the header for OtherReferenceNumber for multi-party communication transactions, such as those in LTC;
- Addition of a response type of Pending for RxChangeResponse and RxRenewalResponse for communicating when to expect an approval or denial of the request or delays in approval or denial of requests;

- Addition of a new RequestExpirationDate element to NewRxRequest, RxChangeRequest, and RxRenewalRequest to notify the prescriber to not send a response after this date;

- Addition of a new a new element NoneChoiceID to PAMSelectType so that a “none of the above” answer can be selected by the provider and allow branching to the next question in a series;

- Addition of a new element for REMSReproductivePotential replacing REMSPatientRiskCategory in the prescribed medication element group in the NewRx and RxChangeRequest message and in the replace medication element group for the RxRenewalResponse;

- Addition of a new element group of ReviewingProvider to the Resupply and Recertification messages to allow for the reporting of the provider who reviewed the chart and certified continued need of a specific medication; and

- Revised guidance in the SCRIPT Implementation Guide.

NCPDP SCRIPT standard version 2023011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071. This allows for a less burdensome implementation process and flexible adoption timeline for pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing, since backwards compatibility permits a transition period where both versions of the NCPDP SCRIPT standards may be used simultaneously without the need for entities involved to utilize a translator program.

Even though we are withdrawing the proposals contained in section III.S. Standards for Electronic Prescribing in the December 2022 proposed rule (87 FR 79548), we have considered comments we received on the December 2022 proposed rule when crafting our proposals for this proposed rule. For instance, several commenters asked that CMS clearly indicate that the proposed version of the NCPDP SCRIPT standard will apply to medication history functions. Several commenters noted that the regulation text at § 423.160(b)(4)(ii) does not list the NCPDP SCRIPT standard-specific medication history transactions. Commenters asked that CMS list the corresponding medication history transactions (RxHistoryRequest and RxHistoryResponse) in the regulation text so as to minimize ambiguity. After considering these comments, we propose to list the RxHistoryRequest and RxHistoryResponse transactions at § 423.160(b)(1)(i)(U) subsequent to our

technical reorganization of the section proposed in section III.B.9. of this rule, rather than list the transactions under § 423.160(b)(4).

With respect to ePA transactions in the NCPDP SCRIPT standard currently listed at § 423.160(b)(8)(i)(A) through (D) (PAMInitiationRequest, PAMInitiationResponse, PAMRequest, PAMResponse, PAMAppealRequest, PAMAppealResponse, PACancelRequest, PACancelResponse) and a new ePA transaction (PANotification) available in NCPDP SCRIPT standard version 2023011, we propose to list all transactions at § 423.160(b)(1)(i)(V) through (Z). We are proposing new language at § 423.160(b)(1) to indicate that the transactions listed must comply with a standard in proposed 45 CFR 170.205(b) “as applicable to the version of the standard in use” since an older version of a standard may not support the same transactions as the newer version of the standard. For example, during the proposed transition period where either NCPDP SCRIPT version 2017071 or NCPDP SCRIPT standard version 2023011 may be used, entities that are still using NCPDP SCRIPT standard version 2017071 would not be expected to use the PANotification transaction because the PANotification transaction is only supported in the NCPDP SCRIPT standard version 2023011.

Since the NCPDP SCRIPT standard version 2023011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071, the pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing can accommodate a transition period when either version may be used. That is, during a transition period, transactions taking place between entities using different versions of the same standard maintain interoperability without the need for entities to utilize (that is, purchase) a translator software program. The cross reference to proposed 45 CFR 170.205(b) permits a transition period starting as of the effective date of a final rule during which either NCPDP SCRIPT standard version 2017071 or NCPDP SCRIPT standard version 2023011 may be used. If finalized as proposed, the transition period will end and exclusive use of NCPDP SCRIPT standard version 2023011 will be required starting January 1, 2027, when NCPDP SCRIPT standard version 2017071 will expire for the purposes of HHS use.

Instead of independently naming the NCPDP SCRIPT standard version 2023011 and incorporating the corresponding implementation guide by

²² National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdp.org. The NCPDP SCRIPT standard version 2023011 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

²³ https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

reference at § 423.160(c), we propose at § 423.160(b)(1) to cross reference a standard in 45 CFR 170.205(b). ONC proposes to adopt NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2) as described in section III.C.8.a. of this proposed rule. The proposed approach would enable CMS and ONC to avoid misalignment from independent adoption of NCPDP SCRIPT standard version 2023011 for their respective programs. Updates to the standard would impact requirements for both programs at the

same time, ensure consistency, and promote alignment for providers, payers, and health IT developers participating in and supporting the same prescription transactions. See section III.C.5. of this proposed rule for additional discussion of this coordination effort.

In its letter to CMS requesting CMS to adopt NCPDP SCRIPT standard version 2022011, NCPDP requested that CMS identify certain transactions for prescriptions for which use of the standard is mandatory.²⁴ As previously mentioned in this preamble, in response

to the December 2022 proposed rule, NCPDP and other commenters requested additional transactions be named in regulation. As part of our proposed reorganization of § 423.160, we propose to list all transactions associated with the NCPDP SCRIPT standard requirements in one place in the regulation. We propose the transactions for prescriptions, ePA, and medication history for which use of the standard is mandatory at § 423.160(b)(1)(i)(A) through (Z), as described in Table C–C1.

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TABLE C-C1: PROPOSED TRANSACTIONS FOR COMMUNICATION OF PRESCRIPTION AND PRESCRIPTION RELATED INFORMATION USING THE NCPDP SCRIPT STANDARD

Transaction	Function Supported by Transaction ²⁵
GetMessage	Requests from a mailbox, a renewal prescription request, prescription change request, new prescription request, prescription fill status notification, verification, transfer request, transfer response, transfer confirmation or an error or other transactions that have been sent by a pharmacy or prescriber system.
Status	Relays acceptance of a transaction back to the sender.
Error	Indicates an error has occurred indicating the request was terminated.
RxChangeRequest and RxChangeResponse	Request from a pharmacy to a prescriber asking for a change in a new or "fillable" prescription; additional usage includes verification of prescriber credentials and request on a prior authorization from the payer. Response is sent from a prescriber to the requesting pharmacy to either approve, approve with change, validate, or deny the request.
RxRenewalRequest and RxRenewalResponse	Request from the pharmacy to the prescriber requesting additional refills. Response is sent from the prescriber to the requesting pharmacy to allow pharmacist to provide a patient with additional refills, a new prescription, or decline to do either.

²⁴ <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf>.

Transaction	Function Supported by Transaction ²⁵
Resupply	Request from a Long Term or Post-Acute Care (LTPAC) organization to a pharmacy to send an additional supply of medication for an existing order.
Verify	Response to a pharmacy or prescriber indicating that a transaction requesting a return receipt has been received.
CancelRx and CancelRxResponse	Request from the prescriber to the pharmacy to inactivate a previously sent prescription. Response is sent from the pharmacy to the prescriber to acknowledge a cancel request.
RxFill	Indicates the dispensing or activity status. It is the notification from one entity to another conveying the status of dispensing activities or other clinical activities.
DrugAdministration	Communicates drug administration events from a prescriber/care facility to the pharmacy or other entity. It is a notification from a prescriber/care facility to a pharmacy or other entity that a drug administration event has occurred.
NewRxRequest	Request from a pharmacy to a prescriber for a new prescription for a patient. If approved, a NewRx transaction would be sent.
NewRx	New prescription is sent from the prescriber to the pharmacy electronically so it can be dispensed to a patient.
NewRxResponseDenied	Denied response to a previously sent NewRxRequest.
RxTransferInitiationRequest (previously named RxTransferRequest in NCPDP SCRIPT standard version 2017071)	Used when the destination pharmacy is asking for a transfer of one or more prescriptions for a specific patient from the source pharmacy.
RxTransfer (previously named RxTransferResponse NCPDP SCRIPT standard version 2017071)	In the solicited model, it is the response to the RxTransferInitiationRequest which includes the prescription(s) being transferred from the source pharmacy to the destination pharmacy or a rejection of the transfer request. In the unsolicited model, it is a push of the prescription(s) being transferred from the source pharmacy to the destination pharmacy.
RxTransferConfirm	Used by the destination pharmacy to confirm the transfer prescription has been received and the transfer is complete.
RxFillIndicatorChange	Sent to the receiver to indicate the sender is changing the types of RxFill responses that were previously requested. The sender may modify the fill status notification of transactions previously selected or cancel future RxFill transactions.
Recertification	Notification on behalf of a reviewing provider to a pharmacy recertifying the continued administration of a medication order. Used in LTPAC only.
REMSInitiationRequest and REMSInitiationResponse	Request to the REMS Administrator for the information required to submit a REMS request (REMSRequest) for a specified patient and drug. Response is from the REMS Administrator with the information required to submit a REMS request (REMSRequest) for a specified patient and drug.

Transaction	Function Supported by Transaction ²⁵
REMSRequest and REMSResponse	Request to the REMS Administrator with information (answers to question set; clinical documents) to make a REMS determination (approved, denied, pended, etc.). Response is the determination from the REMS administrator whether dispensing authorization can be granted.
RxHistoryRequest and RxHistoryResponse	Request from one entity to another for a list of medications that have been prescribed, dispensed, claimed or indicated by the patient. Response includes the medications that were dispensed or obtained within a certain timeframe, optionally including the prescriber that prescribed them.
PAInitiationRequest and PAInitiationResponse	Request from the submitter to a payer for the information required to submit a prior authorization request (PARRequest) for a specified patient and product. Response is from a payer to the submitter with the information required to submit a prior authorization request (PARRequest) for a specified patient and product.
PARRequest and PARResponse	Request from the submitter to the payer with information (answers to question set; clinical documents) for the payer to make a PA determination (approved, denied, pended, etc.). Response from the payer to the submitter indicates the status of a PARRequest. Response could be a PA determination, notice that the request is in process, or specify that more information is required.
PAAppealRequest and PAAppealResponse;	Request from the submitter to the payer to appeal a PA determination. Response from the payer to the submitter indicates what information is needed for an appeal or the status or outcome of a PAAppealRequest.
PACancelRequest and PACancelResponse	Request from the submitter to the payer to notify the payer that the PA request is no longer needed. Response from the payer to the submitter indicates the if the PA request was cancelled or not.
PANotification	Alerts the pharmacist or prescriber when a PA has been requested, or when a PA determination has been received.

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The transactions specific to electronic prescribing remain the same as those required for NCPDP SCRIPT standard version 2017071 (currently codified at § 423.160(b)(2)(iv)(A) through (Z)), except where renamed as noted in Table C-C1. The transactions specific to ePA are also the same as those required with NCPDP SCRIPT standard version 2017071, with one additional transaction (PA Notification), which was incorporated into the standard after NCPDP SCRIPT standard version 2017071. As discussed in section III.C.8.a. of this proposed rule, NCPDP SCRIPT standard version 2023011 is proposed for adoption at 45 CFR 170.205(b)(2), and NCPDP SCRIPT

standard version 2017071 is proposed to expire January 1, 2027, at 45 CFR 170.205(b)(1). Consequently, should we finalize our proposal, use of NCPDP SCRIPT standard version 2023011 for the transactions related to electronic prescribing, medication history, and ePA (proposed at § 423.160(b)(1)(i)(A) through (Z)) will be mandatory starting January 1, 2027, if ONC's proposed adoption of NCPDP SCRIPT version 2023011 and proposed expiration date for NCPDP SCRIPT version 2017071 are adopted as proposed.

²⁵ Section 4. Business Functions, and Section 5. Transactions. National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023. NCPDP SCRIPT standard implementation

As stated previously, in response to the December 2022 proposed rule, several commenters pointed out that if mandatory use of an updated version of the NCPDP SCRIPT standard is delayed, then the EPCS requirement in LTC facilities should also be delayed accordingly, since NCPDP SCRIPT standard version 2017071 lacks appropriate guidance for LTC facilities. CMS was aware of this limitation in the NCPDP SCRIPT standard version

guides are available to NCPDP members for free and to non-members for a fee at [ncdp.org](https://www.ncdp.org). The NCPDP SCRIPT standard version 2023011 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

2017071, and acknowledged the challenges to EPCS faced by LTC facilities in the proposed rule “Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements” (hereinafter referred to as “the July 2022 proposed rule”), which appeared in the **Federal Register** July 23, 2021 (86 FR 39104). However, in the July 2022 proposed rule, CMS also stated that we understood that NCPDP was in the process of creating specific guidance for LTC facilities within the NCPDP SCRIPT standard version 2017071, which would allow willing partners to enable 3-way communication between the prescriber, LTC facility, and pharmacy to bridge any outstanding gaps that impede adoption of the NCPDP SCRIPT standard version 2017071 in the LTC setting (86 FR 39329).

Similarly, in the “Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements” final rule (hereinafter referred to as “the November 2021 final rule”), which appeared in the **Federal Register** November 19, 2021 (86 FR 64996), CMS acknowledged that although 3-way communication is not as seamless in NCPDP SCRIPT standard version 2017071 as it was expected to be in later versions, EPCS was still possible with some modifications (86 FR 65364). CMS delayed EPCS compliance for prescribers’ prescriptions written for beneficiaries in a LTC facility from January 1, 2022, to no earlier than January 1, 2025, in order to give prescribers additional time to make the necessary changes to conduct electronic prescribing of covered Part D controlled substance prescriptions for Part D beneficiaries in LTC facilities using NCPDP SCRIPT standard version 2017071 (86 FR 65365). We are not proposing a change in the EPCS compliance date for covered Part D controlled substance prescriptions for Part D beneficiaries in LTC on the basis of the proposed adoption of NCPDP SCRIPT standard version 2023011; however, we invite comment on the status of EPCS in LTC and the degree to which LTC facilities have been able to

implement guidance from NCPDP to meet the EPCS requirement.

As proposed, § 423.160(b)(1) would require use of the version or versions of the NCPDP SCRIPT standard adopted in 45 CFR 170.205(b) to carry out the transactions listed in § 423.160(b)(1)(i)(A) through (Z). However, it would not require that all transactions be utilized if they are not needed or are not relevant to the entity. We refer readers to ONC’s Interoperability Standards Advisory (ISA) website for descriptions and adoption level of transactions in the NCPDP SCRIPT standard.²⁶ For example, we have been informed that the “GetMessage” transaction described in Table C–C1 is not widely used among prescribers. For this reason, we are reiterating guidance²⁷ that the NCPDP SCRIPT standard transactions named are not themselves mandatory, but rather they are to be used as applicable to the entities specified at § 423.160(a)(1) and (2) when they are completing or supporting the transmission of information related to electronic prescriptions, electronic prior authorization, or medication history. We believe the pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing have been utilizing the standards in this manner, based on discussions with NCPDP.

In summary, with respect to changes related to adopting, via cross-reference to ONC proposals in section III.C.8.a., NCPDP SCRIPT standard version 2023011 and retiring NCPDP SCRIPT standard version 2017071, we propose a revised paragraph § 423.160(b)(1) to:

- Consolidate all transactions for electronic prescribing, ePA, and medication history for which use of the NCPDP SCRIPT standard is mandatory at § 423.160(b)(1)(i)(A) through (Z); and
- Indicate that communication of prescriptions and prescription-related transactions listed must comply with a standard in 45 CFR 170.205(b). In conjunction with ONC proposals in section III.C.8.a., this cross-reference would permit a transition period when either NCPDP SCRIPT standard versions 2017071 or 2023011 may be used beginning as of the effective date of a final rule and ending January 1, 2027, because, as ONC has proposed at 45 CFR 170.205(b)(1), the NCPDP SCRIPT standard version 2017071 would expire January 1, 2027, after which only

²⁶ <https://www.healthit.gov/isa/section/pharmacyinteroperability>.

²⁷ Supporting Electronic Prescribing Under Medicare Part D. September 19, 2008. <https://www.hhs.gov/guidance/document/supporting-electronic-prescribing-under-medicare-part-d>.

NCPDP SCRIPT standard version 2023011 would be available for HHS use.

We solicit comment on these proposals.

5. Requiring NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13

In the May 2019 final rule (84 FR 23832), which implemented the statutory provision at section 1860D–4(e)(2)(D) of the Act, CMS required at § 423.160(b)(7) that Part D plan sponsors implement, by January 1, 2021, one or more electronic real-time benefit tools (RTBT) capable of integrating with at least one prescriber’s e-prescribing system or electronic health record (EHR) to provide prescribers with complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information. CMS indicated that the formulary and benefit information provided by the tool should include cost, clinically appropriate formulary alternatives, and utilization management requirements because, at that time, an industry standard for RTBTs had not been identified (84 FR 23833). NCPDP has since developed and tested an RTPB standard for use with RTBT applications. The NCPDP RTPB standard enables the real-time exchange of information about patient eligibility and patient-specific formulary and benefit information. For a submitted drug product, the RTPB standard will indicate coverage status, coverage restrictions, and estimated patient financial responsibility. “Estimated” financial responsibility accounts for the fact that the RTPB transaction transmits the patient’s cost sharing at that particular moment in time, which could later change if the claim is processed at a later date or in a different sequence relative to other claims (for example, an RTPB transaction could show a cost sharing that reflects a deductible or particular stage in the Part D benefit which could be different from when the prescription claim is actually processed by the pharmacy if other claims were processed in the interim). The RTPB standard also supports providing information on alternative pharmacies and products. In an August 20, 2021 letter to CMS, NCPDP described these features and recommended adoption of RTPB standard version 12.²⁸ Subsequently, in the December 2022 proposed rule, CMS proposed that Part D sponsors’ RTBTs comply with NCPDP RTPB standard version 12. In response

²⁸ https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBAndFandBStandardsAdoptionRequest.pdf.

to that proposal, NCPDP and many other interested parties provided comments to CMS recommending that CMS instead require NCPDP RTPB standard version 13. In their comments on the December 2022 proposed rule,²⁹ NCPDP listed enhancements in NCPDP RTPB standard version 13 that improve the information communicated between the payer and the prescriber. These enhancements include:

- Addition of a Coverage Status Message to enable the payer to communicate at the product level additional clarifying coverage information which is not codified;
- Addition of values to the Coverage Restriction Code and data elements to codify information communicated in the Message to reduce the number of free text messages on the response;
- Addition of a next available fill date to communicate when the patient is eligible to receive a prescription refill in a discrete field instead of via a free text message;
- Addition of fields to communicate formulary status and preference level of both submitted and alternative products in order to clarify pricing; and
- Addition of data elements on the request transaction to convey the patient's address, State/province, zip/postal code and country to aid in coverage determinations.

Even though we are withdrawing the proposals contained in section III.S. Standards for Electronic Prescribing in the December 2022 proposed rule (87 FR 79548), we have considered comments we received on the December 2022 proposed rule when crafting our proposals related to RTBTs for this proposed rule. A commenter on the December 2022 proposed rule requested that CMS specify that adoption of the NCPDP RTPB standard should not impede what the commenter refers to as the industry standard of sending 4 drugs or 4 pharmacies for pricing in a single transaction. We understand that each transaction between a prescriber EHR and the payer or processor is associated with a degree of latency (that is, the amount of time it takes for the RTBT request to travel from the electronic prescribing system to the payer or processor and return a response with the patient's cost sharing and formulary status information for the submitted drug). In order to populate information on alternative formulary drugs or alternative pharmacies, if one alternative is submitted per transaction, then the latency associated with each

transaction becomes additive. If the total latency is too long, then either the RTBT request may "time out" and a response may never be presented to the prescriber, or the prescriber may simply not wait long enough for the RTBT response before moving on through the electronic prescribing process. To illustrate the concept at the center of this issue, if each RTBT transaction is associated with 1 second of latency, then 1 transaction containing the submitted drug, plus 3 alternatives should return the patient-specific cost and formulary status information for all 4 drugs within 1 second. However, if the submitted drug and each alternative are sent as separate transactions, then the total time to return the RTBT response becomes 4 seconds (1 second \times 4 transactions). This longer response time increases the likelihood that the prescriber will not wait for the information to populate or that that EHR system will cause the transaction to time out, meaning the patient-specific cost and formulary status information are not presented to the prescriber. CMS takes interest in how adoption of the proposed NCPDP RTPB standard version 13 could alter functionality of RTBTs already in use. CMS created requirements for RTBTs in the absence of an industry-wide standard because of their potential to increase drug price transparency and lower out-of-pocket costs for Medicare Part D enrollees. The impact of RTBTs is contingent on prescribers actually receiving the patient-specific information in the response from the payer. CMS appreciates that this is relatively new technology and that there are multiple factors that contribute to the overall impact of RTBTs in real-world settings.^{30 31 32} Nevertheless, we seek comment on the issue raised by the commenter. We ask interested parties for their perspective on whether requiring the NCPDP RTPB standard version 13 would limit the ability to send more than one drug or pharmacy per RTBT transaction, and if so, whether the benefit of adopting a standard for

prescriber RTBTs in order to enable widespread integration across EHRs and payers outweighs such limitation.

The NCPDP RTPB standard version 13 standard is designed for prescriber, not beneficiary (that is, consumer), RTBTs. CMS emphasizes that we are not proposing a required standard for beneficiary RTBTs. Beneficiary RTBTs are made available directly to Part D plan enrollees by the Part D sponsor; therefore, beneficiary RTBT applications do not necessarily interface with an electronic prescribing system or EHR, as prescriber RTBTs must. Consequently, CMS believes that Part D sponsors can retain the flexibility to use beneficiary RTBTs that are based on an available standard or a custom application, as long as the information presented to enrollees meets CMS's requirements codified at § 423.128(d)(4). The requirements for the beneficiary RTBT are discussed in the 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," which appeared in the January 19, 2021 **Federal Register** (86 FR 5864). We decline to propose a standard for beneficiary RTBTs at this time, however we welcome comments on this topic which we may consider for future rulemaking.

As discussed in section III.C.8.b. of this proposed rule, ONC proposes to adopt the NCPDP RTPB standard version 13 at 45 CFR 170.205(c)(1). We therefore propose at § 423.160(b)(5) to require that beginning January 1, 2027, Part D sponsors' prescriber RTBT must comply with a standard in 45 CFR 170.205(c).

We solicit comment on these proposals and the related issues raised.

6. Requiring NCPDP Formulary and Benefit Standard Version 60 and Retirement of NCPDP Formulary and Benefit Standard Version 3.0

The NCPDP Formulary and Benefit (F&B) standard provides a uniform means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems. The NCPDP F&B standard transmits, on a batch basis, data on the formulary status of drugs, preferred alternatives, coverage restrictions (that is, utilization management requirements), and cost sharing consistent with the benefit design (for example, cost sharing for drugs on a particular tier). The NCPDP

³⁰ Everson J, Dusetzina SB. Real-time Prescription Benefit Tools—The Promise and Peril. *JAMA Intern Med.* 2022;182(11):1137–1138. Doi:10.1001/jamainternmed.2022.3962.

³¹ Real-Time Benefit Check: Key Insights and Challenges. May 2021. Accessed January 1, 2023. Available at: <https://www.hmpgloballearningnetwork.com/site/frmc/cover-story/real-time-benefit-check-key-insights-and-challenges>.

³² American Medical Association. Council on Medical Service. Access to Health Plan Information regarding Lower-Cost Prescription Options (Resolution 213–NOV–20). Available from https://councilreports.ama-assn.org/councilreports/downloadreport?uri=/councilreports/n21_cms_report_2.pdf.

²⁹ https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

F&B standard serves as a foundation for other electronic prescribing functions including ePA, real-time benefit check, and specialty medication eligibility when used in conjunction with other standards.³³ NCPDP F&B standard version 3.0 is required for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors, consistent with the existing text of § 423.160(b)(1)(v) and (b)(5)(iii). In an April 4, 2023 letter to CMS, NCPDP requested that CMS adopt NCPDP F&B standard version 60 to replace NCPDP F&B standard version 3.0.³⁴ A detailed change log was attached to the letter and is available at the link in the footnote. As described in the letter, compared with NCPDP F&B standard version 3.0, NCPDP F&B standard version 60 includes all of the following major enhancements:

- Normalization of all files (lists), which allows for smaller files and reusability.
- All files have expiration dates.
- Redesigned alternative and step medication files to reduce file sizes and to include support for reason for use (that is, diagnosis).
- Step medication files support a more complex step medication program.
- Updated coverage files to include support for electronic prior authorization and specialty drugs.
- Updated copay files to allow a minimum and maximum copay range without a percent copay and to support deductibles and pharmacy networks.

In its letter to CMS, NCPDP requested mandatory use of NCPDP F&B version 60 24 months after the effective date of a final rule adopting the standard. NCPDP F&B standard version 60 is backwards compatible with NCPDP F&B standard version 3.0, permitting a transition period where both versions of the NCPDP F&B standard may be used simultaneously without the need for entities involved to utilize a translator program.

Following an approach similar to those proposed in sections III.B.4. and III.B.5. of this proposed rule, CMS proposes at § 423.160(b)(3) that transmitting formulary and benefit information between prescribers and Medicare Part D sponsors must either utilize NCPDP F&B standard version 3.0 or comply with a standard in 45 CFR

170.205(u), where ONC proposes to adopt, at 45 CFR 170.205(u)(1), NCPDP F&B standard version 60 as described in section III.C.8.c. of this proposed rule. After January 1, 2027, entities transmitting formulary and benefit information would be required to comply with a standard in 45 CFR 170.205(u) exclusively, if finalized as proposed. Since ONC did not previously adopt NCPDP F&B standard version 3.0, we are maintaining the incorporation by reference of that version in the Part D regulation at § 423.160(c)(1)(i) to permit a transition period where either NCPDP F&B standard version 3.0 or NCPDP F&B version 60 could be used until January 1, 2027.

We solicit comment on these proposals.

7. Date for Required Use of NCPDP SCRIPT Standard Version 2023011, NCPDP RTPB Standard Version 13, and NCPDP F&B Standard Version 60

CMS has received feedback on a number of practical considerations for determining a realistic timeframe to implement new or update existing electronic prescribing standards. We have been informed that organizations generally do not budget for new requirements until a final rule has been published establishing a particular new requirement and, therefore, the timing of when a final rule is finalized relative to budget approval cycles can determine if a requirement can be accounted for in the organization's next annual budget. The health IT industry has indicated to CMS that it requires at least 2 years to design, develop, test, and certify software with trading partners; perform DEA audits for EPCS compliance; and roll out updated software to provider organizations and partners who then must train end users before a transition to a new or updated version of a standard is complete. This account is consistent with NCPDP's requests for up to 24-month implementation timeframes for new standards.³⁵ A commenter on the December 2022 proposed rule requested that CMS either permit 3 years from a final rule before requiring use of a new or updated version of a standard, or use enforcement discretion if requiring use of a new or updated version of a standard less than 3 years from a final rule. CMS will generally aim to provide entities with at least 2 years from when a final rule is finalized; however, we qualify that in some cases

less time may be provided if determined to be necessary.

CMS routinely receives feedback requesting that we do not require the use of new or updated electronic prescribing standards starting on January 1 due to end-of-year "code freezes," which prohibit updates to internal systems and plan enrollment changes that contribute to a general high workload at the start of a new plan year. CMS reminds entities impacted by the proposed regulatory changes that, consistent with § 423.516, CMS is prohibited from imposing new, significant regulatory requirements on Part D sponsors midyear. If the approach proposed in this proposed rule to align CMS's requirements for certain Part D electronic prescribing standards by cross-referencing standards adopted in ONC regulations is finalized, CMS and ONC will coordinate to establish appropriate timeframes for updating adopted standards and expiration dates for prior versions of adopted standards. CMS, working with ONC, will consider transition periods longer than 24 months following publication of a final rule to permit a sufficient transition period prior to January 1. Since a new, significant requirement must be effective January 1, a new or updated version of a standard could be required January 1 of the year following 24 months after a final rule is effective. For example, if a final rule containing a provision to update an electronic prescribing standard to a new version were effective May 30, 2024, then CMS would anticipate requiring the new version of the standard by January 1, 2027. This would allow for a 31-month transition period during which either version of a required standard could be used. Part D sponsors would need to plan accordingly to completely transition to the updated version of the standard ahead of the January 1 date to meet their internal production calendars. Using the prior example, we would assume that to avoid implementing the updated version of a standard on January 1, 2027, Part D sponsors would transition to the updated version of the standard by approximately May 30, 2026.

ONC is proposing January 1, 2027, as the date NCPDP SCRIPT standard version 2023011 would be the required version of this standard, as a product of the proposed expiration for NCPDP SCRIPT standard version 2017071 and our proposed cross-reference, in § 423.160(b)(1), to a standard in 45 CFR 170.205(b). We are proposing the required use of NCPDP F&B standard version 60 and NCPDP RTPB standard version 13 by January 1, 2027, in the

³³ Babbrah P, Solomon MR, Stember LA, Hill JW, Weiker M. Formulary & benefit and real-time pharmacy Benefit: Electronic standards delivering value to prescribers and pharmacists. *J Am Pharm Assoc* (2003). 2023 May–Jun;63(3):725–730. doi: 10.1016/j.japh.2023.01.016.

³⁴ <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230404-to-CMS-Formulary-and-Benefit-V60-Request.pdf>.

³⁵ https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBAndFandBStandardsAdoptionRequest.pdf.

³⁶ <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf>.

text of § 423.160(b)(3) and (5), respectively, as previously discussed. We are also aware that Part D sponsors and the health IT industry are awaiting HHS' final rule on the proposals to update the NCPDP Telecommunication standard from version D.0 to version F6 (87 FR 67638), update the equivalent NCPDP Batch Standard version 15 (87 FR 67639), and implement the NCPDP Batch Standard Pharmacy Subrogation version 10 (87 FR 67640) proposed in the November 2022 Administrative Simplification proposed rule.

Taking all of these proposals into consideration, we ask interested parties to comment on the proposed January 1, 2027, date for the required use of NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60. It is expressly outside the scope of this proposed rule, and we do not seek comment on, the compliance date for the proposals in HHS' November 2022 Administrative Simplification proposed rule; however, we ask for comments on the feasibility of updating multiple standards simultaneously.

8. Standards for Eligibility Transactions

We propose to revise the Part D requirements to indicate that eligibility transactions must comply with 45 CFR 162.1202. The requirements for eligibility transactions currently codified at § 423.160(b)(3)(i) and (ii) name the Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 5010, April 2008, ASC X12N/005010x279 and the NCPDP Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006 supporting Telecommunications Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007. We adopted these standards to align with those adopted at 45 CFR 162.1202, pursuant to the final rule titled "Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards," which appeared in the January 16, 2009, **Federal Register** (74 FR 3326).

The November 2022 Administrative Simplification proposed rule proposes to update the HIPAA standards used for eligibility transactions (87 FR 67638). We therefore propose to update the Part D regulation by proposing, at § 423.160(b)(2), that eligibility inquiries and responses between the Part D

sponsor and prescribers and between the Part D sponsor and dispensers must comply with the applicable HIPAA regulation in 45 CFR 162.1202, as opposed to naming standards independently, which would ensure, should the HIPAA standards for eligibility transactions be updated as a result of HHS rulemaking or in the future, that the Part D regulation would be synchronized with the required HIPAA standards. We foresee no immediate impact of this proposed change since the HIPAA regulation at 45 CFR 162.1202 currently identifies the same standards as those named in the Part D regulation at § 423.160(b)(3)(i) and (ii), but we believe establishing a cross-reference would help avoid potential future conflicts and mitigate potential compliance challenges for the healthcare industry and enforcement challenges for HHS.

Thus, we propose to delete existing § 423.160(b)(3)(i) and (ii) and modify § 423.160(b)(2) (as renumbered per the technical proposals in section III.B.9. of this proposed rule) to require that eligibility transactions must comply with 45 CFR 162.1202.

We solicit comment on these proposals.

9. Technical Changes Throughout § 423.160

In the spirit of alignment with ONC's approach to adopting standards, we reviewed § 423.160 in its entirety and identified areas where we can reorganize text throughout this section. We do not believe we should continue to list historical requirements that are no longer relevant and have resulted in repetitive content being added to the regulation. We propose removing reference to old effective dates (for example, "After January 1, 2009 . . ." at § 423.160(a)(3)(ii)). Additionally, certain exemptions have long since expired. For example, at § 423.160(a)(3)(iv), entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser have not been exempt from using the SCRIPT standard since November 1, 2014.

We are proposing a correction at § 423.160(a)(3)(iii), where regulation text refers to prescriptions and prescription-related information transmitted "internally when the sender and the beneficiary are part of the same legal entity." The exemption currently at § 423.160(a)(3)(iii) was previously codified at § 423.160(a)(3)(ii) as "Entities may use either HL7 messages

or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity . . ." as finalized in the November 2005 final rule, which codified the foundation standards for Medicare Part D electronic prescription drug programs (70 FR 67594). Section 423.160(a)(3)(ii) was redesignated as § 423.160(a)(3)(iii) subsequent to changes made in the final rule titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions," (hereinafter referred to as "the November 2007 final rule") which appeared in the November 27, 2007 **Federal Register** (72 FR 66222). There is no indication of intent in the November 2007 final rule to change the wording in § 423.160(a)(3)(iii) when it was redesignated, nor can we find evidence of when this paragraph may have been altered in subsequent rules. Therefore, we believe the word "recipient" was inadvertently changed to "beneficiary" in the distant past and we are proposing to change this back to "recipient."

Section 423.160(a)(1) and (2) already indicate that the entities listed must comply with the applicable standards in § 423.160(b); therefore, the language currently at § 423.160(b)(1), "Entities described in paragraph (a) of this section must comply with the following adopted standards for transactions under this section," is redundant. We propose to remove it from the text of § 423.160(b)(1). Moreover, § 423.160(b)(1)(i) through (iv) and (b)(2)(i) through (iii) contain long-outdated requirements going back to the start of the electronic prescribing program in Medicare Part D. We propose to delete references to outdated requirements so that the regulation text will include only relevant and applicable requirements. Transition periods would no longer be specifically spelled out as starting at a particular date (historically, 6 months after the effective date of a final rule). Rather, the transition period would begin as of the effective date of a final rule effectuating a change from one version of a standard to a new version and would last until the prior version of the standard is expired, as proposed to be codified in ONC regulation, or until the date specified in Part D regulation. For

versions of standards adopted by ONC, CMS would consider the necessary transition period when working with ONC to establish the appropriate expiration date for prior versions of standards in rulemaking. This would align the Part D approach with the approach that ONC has used in its own regulations.

As currently organized, separate sections for “Prescription” at § 423.160(b)(2), “Medication history” at § 423.160(b)(4), and “Electronic prior authorization” at § 423.160(b)(8) has resulted in multiple versions of the NCPDP SCRIPT standard, and relevant transactions, being repeated in these sections. Because § 423.160(a)(1) and (2) state that the entities listed must comply “with the applicable standards in paragraph (b),” we believe that we can group the functions in paragraph (b) according to the standard used for those functions to avoid repetition. Therefore, we propose to combine “Prescriptions, electronic prior authorization, and medication history” at § 423.160(b)(1), which will require the use of the NCPDP SCRIPT standard version or versions as proposed via cross-reference to ONC regulations. We propose to delete § 423.160(b)(4) and (8). The ePA transactions previously listed at § 423.160(b)(8)(i)(A) through (D) are proposed at § 423.160(b)(1)(i)(V) through (Y). We are proposing to delete reference to versions of the NCPDP F&B standard, currently codified at § 423.160(b)(5) introductory text and (b)(5)(i) and (ii), that are no longer applicable. The remaining paragraphs in § 423.160(b) are renumbered such that § 423.160(b)(2) refers to eligibility, § 423.160(b)(3) refers to formulary and benefits, § 423.160(b)(4) refers to provider identifier, and § 423.160(b)(5) refers to real-time benefit tools.

We are proposing to delete standards incorporated by reference at § 423.160(c) that are: no longer applicable (that is, were associated with outdated requirements that we have proposed to delete); are being proposed for incorporation by reference by ONC at 45 CFR 170.299; or are already incorporated by reference by HHS at 45 CFR 162.920. The standards incorporated by reference at § 423.160(c)(1)(i), (ii), and (v) are no longer applicable, and we propose to delete them. The standards for eligibility transactions currently incorporated by reference at § 423.160(c)(1)(iii) and (c)(2)(i) and (ii) have already been incorporated by reference by HHS at 45 CFR 162.920. We propose to delete these specified § 423.160(c)(1) and (2) incorporations by reference in light of our proposals in

section III.B.8. of this proposed rule to indicate that entities must comply with 45 CFR 162.1202 for eligibility transactions. In section III.B.11. of this proposed rule, we discuss how we propose to renumber the applicable standards currently incorporated by reference and where we propose to incorporate by reference the proposed new versions of standards as discussed in sections III.B.4., III.B.5., and III.B.6. of this proposed rule.

We believe these changes improve the overall readability of the section. With the exception of proposed changes described in sections III.B.4., III.B.5., III.B.6., and III.B.8., we do not intend for technical changes to alter current requirements.

We solicit comment on these proposals.

10. Summary of Standards for Electronic Prescribing Proposals

Sections III.B.4. through III.B.9. of this proposed rule include the following proposals:

- Requiring, via cross-reference to a standard in 45 CFR 170.205(b), use of NCPDP SCRIPT standard version 2023011, which ONC proposes for adoption at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071, via the same proposed cross-reference, for communication of a prescription or prescription-related information supported by Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule when either version of the NCPDP SCRIPT standard may be used. The transition period would end on January 1, 2027, which is the date that ONC has proposed that NCPDP SCRIPT standard version 2017071 would expire for the purposes of HHS use, as described in section III.C.8.a. of this proposed rule. If finalized as proposed, starting January 1, 2027, NCPDP SCRIPT standard version 2023011 would be the only version of the NCPDP SCRIPT standard available for HHS use and for purposes of the Medicare Part D electronic prescribing program;

- Requiring, beginning January 1, 2027, prescriber RTBTs implemented by Part D sponsors to comply with a standard in 45 CFR 170.205(c), where ONC proposes to adopt NCPDP RTPB standard version 13;

- Requiring transmission of formulary and benefit information between prescribers and Medicare Part D sponsors to comply with a standard in 45 CFR 170.205(u), where ONC proposes to adopt NCPDP F&B standard version 60, and retiring use of NCPDP F&B version 3.0 for transmitting

formulary and benefit information between prescribers and Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule and ending January 1, 2027, where entities would be permitted to use either NCPDP F&B version 3.0 (currently named in regulation at § 423.160(b)(5)(iii) and proposed to be named at § 423.160(b)(3) consistent with the proposed technical changes in this rule) or NCPDP F&B standard version 60, proposed for adoption at 45 CFR 170.205(u). If finalized as proposed, starting January 1, 2027, only a version of the standard adopted for HHS use at 45 CFR 170.205(u) would be permitted for use in Part D electronic prescription drug program, which would be NCPDP F&B standard version 60 if the proposal in section III.C.8.c. of this rule is finalized as proposed;

- Cross-referencing standards adopted for eligibility transactions in HIPAA regulations at 45 CFR 162.1202 for requirements related to eligibility inquiries; and

- Making multiple technical changes to the regulation text throughout § 423.160 for clarity by removing requirements and incorporations by reference that are no longer applicable or redundant, re-organizing existing requirements, and correcting a technical error. CMS invites comment on all aspects of these proposals, including the proposed date of January 1, 2027, for required use of NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60.

11. Incorporation by Reference and Availability of Incorporation by Reference Materials

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference (IBR) at 1 CFR part 51. If the regulations reference a standard, either in general or by name, in another section, IBR approval is required. In order for CMS to require use of standards in § 423.160 by cross citation to 45 CFR 170.205(b), those standards must be published in full in the **Federal Register** or CFR. Therefore, CMS must incorporate by reference the materials referenced in the proposals in sections III.B.4., III.B.5., and III.B.6. of this proposed rule which cross cite standards in ONC regulations.

For a proposed rule, agencies must discuss in the preamble to the proposed rule ways that the materials the agency proposes to incorporate by reference are reasonably available to interested parties or how the agency worked to make the materials reasonably available.

Additionally, the preamble to the proposed rule must summarize the materials. See also section III.C.10. of this proposed rule for summaries of the standards proposed for incorporation by reference by ONC.

Consistent with those requirements CMS has established procedures to ensure that interested parties can review and inspect relevant materials. The proposals related to the Part D electronic prescribing standards have relied on the following materials which we propose to incorporate by reference where specified:

- NCPDP SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017, which is currently incorporated by reference at § 423.160(c)(1)(vii). We propose to renumber this incorporation by reference as § 423.160(c)(2);

- NCPDP SCRIPT Standard, Implementation Guide Version 2023011, published April 2023, (Approval Date for American National Standards Institute [ANSI]: January 17, 2023). We propose to incorporate by reference at § 423.160(c)(3);

- NCPDP Real-Time Prescription Benefit Standard, Implementation Guide Version 13, published July 2023 (Approval Date for ANSI: May 19, 2022). We propose to incorporate by reference at § 423.160(c);

- NCPDP Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published April 2012, which is currently incorporated by reference at § 423.160(c)(1)(vi). We propose to renumber this incorporation by reference at § 423.160(c)(1); and

- NCPDP Formulary and Benefit Standard, Implementation Guide Version 60, published April 2023 (Approval Date for ANSI: April 12, 2023). We propose to incorporate by reference at § 423.160(c)(5).

NCPDP members may access these materials through the member portal at www.ncpdp.org. Non-NCPDP members may obtain these materials for information purposes by contacting the CMS at 7500 Security Boulevard, Baltimore, Maryland 21244 by calling (410) 786-4132 or (877) 267-2323 (toll free), or emailing PartDPolicy@cms.hhs.gov.

C. Adoption of Health IT Standards and Incorporation by Reference (45 CFR 170.205 and 170.299)

1. Overview

In this section, ONC proposes to adopt standards for electronic prescribing and related activities on behalf of HHS under the authority in

section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14). ONC is proposing these standards for adoption by HHS as part of a nationwide health information technology infrastructure that supports reducing burden and health care costs and improving patient care. ONC proposes to adopt these standards on behalf of HHS in one location within the Code of Federal Regulations for HHS use, including by the Part D Program as proposed in section III.B. of this proposed rule. These proposals reflect a unified approach across the Department to adopt standards for electronic prescribing (e-prescribing) activities that have previously been adopted separately by CMS and ONC under independent authorities. This approach is intended to increase alignment across HHS and reduce regulatory burden for interested parties subject to program requirements that incorporate these standards.

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, 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” (December 2022 proposed rule), which appeared in the **Federal Register** December 27, 2022 (87 FR 79552 through 79557), we proposed the adoption of NCPDP SCRIPT standard version 2022011 and NCPDP Real-Time Prescription Benefit standard version 13, as well as related proposals. We considered whether to issue a final rule based on that proposed rule, but considering the concerns raised by the commenters regarding which version of the standards to use, we have opted not to do so. Specifically, some commenters recommended adoption of NCPDP SCRIPT standard version 2023011, rather than the proposed NCPDP SCRIPT standard version 2022011. Other commenters recommended adoption of NCPDP RTPB standard version 13, rather than the proposed NCPDP RTPB standard version 12. See additional discussion in section III.B.5. of this rule. Therefore, we are withdrawing the proposals in sections III.T. and III.U. of the December 2022 proposed rule (87 FR 79552 through 79557). We are issuing a series of new proposals in this proposed rule that take into consideration the feedback we received from commenters on the December 2022 proposed rule and

further build on these proposals. Additionally, summaries of the standards we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations can be found below in section III.C.10. of this rule.

2. Statutory Authority

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111-5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and exchange of electronic health information (EHI). Subsequently, Title IV of the 21st Century Cures Act (Pub. L. 114-255) (Cures Act) amended portions of the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

3. Adoption of Standards and Implementation Specifications

Section 3001 of the PHSA directs the National Coordinator for Health Information Technology (National Coordinator) to perform duties in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information. Section 3001(b) of the PHSA establishes a series of core goals for development of a nationwide health information technology infrastructure that—

- Ensures that each patient’s health information is secure and protected, in accordance with applicable law;
- Improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;
- Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;
- Provides appropriate information to help guide medical decisions at the time and place of care;
- Ensures the inclusion of meaningful public input in such development of such infrastructure;
- Improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

- Improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;
- Facilitates health and clinical research and health care quality;
- Promotes early detection, prevention, and management of chronic diseases;
- Promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and
- Improves efforts to reduce health disparities.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria, and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1) of the PHSA, the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) of the PHSA and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, which is titled “Subsequent Standards Activity,” provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the Health IT Advisory Committee (HITAC). As noted in the final rule, “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications,” which appeared in the October 16, 2015 **Federal Register**, we consider this provision in the broader context of the HITECH Act and the Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria (80 FR 62606).

Under the authority outlined in section 3004(b)(3) of the PHSA, the Secretary may adopt standards, implementation specifications, and certification criteria as necessary even if those standards have not been recommended and endorsed through the process established for the HITAC under section 3002(b)(2) and (3) of the PHSA. Moreover, while HHS has traditionally adopted standards and implementation specifications at the same time as adopting certification criteria that reference those standards, the Secretary’s authority under section 3004(b)(3) of the PHSA is not limited to adopting standards or implementation specifications at the same time certification criteria are adopted.

Finally, the Cures Act amended the PHSA by adding section 3004(c), which specifies that in adopting and implementing standards under section 3004, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.

4. Alignment With Federal Advisory Committee Activities

The HITECH Act established two Federal advisory committees, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC). Each was responsible for advising the National Coordinator on different aspects of health IT policy, standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended section 3002 of the PHSA and replaced the HITPC and HITSC with one committee, the HITAC. After that change, section 3002(a) of the PHSA establishes that the HITAC advises and recommends to the National Coordinator standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. The Cures Act specifically directed the HITAC to advise on two areas: (1) A policy framework to advance an interoperable health information technology infrastructure (section 3002(b)(1) of the PHSA); and (2) priority target areas for standards, implementation specifications, and certification criteria (section 3002(b)(2) of the PHSA).

For the policy framework, as described in section 3002(b)(1)(A) of the PHSA, the Cures Act tasked the HITAC with providing recommendations to the National Coordinator on a policy framework for adoption by the Secretary

consistent with the Federal Health IT Strategic Plan under section 3001(c)(3) of the PHSA. In February of 2018, the HITAC made recommendations to the National Coordinator for the initial policy framework³⁷ and subsequently published a schedule in the **Federal Register** and an annual report on the work of the HITAC and ONC to implement and evolve that framework.³⁸ For the priority target areas for standards, implementation specifications, and certification criteria, section 3002(b)(2)(A) of the PHSA identified that in general, the HITAC would recommend to the National Coordinator, for purposes of adoption under section 3004 of the PHSA, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. In October of 2019, the HITAC finalized recommendations on priority target areas for standards, implementation specifications, and certification criteria.³⁹

5. Aligned Approach to Standards Adoption

Historically, the ONC Health IT Certification Program and the Part D Program have maintained complementary policies of aligning health IT certification criteria and associated standards related to electronic prescribing, medication history, and electronic prior authorization for prescriptions. While CMS and ONC have worked closely together to ensure consistent adoption of standards through regulatory actions, we recognize that the practice of different HHS components conducting parallel adoption of the same standards may result in additional regulatory burden and confusion for interested parties. For instance, due to discrepancies between regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules (respectively, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC

³⁷ HITAC Policy Framework Recommendations, February 21, 2018: https://www.healthit.gov/sites/default/files/page/2019-07/2018-02-21_HITAC_Policy-Framework_FINAL_508-signed.pdf.

³⁸ Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019 published March 2, 2020: https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf.

³⁹ HITAC recommendations on priority target areas, October 16, 2019: https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf.

Health IT Certification Program final rule (85 FR 25642) and 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** (83 FR 16440)) led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program.⁴⁰ Given these concerns, ONC and CMS proposed in the December 2022 proposed rule (87 FR 79552 through 79557) reflected a new approach to alignment of standards under which ONC proposed to adopt and incorporate by reference, on behalf of HHS, the NCPDP SCRIPT standard version 2022011 and the NCPDP RTPB standard version 12 in a single Code of Federal Regulations location at 45 CFR 170.205, where CMS proposed to cross-reference these standards for requirements in the Part D program.

For additional discussion of this approach see the December 2022 proposed rule (87 FR 79552 through 79557) and CMS's discussion in sections III.B.3 through III.B.7. of this proposed rule. We note that the proposals in this rule continue to reflect an aligned approach with CMS to adoption of health IT standards for e-prescribing and related purposes. We believe our proposed adoption of these standards in a single CFR location for HHS use will help to address concerns around alignment across HHS programs.

6. Regulatory History

For a summary of past standards adoption activities under section 3004 of the PHSA intended to ensure alignment for electronic prescribing and related activities across the ONC Health IT Certification Program and the Part D Program, we refer readers to the December 2022 proposed rule (87 FR 79553). In this proposed rule, we also propose to adopt the NCPDP Formulary and Benefit (F&B) standard version 60, which was not previously discussed in the December 2022 proposed rule (87 FR 79553). For a summary of previous notice-and-comment rulemaking related to formulary and benefit management capabilities in the ONC Health IT Certification Program, we refer readers to the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and

Information Sharing" proposed rule (HTI-1 Proposed Rule) (88 FR 23853 through 23854).

7. Interoperability Standards Advisory

ONC's Interoperability Standards Advisory (ISA) supports the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the health care industry to address specific interoperability needs.⁴¹ The ISA is updated on an annual basis based on recommendations received from public comments and subject matter expert feedback. This public comment process reflects ongoing dialogue, debate, and consensus among industry interested parties when more than one standard or implementation specification could be used to address a specific interoperability need.

ONC currently identifies the standards proposed for adoption in this section within the ISA as available standards for a variety of potential use cases. The NCPDP SCRIPT standard version 2023011, the NCPDP Real-Time Prescription Benefit standard version 13, and the NCPDP Formulary and Benefits standard version 60 are currently identified in sections of the ISA including the "Pharmacy Interoperability"⁴² and "Administrative Transactions—Non-Claims."⁴³ We encourage interested parties to review the ISA to better understand key applications for the implementation specifications proposed for adoption in this proposed rule.

8. Proposal To Adopt Standards for Use by HHS

Consistent with section 3004(b)(3) of the PHSA and the efforts, as previously described, to evaluate and identify standards for adoption, we propose to adopt the following implementation specifications in 45 CFR 170.205(b)(2), (c)(1), and (u)(1), on behalf of the Secretary, to support the continued development of a nationwide health information technology infrastructure as described under section 3001(b) of the PHSA, and to support Federal alignment of standards for interoperability and health information exchange. Specifically, we propose to adopt the following standards:

- NCPDP SCRIPT Standard, Implementation Guide, Version 2023011.

- NCPDP Real-Time Prescription Benefit (RTPB) Standard, Implementation Guide, Version 13.
- NCPDP Formulary and Benefits (F&B) Standard, Implementation Guide, Version 60.

In addition to comments on the individual proposals below, we invite comments on whether there are alternative versions, including any newer versions, of these or other standards that we should consider for adoption for HHS use. In particular, we would be interested in, and would consider for adoption in a final rule, any newer version of the proposed standard(s) that may correct any unidentified errors or clarify ambiguities that would support successful implementation of the standard(s) and the interoperability of health IT.

a. NCPDP SCRIPT Standard Version 2023011 (45 CFR 170.205(b))

ONC has previously adopted three versions of the NCPDP SCRIPT standard in 45 CFR 170.205. Most recently, we adopted NCPDP SCRIPT standard version 2017071 in the ONC 21st Century Cures Act final rule to facilitate the transfer of prescription data among pharmacies, prescribers, and payers (85 FR 25678).

The updated NCPDP SCRIPT standard version 2023011 includes important enhancements relative to NCPDP SCRIPT standard version 2017071. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies. NCPDP SCRIPT standard version 2023011 also includes functionality that supports a 3-way transaction among prescriber, facility, and pharmacy, which will enable electronic prescribing of controlled substances in the long-term care (LTC) setting.⁴⁴

We propose to adopt NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2), replacing NCPDP SCRIPT standard version 10.6 which is currently in 170.205(b)(2). We propose to incorporate NCPDP SCRIPT standard version 2023011 by reference in 45 CFR 170.299. Regarding NCPDP SCRIPT standard version 2017071, we propose to revise the regulatory text in 45 CFR 170.205(b)(1) to specify that adoption of this standard will expire on January 1, 2027. If these proposals are finalized, this would mean that both the 2017071 and 2023011 versions of the NCPDP SCRIPT standard would be available for

⁴⁰ See the archived version of the Certification Companion Guide for the "electronic prescribing" certification criterion in 45 CFR 170.315(b)(3): https://www.healthit.gov/sites/default/files/page/2020-12/b3_ccg.pdf.

⁴¹ See <https://www.healthit.gov/isa>.

⁴² See <https://www.healthit.gov/isa/section/pharmacyinteroperability>.

⁴³ See <https://www.healthit.gov/isa/section/administrative-transactions-non-claims>.

⁴⁴ See https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

HHS use from the effective date of a final rule until January 1, 2027. On and after January 1, 2027, only the 2023011 version of the NCPDP SCRIPT standard would be available for HHS use, for instance, where use of a standard in 45 CFR 170.205(b) is required. We refer readers to section III.B.4. of this proposed rule, where CMS discusses its proposal at § 423.160(b)(1) to require use of a standard in 45 CFR 170.205(b) for communication of a prescription or prescription-related information to fulfill the requirements for prescriptions, electronic prior authorization, and medication history.

We request comment on these proposals.

b. NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13 (45 CFR 170.205(c))

The NCPDP Real-Time Prescription Benefit standard version 13 enables the exchange of coverage status and estimated patient financial responsibility for a submitted product and pharmacy, and identifies coverage restrictions and alternatives when they exist. See section III.B.5. of this proposed rule for a description of Real-Time Prescription Benefit standard functionality and enhancements of NCPDP Real-Time Prescription Benefit standard version 13 relative to NCPDP Real-Time Prescription Benefit standard version 12.

Our proposal to adopt this standard supports the requirements of Division CC, Title I, Subtitle B, section 119 of the Consolidated Appropriations Act, 2021 (CAA), Public Law 116–260, which required sponsors of Medicare prescription drug plans to implement a real-time benefit tool that meets technical standards named by the Secretary, in consultation with ONC. In addition, section 119(b) of the CAA amended the definition of a “qualified electronic health record” in section 3000(13) of the PHSA to specify that a “qualified electronic health record” must include or be capable of including a real-time benefit tool. ONC intends to address this provision in future rulemaking for the ONC Health IT Certification Program and will ensure alignment with the proposed NCPDP Real-Time Prescription Benefit standard version 13, if finalized, and related proposals in the Part D program where appropriate.

We also note that the HITAC has previously addressed real-time prescription benefit standards, consistent with its statutory role to recommend standards. In 2019, the HITAC accepted the recommendations included in the 2018 report of the

Interoperability Priorities Task Force, including recommendations to continue to monitor standards then being developed for real-time prescription benefit transactions, and, when the standards are sufficiently validated, to require EHR vendors to provide functionality that integrates real time patient-specific prescription benefit checking into the prescribing workflow.⁹ In early 2020, the National Committee on Vital and Health Statistics (NCVHS) and HITAC convened another task force, the Intersection of Clinical and Administrative Data (ICAD) Task Force, which was charged with convening industry experts and producing recommendations related to electronic prior authorizations. The task force report was presented to HITAC in November 2020¹⁰ and discussed the NCPDP Real-Time Prescription Benefit standard as an important tool for addressing administrative transactions around prescribing.

We are proposing in 45 CFR 170.205(c) to add a new section heading “Real-Time Prescription Benefit.” We are also proposing to adopt the NCPDP Real-Time Prescription Benefit standard version 13⁴⁵ in 45 CFR 170.205(c)(1) and to incorporate this standard by reference in 45 CFR 170.299. We refer readers to section III.B.5. of this rule, where CMS proposes at § 423.160(b)(5) to require Part D sponsors’ RTBTs to comply with a standard in 45 CFR 170.205(c) by January 1, 2027, to fulfill the requirements for real-time benefit tools. As previously noted, ONC will consider proposals to require use of this standard to support real-time benefit tool functionality in the ONC Health IT Certification Program, consistent with section 119 of the CAA, in future rulemaking.

We request comment on these proposals.

c. NCPDP Formulary and Benefit (F&B) Standard Version 60 (45 CFR 170.205(u))

The NCPDP Formulary and Benefit (F&B) standard version 60⁴⁶ provides a uniform means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems. The NCPDP F&B standard transmits, on a batch basis, data on the formulary status of drugs, preferred alternatives, coverage restrictions (that is., utilization

management requirements), and cost sharing consistent with the benefit design for example, cost sharing for drugs on a particular tier). The NCPDP F&B standard serves as a foundation for other electronic prescribing transactions including ePA, real-time benefit check, and specialty medication eligibility when used in conjunction with other standards.

We propose to add a new paragraph heading at 45 CFR 170.205(u), “Formulary and benefit.” We propose to adopt the NCPDP Formulary and Benefit standard version 60 at 45 CFR 170.205(u)(1) and to incorporate this standard by reference in 45 CFR 170.299. We refer readers to section III.B.6. of this proposed rule, where CMS proposes at § 423.160(b)(3) to require, by January 1, 2027, use of a standard in 45 CFR 170.205(u) by Part D plan sponsors to fulfill the requirements for exchange of formulary and benefit information with prescribers.

9. ONC Health IT Certification Program

We are not proposing new or revised certification criteria based on the proposed adoption of standards within this rulemaking. We note that section 119 of the CAA does not require ONC to adopt certification criteria for real-time prescription benefit capabilities at the same time as a standard is adopted by HHS. We are therefore proposing to adopt the standard for HHS use and, as previously discussed, ONC would address new or revised certification criteria referencing the standard, if finalized, in separate rulemaking. ONC recently published a Request for Information in the HTI–1 Proposed Rule seeking information related to a real-time prescription benefit criterion (88 FR 23853 through 23854). ONC will continue to collaborate with CMS to ensure that any future proposals in the ONC Health IT Certification Program continue to advance alignment with program requirements under the Part D Program.

We believe the approach reflected in the standards proposals in this proposed rule will support Federal alignment and coordination of Federal activities with adopted standards and implementation specifications for a wide range of systems, use cases, and data types within the broad scope of health information exchange. Historically, State, Federal, and local partners have leveraged the standards adopted by ONC on behalf of HHS to inform program requirements, technical requirements for grants and funding opportunities, and systems implementation for health information

⁴⁵ See <https://standards.ncdpd.org/Access-to-Standards.aspx>.

⁴⁶ See <https://standards.ncdpd.org/Access-to-Standards.aspx>.

exchange. We believe the adoption of these standards will support HHS partners in setting technical requirements and advancing the use of innovative health IT solutions for electronic prescribing and related activities.

10. Incorporation by Reference (45 CFR 170.299)

The Office of the Federal Register has established requirements for materials (for example, standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(a)). Specifically, 1 CFR 51.5(a) requires agencies to discuss, in the preamble of a proposed rule, the ways that the materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties; and summarize, in the preamble of the proposed rule, the material it proposes to incorporate by reference.

To make the materials we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URLs provided. In instances where they are not directly available, we note the steps and requirements necessary to gain access to the standard or implementation specification. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. In certain instances, where noted, access requires a fee or paid membership. As an alternative, a copy of the standards may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690-7171 in advance to arrange inspection.

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A-119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA

and OMB Circular A-119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. We have followed the NTTAA and OMB Circular A-119 in proposing standards and implementation specifications for adoption, and note that the technical standards proposed for adoption in 45 CFR 170.205 in this proposed rule were developed by NCPDP, which is an ANSI-accredited, not-for-profit membership organization using a consensus-based process for standards development.

As required by 1 CFR 51.5(a), we provide summaries of the standards we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations. We also provide relevant information about these standards and implementation specifications in the preamble where these standards are proposed for adoption. We propose to revise § 170.299(k) with the following updated standards:

- National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023 (Approval Date for ANSI: January 17, 2023)

URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: SCRIPT is a standard created to facilitate the transfer of prescription data between pharmacies, prescribers, and payers. The current standard supports transactions regarding new prescriptions, prescription changes, renewal requests, prescription fill status notification, and prescription cancellation. Enhancements have been added for drug utilization review/use (DUR/DUE) alerts and formulary information as well as transactions to relay medication history and for a facility to notify a pharmacy of resident information. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies.

- National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, July 2023 (Approval Date for ANSI: May 19, 2022)

URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: The NCPDP Real-Time Prescription Benefit Standard Implementation Guide is intended to meet the industry need within the pharmacy services sector to facilitate the ability for pharmacy benefit payers/processors to communicate to providers and to ensure a consistent implementation of the standard throughout the industry. The Real-Time Prescription Benefit (RTPB) Standard enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions, and alternatives when they exist.

- National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard, Implementation Guide, Version 60, April 2023 (Approval Date for ANSI: April 12, 2023)

URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: The NCPDP Formulary and Benefit Standard Implementation Guide is intended to provide a standard means for pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to prescribers via technology vendor systems.

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

Section 1860D-4(c)(5)(A) of the Social Security Act (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 has sickle-cell disease, residing 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 2016.⁴⁷ 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 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)⁴⁸ 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 are proposing 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 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.

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

As discussed above, 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 (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 would not be sent; instead, an alternate second notice would be 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.

Based on program experience during the first several years of DMPs, we propose 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 propose 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 propose to remove the 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

⁴⁷ <https://www.cdc.gov/mmwr/volumes/65/rr/r6501e1.htm>.

⁴⁸ <https://www.cdc.gov/mmwr/volumes/71/rr/r7103a1.htm>.

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 it is required to 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.

On April 20, 2023, CMS released updated DMP guidance.⁴⁹ Sections 8.1 and 8.2.2 of the guidance 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. If this proposal to require sponsors to provide an alternate second notice to a beneficiary who is determined to be exempt from the DMP prior to the required 30 days elapsing since the initial notice is finalized, 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 are not estimating 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 exempted. However, we believe the current 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 propose an additional technical change related to the timeframe for providing second and alternate second notices. The current regulation at § 423.153(f)(8)(i) requires that a sponsor provide a second 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 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 USPS mail service, or later in the day after files have been sent to a print vendor.

Specifically, we propose 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 note a 3-day window would align with requirements for providing written notice of a standard or expedited Part D coverage determination after initial oral notice, as described at §§ 423.568(d) and (f) and 423.572(b), respectively, and is therefore familiar to sponsors. However, unlike the circumstances covered by those regulatory provisions, sponsors would not be providing an initial oral notice, as it would be impracticable to verbally convey the details of a second notice or alternate second notice to an enrollee. This proposed 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 are not proposing 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.

3. OMS Criteria Request for Feedback

CMS regulations at § 423.153(f)(16) specify that PARBs and ARBs are identified 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 whom CMS believes are potentially at the highest risk of opioid-related adverse events or overdose. The current minimum OMS criteria⁵⁰ 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 Disorder⁵¹ (MOUD)) within the most recent 6 months (also referred to as "MIN2" minimum OMS criteria). The current supplemental OMS criteria are for sponsors to address plan members who are receiving opioids from a large number of prescribers or

⁴⁹ 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>.

⁵¹ Referred to as medication-assisted treatment (MAT) in past guidance.

⁴⁹ <https://www.cms.gov/files/zip/cy-2023-part-d-dmp-guidance-april-20-2023.zip>.

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 Medicare Part D prescription opioid overutilization, but opioid-related overdose deaths continue to be a growing problem throughout the United States.⁵² 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 2020,⁵³ we must remain vigilant regarding the risks of prescription opioids including misuse, opioid use disorder (OUD), overdoses, and death. CMS tracks prevalence rates for Medicare Part D beneficiaries with an OUD⁵⁴ diagnosis and beneficiaries with an opioid poisoning (overdose). While overall opioid-related overdose prevalence rates among Medicare 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.⁵⁵ 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,⁵⁶ CMS is working on models that can 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.⁵⁷ 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 are not proposing changes to the clinical guidelines or OMS criteria in this proposed rule, we provide 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 anticipate no burden since, as indicated, we are not proposing regulatory changes and are soliciting feedback.

In this analysis, we utilize 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)⁵⁸ 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

⁵² Spencer, Merianne R. et al. (2022). Drug Overdose Deaths in the United States, 2001–2021. (457).

⁵³ <https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html>.

⁵⁴ 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.

⁵⁵ Bohnert K.M., Ilgen M.A., Louzon S., McCarthy J.F., Katz I.R., 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.

⁵⁶ 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).

⁵⁷ Lo-Ciganic WH, Huang J.L., Zhang H.H., Weiss J.C., Wu Y., Kwok C.K., Donohue J.M., Cochran G., Gordon A.J., Malone D.C., Kuza C.C., Gellad W.F. 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/jamanetworkopen.2019.0968. Erratum in: *JAMA Netw Open*. 2019 Jul 3;2(7):e197610. PMID: 30901048; PMCID: PMC6583312.

⁵⁸ 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.

overdose event or new OUD diagnosis was from July 1 to December 31, 2019.

The following risk factors⁵⁹ were incorporated into the XGBoost model:

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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 ⁶⁰)
Number of MOUD Days	Number of Medication-Assisted Treatment (MOUD) days
Hepatitis	Hepatitis diagnosis
Cervical nerve injury	Cervical nerve injury diagnosis

⁵⁹ Multicollinearity tests were undertaken in order to ensure that there was no collinearity among the explanatory variables used in the model.

⁶⁰ 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
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
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.

Confusion Matrix and Performance
Metrics 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

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:

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.

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.⁶¹ 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.

⁶¹ 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.

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 solicit 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.

E. 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, 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 Medicare Advantage (MA) organizations, Part D sponsors, Cost plans, and PACE organizations for purposes of this proposal.

We are proposing 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 MA organizations and Part D sponsors to address and resolve complaints received by CMS against the MA organization and Part D sponsor through the CTM; we are proposing to codify the expectation in guidance that Cost plans and PACE organizations also address and resolve complaints in the CTM. We are proposing 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 three (3) calendar days. This time frame would not apply to immediate need complaints because those complaints need to be resolved within two calendar days.

CMS codified the requirement for MA organizations 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 MA organizations 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 are proposing 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 would 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,⁶² 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 MA organizations, 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 MA organizations, 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,”⁶³ 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.

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 MA organizations per § 417.600), part 423, subpart M, for Part D sponsors, and §§ 460.120 through 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 would 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 are proposing to codify the timeliness requirements for MA organizations and Part D plans at new §§ 422.125 and 423.129, both titled “Resolution of Complaints in Complaints Tracking Module.” We are

⁶² Available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ctm%20plan%20sop%20eff053019.pdf>.

⁶³ Available at <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/dwnlds/chapter7pdf>.

proposing to codify these requirements for Cost plans and PACE organizations at §§ 417.472(l) and 460.119 by incorporating §§ 422.504(a)(15) and 422.125 by reference into the requirements for Cost plans and PACE organizations, respectively.

Specifically, we propose 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 propose 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 MA organization (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 propose 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 seven (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 would 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 propose 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 would 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% of such complaints were resolved by plans within 30 days in 2022.

All timeframes for resolution would 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 2 calendar days, 97 percent of

urgent complaints within 7 calendar days, and 98 percent of complaints with no issue level designated within 30 calendar days. Codifying the timeframes as proposed merely formalizes CMS’s current expectations and the level of responsiveness currently practiced by plans.

We are also proposing to create a new requirement for plans to contact individuals filing non-immediate need complaints. At §§ 422.125(c) and 423.129(c), we propose 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 are proposing 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 would 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 are proposing a 3 calendar day timeframe for reaching out to the

individual filing the complaint because it would provide a timely update to individuals filing both urgent and uncategorized complaints without delaying resolution of immediate need complaints. We expect that a plan would 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 solicit comment on whether this timeframe is appropriate and whether a longer or shorter timeframe would better balance the needs of beneficiaries with the capacity of plans to respond to complaints.

We are also proposing conforming changes to §§ 422.504(a)(15) and 423.505(b)(22) to incorporate the proposed new requirements into the existing contractual requirements for MA organizations 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.

F. Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2))

1. Introduction

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 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), 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);⁶⁴ and (2) Part D sponsors providing notice of such changes.

The December 2022 proposed rule proposed to reorganize current regulatory text to incorporate and as necessary conform with longstanding sub-regulatory guidance and operations with respect to changes to an approved formulary and associated notice provisions. For example, § 423.120(b)(5)(iv) currently permits a plan sponsor to immediately remove a brand name drug from its formulary when adding a therapeutically equivalent generic drug, subject to certain requirements. If finalized, the December 2022 proposed rule would expand immediate substitutions in a new § 423.120(e)(2)(i) to allow plan sponsors to substitute an authorized generic for a brand name drug, an interchangeable biological product for a reference product, or an unbranded biological product for its corresponding brand name biological product under the same biologics license application (BLA).

These and other proposals discussed in section III.Q., Changes to an Approved Formulary, of the December 2022 proposed rule have not been finalized and remain under consideration. As we noted in the April 2023 final rule, CMS intends to address remaining proposals from the December

2022 proposed rule in subsequent rulemaking, which would be effective no earlier than January 1, 2025. As we continue to consider comments we received in response to the December 2022 proposed rule, we identified a limited number of changes that we would like to make to the proposed regulatory text relating to section III.Q. of the December 2022 proposed rule. Accordingly, this proposed rule reflects our intent to consider section III.Q. of the December 2022 proposed rule, as updated by the limited proposed changes discussed herein, for inclusion in future rulemaking. While we discuss below certain comments regarding the December 2022 proposed rule that informed the limited proposed changes herein, we will 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 below, if we decide to move forward with such proposals in future rulemaking.

Commenters on section III.Q. of the December 2022 proposed rule did not agree on the requirements that should apply to formularies substituting Food and Drug Administration (FDA) approved and licensed biosimilar biological products. Different commenters submitted divergent requests that 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 did not specify how Part D sponsors could treat substitution of biosimilar biological products other than interchangeable biological products, and we believe, in part because of the interest in the topic, that it would be appropriate to propose to do so now in order to solicit comment directly on the subject.

Accordingly, we are proposing 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, for the reasons discussed below. We are also proposing to define a new term, “biosimilar biological product,” distinct from our previously proposed term “interchangeable biological products.” (We propose some technical changes to the latter term as well.)

⁶⁴ We note the distinction between formulary substitutions made by a plan sponsor and product substitutions made by a pharmacist at the point-of-dispensing. As we describe in section III.F.2.a.(2) of this proposed rule, State laws 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 throughout section III.F of this proposed rule 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.

We propose to define biosimilar biological products consistent with sections 351(i) and (k) of the Public Health Service Act to include interchangeable biological products. In section III.Q (87 FR 79536) of the December 2022 proposed rule, we proposed to permit maintenance changes and immediate substitutions involving interchangeable biological products, and that proposal is still under consideration. In this proposed rule, we are also proposing to allow substitution of biosimilar biological products other than interchangeable biological products for reference products as a maintenance change. To ensure clarity, we are proposing 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 also determined it would be appropriate to propose providing Part D sponsors with additional flexibility with respect to 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,” we are proposing additional flexibility. Specifically, we propose to allow Part D sponsors to make a negative formulary change to the related drug within a certain period of time following the addition of the corresponding drug—rather than at the same time they add the corresponding drug.

Additionally, we propose 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 be a reference to “an unbranded biological product marketed under the same BLA as a brand name biological product.”

Lastly, we are taking this opportunity 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 changes apply with respect to “a covered Part D drug.”

Our goal in this proposed rule is to focus only on these specific changes to

the original proposals in the December 2022 proposed rule that remain under consideration, but as updated below. We are re-proposing in this proposed rule only the regulatory text in the December 2022 proposed rule necessary to address new policy considerations and, therefore, we include only the updated parts of the three following sections of proposed regulatory text in the December 2022 proposed rule: §§ 423.4; 423.100; and 423.120(e)(2). Section III.F.2.a. of this proposed rule includes both language and synopses of the preamble to the December 2022 proposed rule as necessary to provide context for the updates we are proposing in this proposed rule. Except as specified in this proposed rule, stakeholders should assume, as does the discussion in this proposed rule, that the proposals for regulatory text regarding changes to approved formularies otherwise remain under consideration as proposed in the December 2022 proposed rule. If any provisions regarding this topic are finalized, the final rule would include the provisions proposed in the December 2022 proposed rule, as revised by the proposed changes in this proposed rule and taking into consideration any potential changes in response to comments.

We received numerous comments on section III.Q. of the December 2022 proposed rule on changes to an approved formulary, comments which we have carefully reviewed and continue to consider (and some of which are discussed in this proposed rule). We solicit comments on any aspects regarding the changes we are proposing in this rule to the December 2022 proposed rule’s provisions.

2. Substituting Biosimilar Biological Products for Their Reference Products as Maintenance Changes

a. Previously Proposed Provisions

(1) Certain Previously Proposed Provisions Related to Maintenance and Non-Maintenance Changes

In section III.Q.2.b., Proposed Provisions for Approval of Formulary Changes, of the December 2022 proposed rule, we proposed to define terms such as “negative formulary change” and “affected enrollee.” In categorizing negative formulary changes, we discussed the fact that chapter 6 of the Prescription Drug Benefit Manual also classifies negative formulary changes as either maintenance or non-maintenance changes. Maintenance changes are changes generally expected to pose a minimal risk of disrupting drug therapy

or are warranted to address safety concerns or administrative needs (for example, drug availability due to shortages and determining appropriate payment such as coverage under Part B or Part D). We noted that in our experience the vast majority of negative formulary changes are “maintenance” changes that CMS routinely approves, and the vast majority of maintenance changes are generic substitutions, in which the Part D sponsor removes a brand name drug and adds its generic equivalent.

We then noted that consistent with our current manual policy and operations, we were proposing at § 423.100 to define “maintenance changes” to mean the following negative formulary changes: (1) making any negative formulary changes to a drug and at the same time adding a corresponding drug at the same or lower cost-sharing tier and with the same or less restrictive prior authorization (PA), step therapy (ST), or quantity limits (QL) requirements (other than those meeting the requirements of immediate substitutions currently permitted and that we proposed to permit in the December 2022 proposed rule); (2) removing a non-Part D drug; (3) adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning; (4) removing a drug deemed unsafe by FDA or withdrawn from sale by the manufacturer if the Part D sponsor chooses not to treat it as an immediate negative formulary change; (5) removing a drug based on long-term shortage and market availability; (6) making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization; or (7) adding PA to help determine Part B versus Part D coverage. We additionally stated that we intended through the use of the plural tense to clarify that Part D sponsors may request to apply more than one negative formulary change simultaneously to that drug.

We noted that non-maintenance changes, which are infrequently warranted, are negative formulary changes that limit access to a specific drug without implementing a corresponding offset (such as adding an equivalent drug) or addressing safety or administrative needs. We proposed to define “non-maintenance change” at § 423.100 to mean a negative formulary change that is not a maintenance change or (as discussed in the next paragraph) an immediate negative formulary change.

We also introduced a third category of negative formulary changes in § 423.100 to capture negative formulary changes

that fall within certain parameters and that may be made immediately. We proposed to define “immediate negative formulary changes” as those which meet the requirements as either an immediate substitution or market withdrawal under § 423.120(e)(2)(i) or (ii) respectively. We noted, however, that while such changes may be made immediately, Part D sponsors retain the option to implement such changes as maintenance changes. This means that those Part D sponsors that can meet all applicable requirements would have a choice as to whether to make such changes immediately and thereafter provide notice of specific changes or submit a negative change request and provide specific notice of such changes to affected enrollees at least 30 days before they occur.

We also proposed to define “corresponding drug” in § 423.100 to mean, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product of a biological product and to move and retain our current regulatory description of “other specified entities” currently in § 423.120(b)(5)(i) to be a standalone definition of the term in § 423.100.

We proposed 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 our existing policy with respect to maintenance changes, which would, at proposed § 423.120(e)(3)(i), permit Part D sponsors that have submitted a maintenance change request to assume that CMS has approved their negative change request if they do not hear back from CMS within 30 days of submission. We proposed to codify our existing policy with respect to non-maintenance changes as well, which would specify at § 423.120(e)(3)(ii) that Part D sponsors must not implement 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 section III.Q.3.b., Alignment of Approval and Notice Policy, of the December 2022 proposed rule, we noted in relevant part that: we first proposed in § 423.120(f)(1) to specify that only maintenance and non-maintenance negative formulary changes would require 30 days’ advance notice to CMS and other specified entities, and in

writing to affected enrollees. We also proposed to retain at § 423.120(f)(1) an alternative option for Part D sponsors to provide an affected enrollee who requests a refill of an approved month’s supply of the Part D drug under the same terms as previously allowed, as well as written notice of the change. We further proposed in § 423.120(f)(5)(i) to require Part D sponsors to provide advance general notice of other formulary changes to all current and prospective enrollees and other specified entities, in formulary and other applicable beneficiary communication materials, advising that the formulary may change subject to CMS requirements; providing information about how to access the plan’s online formulary and contact the plan; and stating that the written notice of any change made when provided would describe the specific drugs involved. For immediate substitutions, we indicated we would require information on the steps that enrollees may take to request coverage determinations and exceptions. We noted that our current model documents already largely provide advance general notice of such changes. Section 423.120(f)(5)(ii) as proposed in the December 2022 proposed rule would further require that Part D sponsors provide enrollees and other specified entities notice of specific formulary changes by complying with § 423.128(d)(2) and provide CMS with notice of specific changes through formulary updates.

We proposed to revise and renumber the existing regulation to specify that, except for immediate negative formulary changes, negative formulary changes require at least 30 days advance notice. Consistent with our proposal for approval of maintenance changes, we proposed that a Part D sponsor could submit the negative change request, which would constitute its notice to CMS, and notice to other specified entities at the same time. We explained this would permit the Part D sponsor to implement the maintenance change once it is deemed approved under proposed § 423.120(e)(3)(i)—although facing the risk of sending notice of a change that is subsequently disapproved by CMS.

We also noted that Part D sponsors currently submit negative change requests to CMS via HPMS that specify the negative change’s intended effective date, which under our proposed approach, would have to be at least 30 days after submission for a maintenance change. However, consistent with our previous proposal under § 423.120(f)(3)(ii) to prohibit Part D

sponsors from implementing non-maintenance changes until they receive notice of approval from CMS, Part D sponsors would not be permitted to provide notice to other specified entities or affected enrollees, or to otherwise update formularies or other materials, until CMS has approved the non-maintenance change. We also discussed updating online notice of negative formulary changes at § 423.128(d)(2)(iii).

(2) Certain Previously Proposed Provisions Related to Interchangeable Biological Products as Immediate Negative Formulary Changes

In section III.Q.2.b.(3), Immediate Negative Formulary Changes, of the December 2022 proposed rule, we proposed to permit immediate substitutions of interchangeable biological products for their reference products. In our preamble, we reviewed how, under the current § 423.120(b)(5)(iv), we permit immediately substituting new generic drugs for brand name drugs, and that current § 423.120(b)(5)(iii) permits the immediate removal of drugs deemed unsafe by FDA or withdrawn from sale by their manufacturers. We then discussed our proposal to broaden the scope of permitted immediate substitutions at § 423.120(e)(2)(i) to include authorized generics as defined at § 423.4.

We noted that when we first adopted the immediate substitution policy, we stated that the regulation would not apply to biological products, but that we would reconsider the issue when interchangeable biological products became available in Part D. In the December 2022 proposed rule, we noted there was at least one interchangeable biological product and also an unbranded biological product marketed under the same license, and that other licensed interchangeable biological products may become available in Part D in the future.⁶⁵ Accordingly, we stated we believed it appropriate to expand our policy to include interchangeable biological products and unbranded biological products marketed under the same license as the brand name biological products when immediate substitution would not disrupt existing therapy. We noted that as discussed in the preamble to the proposed rule titled, “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the

⁶⁵The December 2022 proposed rule cited Semglee® (insulin glargine-yfgn). Other interchangeable biological products now available include Cyltezo® (adalimumab-adbm) and Rezvoglar™ (insulin glargine-aglr).

Medicare Prescription Drug Benefit Programs, and the PACE Program,” which appeared in the November 28, 2017 **Federal Register** (82 FR 56413), in deciding to permit immediate generic substitutions without advance direct notice of specific changes to affected enrollees, CMS, or other specified entities, we weighed the need to maintain the continuity of a plan’s formulary for beneficiaries who enroll in plans based on the drugs offered at the time of enrollment against the need to provide Part D sponsors more flexibility to facilitate the use of new generics. We stated that key to our decision to permit such substitutions was the fact that the rule would apply only to therapeutically equivalent generics of the affected brand name drug because such generics are the same as an existing approved brand name drug in dosage form, safety, strength, route of administration, and quality. Congress, we noted, defined “interchangeable” in reference to biological products, stating that interchangeable biological products “may be substituted for the reference product without the intervention of the health care professional who prescribed the reference product.”⁶⁶ We also explained that FDA reports that this is similar to how generic drugs are routinely substituted for brand name drugs.⁶⁷

We then noted that all 50 States now permit or require pharmacists to substitute interchangeable biological products when available, for prescribed reference products at the point-of-dispensing, subject to varying requirements regarding patient and prescriber notice, documentation of the substitution, and patient savings as a result of the substitution, among other safeguards.⁶⁸ In the context of a growing market for interchangeable biological products, to follow the lead of FDA in encouraging uptake of these products, and to provide flexibility that could lead to better management of the Part D benefit that does not impede State pharmacy practices, we proposed at § 423.120(e)(2)(i) to permit Part D sponsors meeting the applicable requirements to immediately substitute an interchangeable biological product for the reference product on its

formulary. In support of that proposal, we also proposed the following definitions at § 423.4: An “interchangeable biological product” would mean a product licensed under section 351(k) of the Public Health Service Act (PHSA) (42 U.S.C. 262(k)) that FDA has determined to be interchangeable with a reference product in accordance with sections 351(i)(3) and 351(k)(4) of the PHSA (42 U.S.C. 262(i)(3) and 262(k)(4)).⁶⁹ We stated that a “biological product” would mean a product licensed under section 351 of the PHSA, and a “reference biological product” would mean a product as defined in section 351(i)(4) of the PHSA.

We also noted that in addition to interchangeable biological products, unbranded biological products have recently been marketed. We explained that in the frequently asked questions of FDA’s “Purple Book Database of Licensed Biological Products,” available at <https://purplebooksearch.fda.gov/faqs#11>, FDA describes an “unbranded biologic” or “unbranded biological product” as an approved brand name biological product that is marketed under its approved BLA without its brand name on its label. Thus, like an authorized generic, an unbranded biological product is the same product as the brand name biological product. Accordingly, since we proposed in the December 2022 proposed rule to permit Part D sponsors to immediately substitute an authorized generic for a brand name drug, we similarly proposed at § 423.120(e)(2)(i) in that proposed rule to permit immediately substituting, as specified, unbranded biological products for corresponding brand name biological products. We further proposed at § 423.4 to define “brand name biological products” to mean biological products licensed under section 351(a) or 351(k) of the PHSA and marketed under a brand name. We also proposed at § 423.4 to define “unbranded biological products” as biological products licensed under a BLA under section 351(a) or 351(k) of the PHSA and marketed without a brand name.

We also noted we were not proposing to permit Part D sponsors to immediately substitute all “biosimilar products” (87 FR 79539) because not all biosimilar biological products have met additional requirements to support a demonstration of interchangeability, as outlined by the Biologics Price Competition and Innovation (BPCI) Act of 2009.⁷⁰ Nevertheless, we encouraged Part D plan sponsors to offer such products on their formularies.

The remainder of the section covered a variety of topics including proposed changes to terminology; use of plural tense for negative formulary changes to reflect the possibility of concurrent changes; exemption of immediate negative formulary changes from negative change request and approval processes and inclusion in formulary updates; market withdrawals including renumbering; and exemption of all immediate negative formulary changes from transition requirements.

In section III.Q.3.c., Notice of Negative Immediate Changes, of the December 2022 proposed rule, we noted that, consistent with our existing requirements for immediate generic substitutions (which we proposed to broaden to include other corresponding drugs), we were proposing to require advance general notice of immediate substitutions and market withdrawals at § 423.120(f)(2), followed by written notice to affected enrollees as soon as possible under § 423.120(f)(3), but by no later than the end of the month following any month in which a change takes effect. We provided details on the content of the direct written notice at § 423.120(f)(4), noted it could be provided for both maintenance and non-maintenance changes, and noted that we were renumbering some current regulatory requirements.

b. Current Proposals

(1) Substituting Biosimilar Biological Products for Their Reference Products as Maintenance Changes

In the December 2022 proposed rule, we indicated that biosimilar biological products⁷¹ other than interchangeable

⁶⁶ Public Health Service Act section 351(i)(3) (42 U.S.C. 262(i)(3)).

⁶⁷ “Biosimilar and Interchangeable Biologics: More Treatment Choices” at the following FDA website: <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>. Accessed April 26, 2022.

⁶⁸ Cardinal Health. Biosimilar Interchangeability Laws by State. Updated July 2021. Available from: <https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf>.

⁶⁹ See section 351(k)(4) of the PHSA (42 U.S.C. 262(k)(4)). We cited as current at the time, “Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry” at the following FDA website: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry>. Accessed September 2, 2022. See also section 351(i)(3) of the PHSA (42 U.S.C. 262(i)(3)) for the statutory definition of the term “interchangeable” or “interchangeability.”

⁷⁰ We note that in the December 2022 proposed rule, the actual statement read: “Biosimilar products have not met additional requirements to support a demonstration of interchangeability based on further evaluation and testing of the product, as outlined by the Biologics Price Competition and Innovation (BPCI) Act.” This statement failed to capture the nuances that the definition of a biosimilar biological product includes interchangeable biological products, and that a determination of interchangeability may not require additional testing.

⁷¹ We propose a definition of “biosimilar biological product” later in this section.

biological products did not qualify for immediate substitutions but nonetheless encouraged their inclusion on formularies. However, neither the preamble at section III.Q., Changes to an Approved Formulary, in the December 2022 proposed rule, nor the accompanying proposed regulatory text, explicitly discussed whether we would treat the substitution of biosimilar biological products other than interchangeable biological products for their reference products as non-maintenance changes or as maintenance changes, as respectively proposed to be defined in section § 423.100 in the December 2022 proposed rule. Our current guidance treats such substitutions as non-maintenance changes.

Nevertheless, we received multiple comments regarding this issue with a range of views. Commenters asking CMS to treat substitutions of reference products with biosimilar biological products, including interchangeable biological products, as immediate formulary changes or maintenance changes noted, for example, that FDA states that biosimilar biological products, including interchangeable biological products, are as safe and effective as the reference product they were compared to,⁷² and that beneficiaries could benefit from additional treatment options and the potential for savings. Commenters asking CMS to restrict immediate substitutions to interchangeable biological products noted, among other things, that the PHSA distinguishes between biosimilar biological products based on interchangeability. Commenters asking us not to permit immediate substitutions, or even any substitutions, of biosimilar biological products, including interchangeable biological products, for reference products noted, for instance, that established drug therapies should not be changed for non-clinical reasons to avoid risk to patient safety and that prescribers need to be consulted before changing medications.

We appreciate all the comments we received. In response thereto, and after further consideration of these issues, we have revisited our current policy, which treats substitutions of biosimilar biological products for reference products as non-maintenance changes, as well as our proposal in the December 2022 proposed rule. Upon further consideration, we are now proposing in this rule to include substitutions of

biosimilar biological products other than interchangeable biological products⁷³ for their reference products as maintenance changes. All FDA-licensed biosimilar biological products, including FDA-licensed interchangeable biological products, must be highly similar to and have no clinically meaningful differences from the reference product in terms of safety and effectiveness notwithstanding minor differences in clinically inactive components. Thus, based on FDA's standards for approval, health care providers and patients can be confident in the safety and effectiveness of all biosimilar biological products, just as they would be for their reference products. The FDA has noted that all biosimilar biological products are as safe and effective as their reference product:

Both 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.

In addition, the FDA closely regulates the manufacturing of [biosimilar biological products]. The same quality manufacturing standards that apply to the [reference product] also apply to the

[biosimilar biological product]. It must be manufactured in accordance with Current Good Manufacturing Practice⁷⁴ requirements, which cover: Methods, Facilities, and Controls for the manufacturing, processing, packaging, or holding of a medication. This helps to prevent manufacturing mistakes or unacceptable impurities, and to ensure consistent product quality.

* * * * *

[All biosimilar biological products, not just interchangeable biological products,] are as safe and effective as the [reference product] they were compared to, and they can both be used in its place. This means that health care professionals can prescribe either a biosimilar [biological product] or interchangeable [biological] product instead of the [reference product].⁷⁵

However, we note that under the PHSA an FDA determination that a biological product is interchangeable with the reference product means that the interchangeable biological product may be substituted without the intervention of the health care provider who prescribed the reference product. A manufacturer of a proposed interchangeable biological product must show that the product is biosimilar to its reference product and that it can be expected to produce the same clinical results as the reference product in any given patient and there are no greater risks in terms of safety or diminished efficacy with alternating or switching between the reference product and the interchangeable biological product.⁷⁶ We appreciate the importance of provider and patient education to advance uptake and acceptance as the development and market for biosimilar biological products, including interchangeable biological products, continues to grow.

We believe that including substitutions of biosimilar biological products other than interchangeable biological products for their reference products as maintenance changes would strike the right balance between promoting utilization of more biosimilar biological products and providing enrollees with sufficient advance notice

⁷³ We would note that in our December 2022 proposed rule, we already proposed the option for Part D sponsors to treat substitution of interchangeable biological products for their reference products as maintenance changes: We proposed in paragraph (1) of the proposed definition of "maintenance change" in § 423.100 to mean, in part, making any negative formulary changes to a drug and at the same time adding a corresponding drug as specified. In turn, we proposed to define "corresponding drug" in § 423.100 to include an interchangeable biological product of a reference product. In this proposed rule, we are proposing to add a new paragraph (2) to the proposed definition of "maintenance change" in § 423.100 to treat substitution of biosimilar biological products other than interchangeable biological products for their reference products as maintenance changes.

⁷⁴ <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>. Accessed October 18, 2023.

⁷⁵ 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>. Accessed October 18, 2023.

⁷⁶ See 42 U.S.C. 262(i)(3) and (k)(4).

⁷² FDA. Overview of Biosimilar Products. Available from: <https://www.fda.gov/media/151058/download?attachment>.

of such changes. This proposal would provide Part D sponsors with more flexibility than the current policy of treating such changes as non-maintenance changes (which do not apply to enrollees who are currently taking a reference product when the change takes effect⁷⁷) but would not extend the flexibility to what is permitted for immediate substitutions (which apply to all enrollees, including those currently taking a reference product, but only require direct notice of specific changes made to affected enrollees after the fact⁷⁸). We realize now that not addressing in the December 2022 proposed rule the treatment of biosimilar biological products other than interchangeable biological products suggested that we wanted to continue our sub-regulatory policy of treating substitution of reference products by biosimilar biological products other than interchangeable biological products as non-maintenance changes. However, continuing to treat such changes as non-maintenance would not support our goal to encourage greater use of biosimilar biological products.

At the same time, we are not convinced that it is appropriate at this time to propose to permit immediate substitutions of reference products for biosimilar biological products other than interchangeable biological products without 30 days advance notice. In this regard, we would note that, pharmacists generally cannot substitute a biosimilar biological product other than an interchangeable biological product for its reference product without first consulting the prescribing health care provider, subject to State pharmacy laws. If a biosimilar biological product other than an interchangeable biological product were able to be immediately substituted, the result is that any enrollee seeking a refill on their prescription for a reference product after a Part D sponsor has substituted a biosimilar biological product for that reference product (regardless of whether such a formulary change were permitted to take place as an immediate substitution or a maintenance change) would be told that their plan no longer covers the reference product. And, subject to State pharmacy laws, a pharmacist in most cases would not be able to provide the corresponding biosimilar biological product to the

enrollee unless they receive a new prescription from a prescriber.

The above would mean that, were we to treat substitutions of biosimilar biological products other than interchangeable biological products as immediate substitutions, enrollees currently taking a reference product would receive no direct advance notice of specific changes made and would likely find themselves at the pharmacy counter unable to obtain coverage for their reference product and needing to either request an exception or obtain a new prescription for the biosimilar biological product. Such enrollees would receive a notice at the point of sale telling them what they or their prescriber would need to do to request an exception to stay on the reference product and that they can call their plan for more information. To avoid a situation in which the enrollee might not have medication on hand and need to take quick action, but at the same time still encourage the use of all biosimilar biological products, we are proposing to treat such substitutions as maintenance changes. Given that maintenance changes would apply to all enrollees under proposed § 423.120(e)(3) in the December 2022 proposed rule, permitting Part D sponsors to substitute such biosimilar biological products for their reference products as maintenance changes would presumably result in more widespread use of such products than continuing our current sub-regulatory policy that treats such substitutions as non-maintenance changes. Further, under current sub-regulatory policy and proposed § 423.120(e)(3)(i) in the December 2022 proposed rule, Part D sponsors that submit a maintenance change request are able to assume that CMS has approved their negative change request if they do not hear back from CMS within 30 days of submission, which could result in changes that take place more quickly.

Additionally, we believe that the 30-day notice period is appropriate for a variety of reasons. We have applied the 30-day time frame in other contexts (such as notice of changes required under current § 423.120(b)(5)(i)(A) and for changes proposed in our December 2022 proposed rule) and are hesitant to create more confusion by carving out certain biosimilar biological products. We understand the nature of the change is different from, for instance, substituting generic drugs for brand name drugs, in that in most states the enrollees that are prescribed reference products must at this time obtain new prescriptions for biosimilar biological products other than interchangeable

biological products. However, this would not be the only time an enrollee has 30 days' notice within which to obtain a new prescription. For instance, in the final 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 April 16, 2018 **Federal Register**, we reduced the time for advance direct notice of certain formulary changes from 60 to 30 days and since its effective date, § 423.120(b)(5)(i)(A) has required only 30 days' notice of changes to the formulary that are not immediate. A similar period applies to the transition process for enrollees prescribed Part D drugs that are not on the Part D plan's formulary: under § 423.120(b)(3)(iii), enrollees receive a month's supply of a drug after which they must obtain a new prescription for an alternate drug or apply for an exception. If we required Part D sponsors to issue notice earlier, for instance to provide advance notice 90 days prior to the formulary change, the lengthened notice period would provide Part D sponsors less time within a year for a change to be effective and might unintentionally motivate them to wait until the next plan year—which would defeat the goal of this proposal to encourage uptake of biosimilar biological products other than interchangeable biological products sooner than would otherwise be the case.

If a Part D sponsor were to implement a maintenance change for a biosimilar biological product other than an interchangeable biological product under our proposal, then it would work as follows: Part D sponsors removing or making any negative changes to a reference product would be required to add a biosimilar biological product other than an interchangeable biological product at the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements as the reference product. Part D sponsors adding a biosimilar biological product other than an interchangeable biological product would also be required to provide 30 days' advance written notice before making any negative change to the reference product. The written notice under proposed § 423.120(f)(4) would include details regarding the change, including the specific biosimilar biological product to be added to the formulary; whether the sponsor will be removing the related reference product, subjecting it to a new or more restrictive PA, ST,

⁷⁷ See proposed § 423.120(e)(3)(ii), of the December 2022 proposed rule, which would codify longstanding policy regarding non-maintenance changes.

⁷⁸ See § 423.120(b)(5)(iv).

or QL, or moving it to a higher cost-sharing tier; and identification of whether appropriate alternatives, other than the biosimilar biological product that is the subject of the notice, are available on the formulary at the same or lower cost-sharing tier as the reference product. The written notice would also include the means by which the affected enrollee can request a coverage determination under § 423.566 or an exception to a coverage rule under § 423.578. Specifically, under § 423.566, the enrollee can always ask for a coverage determination, including an exception to a coverage rule, and might choose to do so after receiving their notice of a specific change due to occur within 30 days. Furthermore, the enrollee can also request an expedited determination if their health requires. Again, treating the change as a maintenance change would mean enrollees have 30 days to take action before the change becomes effective.

We would note that the Part D transition policy does not apply to midyear maintenance changes. An enrollee is only entitled to a transition supply under § 423.120(b)(3)(i)(A) if the enrollee is new to the plan or stayed in the plan until the next contract year and a drug they are taking is affected by formulary changes in the next contract year. Formulary changes from one contract year to the next do not constitute changes to an approved formulary since formularies are submitted for review and approval annually as part of the Part D bid submission process. Rather, the advance direct notice of changes currently required under § 423.120(b)(5)(i), and which we proposed to require in the December 2022 proposed rule at the proposed § 423.120(f)(1), provides an affected enrollee with time to obtain a new prescription for that biosimilar biological product other than an interchangeable biological product or to seek an exception, before the reference product comes off the formulary.

We assume that in most cases, substituting a biosimilar biological product other than an interchangeable biological product for the reference product on the formulary will be more financially favorable to enrollees since biosimilar biological products are generally lower cost than reference products and must be added to the same or lower cost-sharing tier as the reference product. However, differences in plan benefit designs make it challenging to predict the degree of savings an enrollee may experience. For example, if a Part D sponsor removes a reference product from the formulary and adds a biosimilar biological product

other than an interchangeable biological product to the formulary on the same tier, the affected enrollee likely would experience savings if the cost sharing for the tier is based on a percent coinsurance, but not if the cost sharing for the tier is a fixed copay. If an affected enrollee pursues a formulary exception to continue to take the non-formulary reference product, these enrollees may be faced with higher out-of-pocket costs, depending on the tier that the Part D sponsor designates for Part D drugs obtained through formulary exceptions and the tier that the reference product was originally on. If the reference product was on a preferred tier, but the formulary exception tier designated in the plan benefit package is the non-preferred tier, then affected enrollees who obtain a formulary exception may be subject to higher cost sharing than previously.

For the reasons discussed above, we are now proposing to update the proposed definition of “maintenance changes” at § 423.100 in the December 2022 proposed rule to include a new paragraph (2) on making any negative formulary changes to a reference product when adding a biosimilar biological product other than an interchangeable biological product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements. We would renumber the remaining maintenance changes listed in the proposed definition in the December 2022 proposed rule.

We are also proposing in this proposed rule at § 423.4 to define “biosimilar biological product” to mean a biological product licensed under section 351(k) of the PHSA that, in accordance with section 351(i)(2) of the PHSA, 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. The proposed term, biosimilar biological product, includes interchangeable biological products as we proposed to define them in our December 2022 proposed rule. We are also proposing a technical correction to the proposed definition of an interchangeable biological product to mean a product licensed under section 351(k) of the PHSA (42 U.S.C. 262(k)) that FDA has determined meets the standards described in section 351(k)(4) of the PHSA (42 U.S.C. 262(k)(4)).

We solicit comment on our proposal to treat formulary substitutions of

biosimilar biological products other than interchangeable biological products for reference products as maintenance changes, as well as our proposed definition of biosimilar biological product. We also would be interested in any comments on our proposal that enrollees taking a reference product would receive 30 days’ notice before the change is made and whether that is sufficient time to obtain a new prescription for the biosimilar biological product other than an interchangeable biological product, as well as how that 30-day notice period relates to the timing of other notice requirements. We also solicit comment on our proposal that the biosimilar biological product other than the interchangeable biological product be placed on the same or a lower cost-sharing tier as the reference product it replaces or that is subject to negative formulary changes.

(2) Updated Proposal Related to Timing of Substitutions

In reexamining our proposed definition of “maintenance changes” in § 423.100 in the December 2022 proposed rule to add a new category for biosimilar biological products other than interchangeable biological products in paragraph (2), as discussed above, we also revisited paragraph (1) of the proposed definition, in which we proposed to require Part D sponsors making a negative formulary change to a drug to “at the same time” add a corresponding drug at the same or lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements (excluding immediate substitutions permitted under the proposed § 423.120(e)(2)(i) of the December 2022 proposed rule). Considering that our current sub-regulatory guidance does not require maintenance substitutions to occur “at the same time,” we have reconsidered and do not believe it is necessary to propose imposing such strict timing requirements for a maintenance change—whether it be related to plan sponsors removing or making negative changes (1) to a brand name or reference product when adding a corresponding drug that is not an immediate substitution, or (2) to a reference product when adding a biosimilar biological product other than an interchangeable biological product. We would like to encourage plans to offer more choices by adding corresponding drugs (the proposed definition of which in the December 2022 proposed rule includes interchangeable biological products) and biosimilar biological products other than interchangeable

biological products to their formularies as soon as possible. We are concerned that requiring such an addition to occur “at the same time” as the negative formulary change to the brand name drug or reference product could cause a Part D sponsor to delay adding a corresponding drug or biosimilar biological product other than an interchangeable biological product until the Part D sponsor has taken the steps it deems necessary to operationalize the negative changes that would be made to the brand name drug or reference product currently on the formulary, which in turn would delay enrollee access to the corresponding drug or biosimilar biological product other than an interchangeable biological product.

Therefore, we propose to remove the requirement to have changes take place “at the same time” in the December 2022 proposed rule’s definition of “maintenance change” at proposed § 423.100, and will not add that modifier for the change for biosimilar biological products other than interchangeable biological products that we are proposing in this proposed rule, with the understanding that the addition of the corresponding drug or biosimilar biological product other than an interchangeable biological product would need to come before the negative change is applied to the brand name drug or reference product. Further, this proposed update to the definition of a maintenance change does not alter other proposed requirements for maintenance changes in the December 2022 proposed rule, including that CMS must be provided a 30-day opportunity to review any such changes and in all cases enrollees will receive at least 30 days’ notice before a drug is removed or subject to any other negative formulary change.

At the same time, we are not proposing an unlimited window in which to make a negative formulary change to the related drug after adding a corresponding drug under paragraph (1) or adding a biosimilar biological product other than an interchangeable biological product under paragraph (2) of the proposed § 423.100 definition of a “maintenance change.” We believe Part D sponsors should make such negative changes within a reasonable amount of time after adding corresponding drugs and biosimilar biological products other than interchangeable biological products as specified in order to best achieve the goal of increasing their utilization. We understand that Part D sponsors may be eager to add, for example, a newly approved generic drug or biosimilar biological product to their formularies,

but may need additional time to operationalize the negative formulary change to the brand name or reference product, respectively; however, we do not believe that Part D sponsors should have an unlimited amount of time to effectuate the negative formulary change because this presents challenges for CMS to monitor and deviates from the idea that such formulary changes are in many cases substitutions of one drug for another. In other words, the addition of a corresponding drug or a biosimilar biological product other than an interchangeable biological product justifies the negative formulary change to the brand name or reference product. Nevertheless, we do not want to establish too short a timeframe requirement to make the negative change to the brand name drug or reference product because it could increase the chance that Part D sponsors will miss the formulary update opportunity, resulting in more continued utilization of the brand name drug or reference product and less utilization of the corresponding drug or biosimilar biological product other than an interchangeable biological product than otherwise could be achieved. To strike a balance, we are proposing to codify our longstanding operational limitation of a 90-day timeframe for a Part D sponsor to remove a brand name drug from the formulary when a generic drug is added. Our experience suggests that this timeframe would provide Part D sponsors with sufficient time to implement the negative formulary change for a brand name drug or reference product after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product, but still ensure the removal of the brand name drug or reference product is timely enough to help increase utilization of the corresponding drug or biosimilar biological product other than an interchangeable biological product. Accordingly, we believe negative formulary changes to the brand name drug or reference product should have to take effect within 90 days after a generic or other corresponding drug, or biosimilar biological product other than an interchangeable biological product, is added as specified to the formulary.

To provide Part D sponsors with more flexibility, we propose to remove from paragraph (1) of the proposed definition of “maintenance change” in § 423.100 of the December 2022 proposed rule the requirement that the corresponding drug be added and the related drug be subject to negative formulary changes “at the same time.” Rather, we now propose to

revise paragraph (1) to require Part D sponsors to make any negative formulary changes “within 90 days of” adding a corresponding drug. Similarly, the newly proposed paragraph (2) of the proposed definition of “maintenance change” in § 423.100, as discussed above, would require Part D sponsors to make negative formulary changes to a reference product “within 90 days of” adding a biosimilar biological product other than an interchangeable biological product.

In this vein, we note that a commenter on the December 2022 proposed rule requested that we remove the requirement in the proposed § 423.120(e)(2)(i) of the December 2022 proposed rule (currently appearing at § 423.120(b)(5)(iv)(A)) that Part D sponsors making immediate substitutions remove or make any other negative formulary changes to a related drug “at the same time” they add its corresponding drug. The commenter suggested that this requirement might discourage them from adding new corresponding drugs, which could be lower in cost than related drugs, as soon as possible because they often need more time to implement the changes with respect to the related drug. For instance, they suggested it takes time to evaluate new products; check their availability; communicate changes; update operations; and assess suitability for substitution among interchangeable biological products. We appreciate the comment and reiterate that we favor expeditious access for enrollees to Part D drugs that could be lower in cost. The purpose of the immediate substitutions policy is to encourage quick action with respect to immediately placing a corresponding drug on the formulary after it is released.

Accordingly, with respect to the proposed § 423.120(e)(2)(i) in the December 2022 proposed rule, we now propose to remove the requirement that immediate substitutions occur “at the same time” and instead state that negative formulary changes may still qualify as immediate substitutions if made within 30 days of adding a corresponding drug to a formulary. As proposed in the December 2022 proposed rule, for immediate substitutions, Part D sponsors would be required to submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

We note that we are proposing different windows of time in which Part D sponsors can make negative formulary changes to the related drug based on whether there is an immediate substitution (that is, within 30 days after

adding the corresponding drug) or a maintenance change (that is, within 90 days after adding the corresponding drug). The different requirements reflect a distinction in the nature of the changes themselves. As noted earlier, the entire purpose of immediate substitutions is quick action, such that Part D sponsors can put a newer corresponding drug on the formulary and remove the related drug it is replacing as soon as possible. For that reason, we continue to encourage that immediate substitutions take place “at the same time,” but propose setting a 30-day limit. To encourage this, Part D sponsors implementing immediate substitutions may provide notice to affected enrollees of the specific changes after they have taken effect.

For the reasons discussed above, for other kinds of maintenance changes that are not immediate, we propose that we would approve only negative formulary changes to the related drug that take effect within 90 days after a corresponding drug is added to the formulary.

We invite comment on these proposed changes, the reasons why Part D sponsors would need a period of time after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product in which to take action, and any other appropriate window of time in which to permit maintenance changes or immediate substitutions to take place, including whether we should maintain a distinction between the two.

(3) Miscellaneous Changes

In re-examining our proposed definition of “maintenance change” in the December 2022 proposed rule at § 423.100, we found a technical error, in that we did not specify in the introductory clause that the changes would apply with respect to “a covered Part D drug.” We hereby propose to make that correction in this proposed rule.

We propose a technical change to our proposed definition of “corresponding drug” included in the December 2022 proposed rule in § 423.100 to specify that the reference to “an unbranded biological product of a biological product” is intended to be a reference to “an unbranded biological product marketed under the same BLA as a brand name biological product.”

3. Summary

In conclusion, we are proposing the changes below to three sections of regulatory text originally proposed in the December 2022 proposed rule. We are currently not proposing updates to

the other proposed regulatory text in the December 2022 proposed rule related to section III.Q., Changes to an Approved Formulary, which, as noted above, remains under consideration.

- In § 423.4, to add a definition of “biosimilar biological product;”
- In § 423.4, to make technical corrections to the proposed definition of an “interchangeable biological product;”
- In § 423.100, to revise the proposed definition of “maintenance change” as follows: to add an introductory clause noting its application to covered Part D drugs; to revise paragraph (1) to require changes “within 90 days of,” rather than “at the same time as,” adding a corresponding drug; to add a new paragraph (2) to include substitution of biosimilar biological products other than interchangeable biological products as a type of maintenance change; and to renumber the remaining maintenance changes listed;
- In § 423.100, to revise the proposed definition of “corresponding drug” to specify that the reference to “an unbranded biological product of a biological product” is intended to be a reference to “an unbranded biological product marketed under the same BLA as a brand name biological product;” and
- In proposed § 423.120(e)(2)(i), to require changes “within 30 days of,” rather than “at the same time as,” adding a corresponding drug.

G. 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)) 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 part 422, subpart B, and part 423, subpart B) into plans under the terminating contract(s) unless CMS imposes separate marketing and enrollment sanctions on the terminating contract(s).⁷⁹ A terminating contract that continues to market to and enroll eligible beneficiaries would 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 propose 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 propose 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 propose that MA organizations and Part D sponsors would continue to be afforded the same appeals rights and procedures specific to contract terminations under subpart N of 42 CFR parts 422 and 423, however, there would not be a separate appeal for the sanction (in other words the appeal of the termination would include the associated marketing and enrollment sanctions). In addition, at paragraph (e)(3) of § 422.510 and paragraph (f)(3) of § 423.509 we propose that if an MA organization or Part D sponsor appeals the contract termination, the marketing and enrollment sanctions would 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

⁷⁹Regulations in 42 CFR part 422, subpart B, and part 423, subpart B, permit enrollees to enroll in a plan mid-year during their initial election period or special election periods.

propose that the sanction would remain in effect until the effective date of the termination, or if the termination decision is overturned on appeal, until 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 would 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 would not be required to submit a corrective action plan, and if appealed there would only be one appeal rather than multiple. MA organizations and Part D sponsors would continue to be required to comply with existing regulations that require public and beneficiary notice that their contract is being terminated under this proposal.

H. 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.⁸⁰ For example, Hispanic/Latino individuals with LEP report worse access to care and receipt of fewer preventive services than Hispanic/Latino individuals who speak English proficiently. For Asian Americans who are not proficient in English, language barriers are one of the most significant challenges to accessing health care, including making an appointment, communicating with health care professionals, and gaining knowledge about an illness; this is even more pronounced among older Asian Americans, who are more likely to have limited English proficiency.⁸¹ Studies

show that patients with LEP experience longer hospital stays—leading to a greater risk of line infections, surgical infections, falls, and pressure ulcers—when compared to English-speaking patients; because patients with LEP have greater difficulty understanding medical instructions when those instructions are given in English, they are at higher risk of surgical delays and readmissions.⁸² Although the use of qualified interpreters is effective in improving care for patients with LEP, some clinicians choose not to use them, fail to use them effectively, or rely instead on ad hoc interpreters—such as family members or untrained bilingual staff.⁸³ However, in addition to posing legal and ethical concerns, ad hoc interpreters are more likely to make mistakes than professional interpreters.⁸⁴ Also, clinicians with basic or intermediate non-English spoken language skills often attempt to communicate with the patient on their own without using an interpreter, increasing patient risk.⁸⁵ These barriers contribute to disparities in health outcomes for individuals with LEP, which likely worsened during the COVID–19 pandemic.⁸⁶

The multi-language insert (MLI) required at §§ 422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs

<https://www.tandfonline.com/doi/pdf/10.1080/19371910903240704?needAccess=true>.

⁸² U.S. Department of Health & Human Services, Agency for Healthcare Research & Quality. “Executive Summary: Improving Patient Safety Systems for Patients with Limited English Proficiency”, (September 2020). Retrieved from <https://www.ahrq.gov/health-literacy/professional-training/lepguide/index.html>.

⁸³ Espinoza, J. and Derrington, S. “How Should Clinicians Respond to Language Barriers that Exacerbate Health Inequity?”, *AMA Journal of Ethics* (February 2021) E110. Retrieved from <https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2021-02/cscm3-2102.pdf>.

⁸⁴ Glenn Flores et al., *Errors of Medical Interpretation and Their Potential Clinical Consequences: A Comparison of Professional Versus Ad Hoc Versus No Interpreters*, 5 *Annals of Emerg. Med.* 545 (Nov. 1, 2012), <https://pubmed.ncbi.nlm.nih.gov/22424655/>; Ali Labaf et al., *The Effect of Language Barrier and Non-Professional Interpreters on the Accuracy of Patient-Physician Communication in Emergency Department*, 3 *Adv. J. Emerg. Med.*, June 6, 2019, at p. 4, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6789075/pdf/AJEM-3-e38.pdf>.

⁸⁵ U.S. Department of Health & Human Services, Agency for Healthcare Research & Quality. “Executive Summary: Improving Patient Safety Systems for Patients with Limited English Proficiency”, (September 2020). Retrieved from <https://www.ahrq.gov/health-literacy/professional-training/lepguide/exec-summary.html#what>.

⁸⁶ 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/doi/10.1377/hblog20200724.76821/full/>.

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 are the 15 most common non-English languages in the United States. 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 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).⁸⁷ 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.

On May 18, 2016, the Office for Civil Rights (OCR) published a final rule (81 FR 31375; hereinafter referenced to as the section 1557 final rule) implementing section 1557 of the Patient Protection and Affordable Care Act (ACA).⁸⁸ Section 1557 of the ACA provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et*

⁸⁷ 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.

⁸⁸ Public Law 111–148.

⁸⁰ 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/>.

⁸¹ Wooksoo, K. and Keefe, R. “Barriers to Healthcare Among Asian Americans”, *Social Work in Public Health* (2010) 286–295. Retrieved from

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), under any health program or activity, any part of which is receiving Federal financial assistance; any health program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act. The 2016 regulations implementing section 1557 included the requirement that all covered entities 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).” Because of the inherent duplication with the MLI, CMS issued an HPMS email on August 25, 2016, to revise the Medicare Marketing Guidelines (MMG) at that time to remove the then-applicable MLI requirements.

On June 19, 2020, OCR published a second section 1557 final rule (2020 OCR Rule) (85 FR 37160), which is currently in effect, that repealed the notice and tagline requirements, citing costs, confusion, and waste, but stated that covered entities are still required “to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity.” In the February 2020 proposed rule (85 FR 9002), we proposed to require plans to use a disclaimer tagline about the availability of non-English translations in all required materials. However, we did not finalize that proposal in the January 2021 final rule (86 FR 5864). We based this decision on our belief that future rulemaking regarding non-English disclaimers, if appropriate, would be best addressed by OCR, as those requirements would be HHS-wide instead of limited to CMS. We also stated that deferring to OCR’s oversight and management of any requirements related to non-English disclaimers is in the best interest of the Medicare program (86 FR 5995).

It is important to note that none of the actions 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 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. For a more detailed discussion of previous rulemaking related to section 1557, the MLI, and non-English translation and interpreter requirements, we direct readers to the August 4, 2022 HHS notice of proposed rulemaking regarding section 1557 of the Affordable Care Act (87 FR 47853 through 47856) (hereinafter referred to as the August 2022 proposed rule) and the January 2022 proposed rule (87 FR 1899 through 1900).⁸⁹

In the 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) (hereafter referred to as the May 2022 final rule), we reinstated the requirement to use the MLI at §§ 422.2267(e)(31) and 423.2267(e)(33). 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 CFR 27821). We stated that we consider the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary 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 OCR 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 proposed rule (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 using a “Notice of Availability.” Proposed § 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. If finalized, 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. At the time this proposed rule is published, OCR has not issued a final rule on its August 2022 proposed rule, and the 2020 OCR Rule remains in effect.

In addition, per § 438.10(d)(2), States must require 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. For example, while French Creole is included in the current MLI list for the most common languages nationally, it is not a common

⁸⁹ Specifically, we highlight pages 1899–1900 and 1926–1927 of the August 2022 proposed rule and 87 FR 1899 through 1900 of the January 2022 proposed rule.

language in Minnesota. In Minnesota, Hmong and Somali, which are not included in the MLI, are two of the most prevalent languages. In fact, Minnesota informed CMS that only seven of the languages on the national list were included in their list of the 15 most common languages in their State.

As a result of this conflict between 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 if they want 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. This lengthy list can be a distraction from the main information conveyed in the material. As discussed in greater detail below, we are proposing to update §§ 422.2267(e)(31) and 423.2267(e)(33) to instead require that notice of availability of language assistance services and auxiliary aids and services be provided in the 15 most common languages in a State; we expect that this proposed policy would better align with the Medicaid translation requirements at § 438.10(d)(2).⁹⁰

We believe rulemaking regarding a non-English notice of the availability of language assistance services and auxiliary aids and services 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 will allow 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.

Noting that while OCR has yet to finalize the Notice of Availability policy described in its August 2022 proposed rule, and thus that OCR's proposed policy could be subject to change or not be finalized, 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. Should the OCR final rule differ from the original August 2022 proposed rule, we will consider modifying our final rule to align with OCR's final rule.

Therefore, we propose to amend §§ 422.2267(e)(31) and 423.2267(e)(33). First, we propose to replace references to the MLI with references to a Notice of Availability. We propose to modify the language to reflect CMS's proposal 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. We propose to change paragraphs (e)(31) and (33) to require MA organizations and Part D sponsors to provide enrollees a notice of availability of language assistance services and auxiliary aids and services 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. We are proposing, 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. This proposed State-specific standard would ensure that a significant proportion of each State's particular LEP population receives key information in the appropriate languages. The U.S. Census Bureau's ACS 2009–2013 multi-year data show that the top languages spoken in each State can vary significantly.⁹¹ State-specific language translations provide for flexibility to maximize access to care for individuals with LEP. This 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.

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. As an additional benefit, our proposed changes would mitigate the risk that §§ 422.2267(e)(31) and 423.2267(e)(33) could conflict with § 438.10(d)(2) and the forthcoming OCR final rule, if finalized, requiring applicable Medicare plans to comply with two, disparate sets of requirements. Such an outcome adds undue burden on plans. 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. Notwithstanding OCR's final rule policy, we believe our proposed changes are appropriate given the benefits of a non-English notice of availability of language assistance services and auxiliary aids and service more closely reflecting the actual languages spoken in the service area and alignment with the Medicaid translation requirements.

Additionally, we propose 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 five 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

⁹⁰ 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 proposed rule 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).

⁹¹ <https://www2.census.gov/library/data/tables/2008/demo/language-use/2009-2013-acs-lang-tables-nation.xls>.

there may be a subpopulation in the plan benefit package service area that uses a language that does not fall within the top 15 languages or meet the five percent service area of a plan benefit package threshold that the plan determines can benefit by receiving the notice. We again 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, 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 5 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 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.⁹² However, plans can also use 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 Notes⁹³ 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.

I. 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.⁹⁴

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. Currently, § 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 (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).

⁹⁴ 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).

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, while § 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). Currently, we may release the data only after risk adjustment reconciliation for the applicable payment year has been completed or under certain emergency preparedness or extraordinary circumstances. We note that we included a proposal to publicly report aggregated counts of procedures performed by providers, based on MA encounter data, before risk adjustment reconciliation is complete in the Medicare and Medicaid Programs 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 proposed rule (hereafter referred to as the August 2023 proposed rule; 88 FR 52262).

Here, we are proposing to allow MA encounter data to be used to support the Medicaid program for certain purposes already specified for use to support the Medicare program in § 422.310(f)(1)(vi) and (vii). Under our proposal, MA risk adjustment data could be used for supporting either program separately or in conjunction. In addition, we are proposing to allow release of MA encounter data to State Medicaid agencies (States) in advance of the completion of risk adjustment reconciliation for the specific purpose of care coordination for individuals who are dually eligible for Medicare and Medicaid, also known as dually eligible individuals. These proposals related to disclosure of MA encounter data are focused on expanding allowable disclosures of these data to support not only the Medicare program or Medicare-Medicaid demonstrations, but also the Medicaid program in the interest of improving care for individuals who are eligible for Medicaid.

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. We clarified that States may access and use MA encounter data while "in the administration of Medicare-Medicaid demonstrations" in the Medicare Program; Hospital Inpatient Prospective

⁹² 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-archived-weekly/hpms-memos-wk-4-september-18-22>.

⁹³ 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-archived-weekly/hpms-memos-wk-4-september-18-22>.

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 (hereafter referred to as the August 2014 final rule; 79 FR 50325). Additionally, current regulation text at § 422.310(f)(1)(vi) permits CMS to release MA encounter data to third parties, including States, to “conduct evaluations and other analysis to support the Medicare program (including demonstrations).” This proposal would expand certain allowable use and disclosures of MA encounter data to support the Medicaid program, which would thereby enable State access to comprehensive data for all dually eligible individuals in the State regardless of their enrollment in a demonstration, dual eligible special needs plan (D–SNP), or other MA plan. Our proposal to further expand MA encounter data sharing to include support for the Medicaid program would also be consistent with the goals of the Federal Coordinated Health Care Office, as established in statute. Section 2602 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act) established the office within CMS to better integrate benefits and improve coordination for dually eligible individuals, including specific goals and responsibilities such as:

- Providing dually eligible individuals full access to the benefits to which such individuals are entitled under the Medicare and Medicaid programs.
- Improving the quality of health care and long-term services for dually eligible individuals.
- Improving care continuity and ensuring safe and effective care transitions for dually eligible individuals.
- Improving the quality of performance of providers of services and suppliers under the Medicare and Medicaid programs.
- Supporting 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.

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).^{95 96} 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 limits 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 are proposing changes to § 422.310(f) to improve access for States to MA encounter data, including making a specific exception to the timing of sharing MA encounter data. We do 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). Such provisions would similarly apply to States that receive MA encounter data under the proposed amendments to § 422.310(f) here.

⁹⁵ 2023 Medicare Trustees Report <https://www.cms.gov/oact/tr>.

⁹⁶ <https://www.cms.gov/files/document/managedcareenrollmenttrendsdatabrief2012-2021.pdf>.

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 are proposing to add “and Medicaid program” to the current MA encounter data use purposes codified at § 422.310(f)(1)(vi) and (vii). 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 believe that our release of MA encounter data for these 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.

As stated above, CMS data sharing procedures apply to the release of MA encounter data in accordance with § 422.310(f)(2) and contain provisions regarding access to and storage of CMS data to ensure that beneficiary identifiable information is protected. We make other data available to external entities, including States, in accordance with CMS data sharing procedures and Federal laws, including but not limited to the Privacy Act of 1974. We review data requests for appropriate use justifications, including updated or amended use justifications for existing data requests. 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. 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. This would mean that, under this 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. 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. 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. 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 concerns regarding the release of risk adjustment data, including for beneficiary privacy or commercially sensitive information of 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 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. 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. We have not identified any issues regarding competitive harm or disadvantage in our current data sharing programs.

Under this proposal, we would be able 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. For example, access to MA encounter data could support States’ analysis of geographic trends to create targeted community outreach and education, including identification of geographic areas with higher rates of dementia, diabetes, or emergency room visit overutilization; and evaluation of current Medicaid initiatives, including tracking efficacy of opioid overuse and misuse programs by monitoring service utilization for those with opioid dependency, evaluating appropriate and inappropriate use of antibiotic and psychotropic medications, and analyzing deaths among individuals with opioid use disorder. 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 this proposal, 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.

We are taking this opportunity to make a clarification related to the existing program administration purpose, as specified in § 422.310(f)(1)(vii). 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 are clarifying here 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 believe 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. For example, 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.

We welcome public comment on this proposal.

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, our 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 or under certain emergency preparedness or extraordinary circumstances. Section 422.310(g) specifies the deadlines that we use to determine which risk adjustment data submissions we consider when assigning the risk adjustment factors for payment in a given payment year. This section also establishes a reconciliation process to adjust payments for additional data submitted after the end of the MA risk adjustment data collection year (meaning the year the item or service was furnished to the MA enrollee) but before the established deadline for the payment year, which can be no earlier than January 31 of the year following the payment year. This reconciliation period 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)(1) requires MA organizations to submit data for all items and services provided; therefore, MA organizations must continue to submit encounter data records and data corrections after the final submission deadline if needed. (We note that there are limitations on which submissions after the final reconciliation deadline may be used in risk adjustment. See § 422.310(g).) The timing limitation on release of MA encounter data in our current regulation is tied to the established deadline for the payment year, and it results in a data lag of at least 13 months after the end of the MA risk adjustment data year (that is, the year during which the services were furnished), before CMS may release the MA risk adjustment data for the purposes described in § 422.310(f)(1).⁹⁷ We believe there will be increased utility of MA encounter data for Medicaid programs if the data is released before final reconciliation for coordination of care under the allowable purpose in § 422.310(f)(1)(vii). We believe 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 as discussed further below.

In order to improve utility of MA encounter data for certain approved purposes, we propose to add a new subsection § 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). As discussed above, the proposed amendments 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 are specifying care coordination for our proposal for release of MA encounter data prior to reconciliation as we believe providing States access to this more timely data is critical to effectively coordinating care, 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 timeliness of the MA encounter data we make available to States for coordination of care for dually eligible individuals.

As discussed above, a growing number of dually eligible individuals are enrolled in MA plans. To ensure that these individuals are receiving high quality, efficient care, it is essential that States have access to information on their service utilization in a timely manner. Without timely, comprehensive beneficiary data, which are not currently available to States for all MA enrollees, States cannot conduct care coordination for dually eligible individuals in MA. For example:

- A State looks to coordinate care related to the COVID-19 pandemic for individuals concurrently enrolled in Medicaid and MA plans, such as by identifying people who had COVID-related hospitalizations. In accordance with § 422.310(f)(3), our current release schedule of MA encounter data for research purposes limits available MA encounter data to between 13 and 25 or more months after the service was rendered.⁹⁸ Therefore, with the exception of those dually eligible individuals enrolled in an MA plan under a demonstration or in an MA D-SNP, where the State can use the contract with the plan in accordance with § 422.107 to obtain MA encounter data or other notifications under § 422.107(d)(1) from the D-SNP, States could not access service utilization data for MA enrollees to coordinate care for dually eligible individuals who had a COVID-related hospitalization in a timely manner. Instead, the States would need to wait for the MA encounter data until after risk adjustment reconciliation for the applicable payment year has been completed—which would be months after a dually eligible individual required post-hospitalization follow-up

⁹⁷ "Deadline for Submitting Risk Adjustment Data for Use in Risk Score Calculation Runs for Payment Years 2021, 2022, 2023, and 2024" HPMS memo. <https://www.cms.gov/files/document/py20202021202220232024paymentrunnotice508g.pdf>.

⁹⁸ <https://resdac.org/cms-news/2021-preliminary-medicare-encounter-data-now-available>.

care. However, if States could access timely MA encounter data, then Medicaid care coordinators could follow up after a COVID-related hospitalization to ensure adequate care related to mental health treatment, coordinate approval of durable medical equipment, or ensure physical or rehabilitation therapy while reducing redundant visits or delays in care to the dually eligible individual.

- A State uses a predictive modeling algorithm—using past service utilization, diagnosis, and other data—to identify people at high risk for poor outcomes or institutional placement. The State then targets those high-risk individuals in the Medicaid program for an intensive care management intervention and helps connect such individuals to necessary supports and services. In this case, the timeliness of information on service utilization (for example, an individual discharged from a skilled nursing facility stay could benefit by transition to Medicaid home and community-based services) is more important than the completeness of the available data (that is, whether additional subsequent encounters may later become available) so the State can coordinate care and deliver the intervention when an individual most needs it.

We believe the two examples above represent cases where we would consider sharing MA encounter data with State Medicaid agencies prior to reconciliation as necessary and appropriate to support coordinating care for dually eligible individuals. States cannot rely on MA encounter data after final reconciliation because coordinating services requires access to timely data. For these activities, States rely more on timely data about service utilization than on complete data. Improving access to timely MA encounter data and ensuring Medicaid programs can coordinate care for dually eligible individuals supports our goal to providing dually eligible individuals full access to the benefits to which they are entitled (42 U.S.C. 1315B(d)).

As discussed above, State Medicaid agencies 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 reconciliation given the deadline for submission of risk adjustment data under § 422.310(g), which states that the final submission deadline is a date no earlier than January 31 of the year following the payment year, or that data from some MA organizations or for some enrollees may not be available as quickly as data from or for others.

However, 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 State Medicaid agencies, or their contractors, to identify and contact individuals who have received, or are in need of, services from their providers. 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, we do 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 reconciliation as States have experience using Medicare data that may not be final for effective care coordination. In fact, many States already obtain timely Medicare FFS claims with a lag between 14 days to three months, depending on the data file, for uses such as care coordination, quality improvement, and program integrity in the Medicaid program. 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 reconciliation would not contain disaggregated payment information, in accordance with § 422.310(f)(2)(iv). Unlike MA encounter data used for CMS payment purposes, the pre-reconciliation MA encounter data would have no impact on plan payment. Under this proposal, release of the MA encounter data for care coordination purposes must be necessary and appropriation to support administration of the Medicaid program; we do not believe it would be appropriate or necessary to use the MA data released on this accelerated schedule for payment purposes.

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 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 believe these concerns are 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). 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. We reiterate that this proposal to amend 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 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). Therefore, 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), as well as to any State requests for MA encounter data before the reconciliation deadline to support coordination of care. 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). Other commenters on the August 2014 final rule 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). As noted in the prior rulemaking, we consider what disclaimers are appropriate to provide to requestors to understand the limitations of the MA encounter data (79 FR 50329 through 50330).⁹⁹ As noted above, States, or their contractors, are not required to act on the data and have experience using Medicare FFS claims that may not be final for effective care coordination. We are not aware of any care coordination issues that have arisen as a result of our sharing more Medicare FFS current data with States under our current data sharing processes. Additionally, CMS makes available technical assistance to States to help with State use and understanding of Medicare data; we intend to extend this technical assistance to States requesting MA encounter data to mitigate issues arising from non-final data. We will 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 propose that these amendments to § 422.310(f) would be applicable upon the effective date of the final rule if these proposals are finalized as proposed. As outlined in section I.A., the majority of the proposals in this rule are proposed to be applicable beginning January 1, 2025. We do not believe that 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 welcome public comment on this proposal.

3. Solicitation of Comments on Use of MA Encounter Data To Support Required Medicaid Quality Reporting

In the final rule titled "Medicaid Program and CHIP; Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting," which appeared in the **Federal Register** on August 31, 2023 (88 FR 60278) ("August 2023 final rule"), we established mandatory Core Set reporting requirements for States, as set forth in the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018)

and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018). The new Core Set reporting requirements apply to all States with Medicaid and CHIP programs and include all Medicaid and CHIP participants, including dually eligible individuals enrolled in MA plans.

States can only report certain Child and Adult Core Set measures by using utilization data. For reporting related to dually eligible individuals, this means accessing Medicare data. For dually eligible individuals in Medicare FFS, we make available Medicare FFS claims and events data to States to support, among other purposes, quality reporting for Child and Adult Core Set measures. But we do not currently make available MA encounter data to States in the same way. Although we have not shared MA encounter data broadly for Medicaid quality performance and quality improvement purposes through existing CMS data sharing programs, States may use their contracts with MA D–SNPs, which are required under § 422.107, to obtain Medicare data about the dually eligible individuals enrolled in those plans; this contractual ability to obtain MA encounter data through contracts with plans is specific to D–SNPs and does not include all MA plans. Therefore, we anticipate that reporting on dually eligible individuals enrolled in MA plans will be optional (that is, not mandatory) for States to include in reporting of the Child and Adult Core Sets. As we acknowledged in the August 2023 final rule, "We recognize that States must obtain, link, and analyze Medicare data in order to report the Child and Adult Core Sets of measures for fee-for-service beneficiaries, and that States do not have access to encounter data for Medicare Part C (Medicare Advantage), and we expect to phase in required reporting of Child and Adult Core Set measures for dually eligible beneficiaries" (88 FR 60298 through 60299).

In accordance with current regulation text at § 422.310(f)(2), States may request MA encounter data for the purpose described at § 422.310(f)(1)(iv)—to conduct quality review and improvement activities—which could support Medicaid Child and Adult Core Set reporting. However, the limitations in paragraph (f)(3) on sharing MA encounter data before final reconciliation would frustrate our desire for States to use the data to support timely Child and Adult Core Set reporting. The August 2023 final rule establishes a schedule through which

Core Set reporting to CMS begins in the fall of 2024, applicable to data collected during the 2024 reporting period. However, as stated above, our current release schedule of MA encounter data in accordance with § 422.310(f)(3) limits available MA encounter data to between 13 and 25 or more months after the service was rendered. Therefore, in the fall of 2024, during the 2024 Core Set reporting period, we anticipate only making available MA encounter data for services furnished in the 2022 year. This means that based on the current limitations in paragraph (f)(3), States would be unable to report on 2023 services received by dually eligible individuals enrolled in an MA plan to CMS in the fall of 2024 for the Child and Adult Core Set measures. With over half of dually eligible individuals enrolled in MA plans, we believe it is essential that State Child and Adult Core Set reporting eventually include that population. We are soliciting 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. We intend to take such comments into account in developing future policies and potential additional proposed revisions to § 422.310.

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

In this proposed rule, we are proposing to revise certain timing issues in terms of when RADV medical record review determination and payment error calculation appeals can be requested and adjudicated. Specifically, we are proposing 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 believe that this clarification is necessary because RADV payment error calculations are directly based upon the outcomes of medical record review determinations. We also propose 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

⁹⁹ For example, see the CCW Medicare Encounter Data User Guide: <https://www2.ccwdata.org/web/guest/user-documentation>.

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, 2023.¹⁰⁰

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) through (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) through (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 proposing to revise 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 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

¹⁰⁰ 88 FR 6643; <https://www.federalregister.gov/documents/2023/02/01/2023-01942/medicare-and-medicare-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare>.

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 proposed 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 are proposing that MA organizations must exhaust all levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. We believe that this change is 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 [,] . . . 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, ". . . 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 propose 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 propose 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 propose 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 would 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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.

IV. Benefits for Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. 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 "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), hereinafter referred to as the April 2019 final rule 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 propose 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 propose 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 proposal 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.

B. Evidence as to Whether a Special Supplemental Benefit for the Chronically Ill Has a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (42 CFR 422.102(f)(3)(iii) and (iv) and (f)(4))

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 ("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.

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 16–B of the Medicare Managed Care Manual. We require, 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).

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. Per § 422.102(f)(3)(iii), 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).

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 a Health Plan Management System (HPMS)

memorandum dated April 24, 2019 (“2019 HPMS memo” hereafter), 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 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.

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 when offering items or services as SSBCI.

Supplemental benefits, including SSBCI, are generally funded using MA plan rebate dollars.¹⁰¹ 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.

Based on our internal data, 101 MA plans offered a food and produce benefit in contract year 2020, while 929 MA plans are offering this as an SSBCI in contract year 2023.¹⁰² Similarly, 88 MA plans offered transportation for non-medical needs as an SSBCI in contract year 2020. In contract year 2023, 478 MA plans are offering this as an SSBCI.¹⁰³ MA plans are also continuing

¹⁰¹ 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.

¹⁰² Taken from internal data.

¹⁰³ Taken from internal data.

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, it indicates this in the PBP¹⁰⁴ that it submits 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.¹⁰⁵

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. 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 propose to update our 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

¹⁰⁴ 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.

¹⁰⁵ Taken from internal data.

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 are proposing 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 are proposing, 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 propose 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 propose to redesignate what is currently § 422.102(f)(3) to § 422.102(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 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 also intend, at this time, that the proposal not apply to 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 propose, 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 coverage year as part of CMS’s oversight activities. CMS does not intend, at this time, to require MA organizations to submit these bibliographies as a matter of course in submitting bids.

We propose 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 propose that the MA plan must 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 propose 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 tracks 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.

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 favorable to its SSBCI offering.

We also propose 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 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 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 are not proposing 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 is limited to SSBCI offered as additional primarily health-related supplemental benefits and non-primarily health-related supplemental benefits. We are not proposing 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 is limited to SSBCI that are items or services. Although we are not proposing 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 would 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. 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 proposal would continue to promote SSBCI innovation while helping to ensure that when Medicare funds are used to offer SSBCI, such offerings meet statutory requirements.

We solicit 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 solicit 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 solicit 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 solicit 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.

Second, for clarity, we propose 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 propose to make clear that an MA plan must apply its written policies when making SSBCI eligibility determinations.

We are 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 solicit 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. 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 are proposing 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 solicit 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 are proposing 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 clarify 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. This proposal is 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 propose 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 to decline to approve bids that include SSBCI that lack evidence to support the MA organization's expectations related to the SSBCI, but 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 in light of the information and evidence available at that point in time.

We solicit 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 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 would change 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. As such, we believe this proposal, if implemented, would create efficiency while imposing relatively little burden on MA plans.

In addition, under this proposal, MA plans would 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 would improve the experience of MA plans, enrollees, and CMS in managing and oversight of appeals of such denials. Further, it would 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.¹⁰⁶ 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 propose 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

¹⁰⁶ 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.

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 proposed 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 propose 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.

C. 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) and Bid Pricing Tool (BPT) 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. In 2023, roughly \$61 billion was directed towards supplemental benefits in MA. 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).¹⁰⁷ 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 if finalized, would include requiring MA plans to report utilization and cost data for all supplemental benefit offerings (88 FR 15726). 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.¹⁰⁸ We are concerned that 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) 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.¹⁰⁹

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 upticks 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 marketing tools 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 our proposed collection through Part C reporting, 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) study¹¹⁰ 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,

¹⁰⁷ 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>.

¹⁰⁸ 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.

¹⁰⁹ <https://www.cms.gov/research-statistics-data-and-systems/research/mcbs/data-briefs/dental-coverage-status-and-utilization-preventive-dental-services-medicare-beneficiaries-poster>.

¹¹⁰ <https://www.kff.org/report-section/racial-and-ethnic-disparities-in-access-to-and-utilization-of-care-among-insured-adults-issue-brief/>.

which can adversely affect health. We believe that the ability to offer supplemental benefits provides MA plans the unique opportunity to use 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 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 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 propose 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 propose that MA organizations must provide a model notification to enrollees of supplemental benefits they have not yet accessed. We propose to meet this goal 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 would 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 propose 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 are specifically seeking 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 are considering is to require 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 CMS is considering is to not require the notice to be mailed for 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) at around this same time but will not have had significant time in which 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) 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 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 (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 but has not accessed the SSBCI benefit by June 30 of the plan year, the notice must also include a description of the SSBCI to which the enrollee is entitled and must describe any limitations on the benefit. Note the proposals at section VI.A of this proposed rule that, if finalized, would require specific SSBCI disclaimers for marketing and communications materials that discuss the limitations of the SSBCI benefit being offered; we also

propose 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 are proposing 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 and, as required, a corresponding TTY number to call if additional help is needed. We solicit comments on the required content of the mid-year notice.

We request 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.

D. 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 prior authorization may disproportionately impact individuals who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality,¹¹¹ 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 process¹¹²), a reduction in medication adherence, and overall worse medical outcomes due to delayed or denied care. Research has also shown

¹¹¹ <https://www.hmpglobelearningnetwork.com/site/frmc/commentary/addressing-health-inequities-prior-authorization>; and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10024078/>.

¹¹² <http://abcadio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf>.

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.¹¹³

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).¹¹⁴ 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.¹¹⁵ 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.”¹¹⁶

The April 2023 final rule¹¹⁷ 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 propose to add health equity-related requirements to § 422.137. First, we propose 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 are proposing that health equity expertise 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. 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 Practice¹¹⁸ and the National Board of Public Health Examiners,¹¹⁹ to describe “expertise in health equity” in the context of MA and prior authorization.

We also propose 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 propose that the member of the UM committee, who has health equity expertise, as required at the 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 would examine the impact of prior authorization at the plan level, on 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 Health 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

¹¹³ https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?ga=2.49530854.1703779054.1662938643-470268562.1638986031.

¹¹⁴ 86 FR 7009 (January 25, 2021); <https://www.federalregister.gov/d/2022-26956/p-227>.

¹¹⁵ 87 FR 79479 fn. 7 (December 27, 2022); <https://www.federalregister.gov/d/2022-26956/p-228>.

¹¹⁶ 87 FR 79479 fn. 8 (December 27, 2022); <https://www.federalregister.gov/d/2022-26956/p-229>.

¹¹⁷ “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).

¹¹⁸ https://www.phf.org/resourcestools/Documents/Core_Competencies_for_Public_Health_Professionals_2021October.pdf.

¹¹⁹ <https://www.nbphe.org/cph-content-outline/>.

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 proposed analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. This will allow 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. The proposed 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.

We propose 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 propose 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 welcome comment on this proposal and seek 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.
- CMS is considering adding 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. We believe this would increase accessibility and transparency.

In addition, we request 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 is soliciting 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.

V. Enrollment and Appeals

A. 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 "Medicare+Choice" (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:

- The last day of the month preceding entitlement to Part A and enrollment in Part B, or;
- 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 are proposing to revise the end date for the ICEP for those who cannot use their ICEP during their IEP. That is, we are proposing in § 422.62(a)(1)(i) that an individual would have 2 months after the month in which they are first entitled to Part A and enrolled in Part B to use their ICEP. 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 believe 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 believe 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 proposal also supports President Biden's April 5, 2022 *Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage*,¹²⁰ 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

¹²⁰ 87 FR 20689 (April 8, 2022); <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/04/05/executive-order-on-continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage/>.

that strengthen benefits and improve access to health care providers.

This proposed change in the ICEP timeframe aligns 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 aligns 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 proposal would extend the timeframe of an existing enrollment period and 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 do not believe the proposed changes would have any impact to the Medicare Trust Fund.

B. 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. The NOMNC is subject to the Paperwork Reduction Act (PRA) process and approval by the

Office of Management and Budget (OMB). There is a parallel appeal process in effect for Medicare beneficiaries in Original Medicare (42 CFR 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.

This proposed rule would 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. The proposed 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 proposed 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 an 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 are proposing 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 would also specify that the IRE decision timeframe in § 422.626(d)(5) and the financial liability provision in § 422.626(b) would not apply. The provision for untimely appeal requests by enrollees in proposed § 422.626(a)(2) closely parallel 422 CFR 405.1202(b)(4) which establishes that the QIO will review untimely appeals of terminations of certain provider services from beneficiaries in Original Medicare.

Secondly, we propose 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.

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.

C. 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 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 sponsors are also required to report all data elements included in all its drug claims by § 422.505(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 grievances, 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 sponsors according to the Parts C and D Reporting Requirements that we issue each year, which can be accessed on CMS’s website.¹²¹ 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 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 propose revisions to update §§ 422.516(a) and 423.514(a). Section 422.516 currently reads, “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 propose 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 propose to strike the term “statistics” and add “information.” CMS does not interpret these regulations to limit data collection to statistical or aggregated data and we are using this rulemaking as an opportunity to ensure that we are clear and consistent with our interpretation of these rules.

Additionally, we propose 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 health and drug plans for specific services. In other words, under the existing requirements CMS has the ability to collect information related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions, and we aim to make this more transparent through this proposal. This could include, for example, information on pharmacy rejections, initial determinations, decision rationales, and plan level appeals. Both §§ 422.516(a)(2) and 423.514(a)(2) currently require plans to report “The patterns of utilization of services.” We propose to amend both sections to read, “The procedures related to and utilization of its services and items” to be clear that these regulations authorize reporting and data collection about MA and Part D plan 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 is not proposing to change specific current data collection efforts through this rulemaking. Any future information collection would be addressed 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.

D. 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)

Based on general feedback CMS has received from interested parties regarding a variance in the regulatory timeframe for beneficiaries to file an appeal with an MA organization or Part D plan sponsor, we are proposing 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 proposed amendments aim 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. These proposals would also apply to integrated organization determinations and reconsiderations. In addition, because cost plans are required, by §§ 417.600 and 417.840, to comply with the MA appeal regulations,

¹²¹ 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>.

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 no 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.

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 are proposing 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 are proposing 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. The proposal also includes adding new §§ 422.582(b)(1), 422.633(d)(1)(i), and 423.582(b)(1), which would 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 realize that it is 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 day rule. To ensure consistency throughout the administrative appeals process, we believe it is appropriate and practical 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 or other appropriate party, we are also proposing to add 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 are proposing 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. The 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. If these proposals are 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 are also proposing 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 CMS manual guidance for Part C and Part D appeals has long reflected this 60-calendar day timeframe. We also note 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 guidance¹²² and

¹²² <https://www.cms.gov/medicare/appeals-and-grievances/mmcaag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf>.

standardized denial notices¹²³ that explain an enrollee's right to appeal. Additionally, we have 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 propose 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 would 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, we believe, based on the low level of dismissals at the plan level due to untimely filing, that 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 are not associating impact to the Medicare Trust Fund. We solicit interested party input on the accuracy of this assumption.

E. 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 (for example, 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 4194), we first recognized in § 423.32(b) 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. We also stated that the authorized representative would constitute the “individual” for purposes of making the enrollment or disenrollment request.

Historically, we have provided the definition and policies related to authorized representatives in our sub-

regulatory manuals.¹²⁴ We are now proposing 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 are defining the term “authorized representative” for subpart B (eligibility, election, and enrollment).

Our proposal defers 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 regulations’ 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, our proposal would codify at paragraph (h)(1) of §§ 422.60 and 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 423.32 would clarify 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

¹²³ <https://www.cms.gov/medicare/medicare-general-information/bni/madenialnotices>.

¹²⁴ 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.

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 are proposing 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 represents the codification of longstanding MA and Part D sub-regulatory guidance. Based on questions from plans and beneficiaries related to current guidance, we conclude that the guidance has been previously implemented and is currently being followed by plans. Therefore, there is no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there is 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 numbers 0938–0753 (CMS–R–267), 0938–1378 (CMS–10718), and 0938–0964 (CMS–10141).

F. 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 Medicare+Choice (M+C), later known as Medicare Advantage (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) through (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.¹²⁵

To provide transparency and stability for plans, beneficiaries and their caregivers, and other interested parties about this aspect of MA enrollment, we propose to codify current sub-regulatory guidance that defines when the OEPI ends. Specifically, we propose to codify at new § 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 would define 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 do not believe the proposed changes would have any impact to the Medicare Trust Fund.

G. 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

¹²⁵ This guidance can be found in chapter 2, section 30.3 of the Medicare Managed Care Manual.

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.¹²⁶ 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 guidance¹²⁷ directs the 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 guidance¹²⁸ states that this does not apply to beneficiary requests for enrollment into an employer or union group health plan (EGHP) using the group enrollment

¹²⁶ 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.

¹²⁷ 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.

¹²⁸ 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.

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 a MA or MA-PD plan, CMS's sub-regulatory guidance¹²⁹ 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.¹³⁰

Furthermore, sub-regulatory guidance¹³¹ 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 are proposing 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 propose 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 propose 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 propose 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 represents 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 conclude that the guidance has been previously implemented and is currently being followed by plans. There is no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there is 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.

VI. Medicare Advantage/Part C and Part D Prescription Drug Plan Marketing and Communications

A. 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 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 final rule (hereinafter referred to as 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. 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

¹²⁹ This guidance on effective dates of elections is currently outlined in section 30.6 of chapter 2 of the Medicare Managed Care Manual.

¹³⁰ This guidance on effective dates of elections is currently outlined in section 30.4 of chapter 3 of the Medicare Prescription Drug Benefit Manual.

¹³¹ 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.

disclaimer guards 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 that plan's 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 beginning January 1, 2022. Since MA organizations have had over a year to implement their use of the SSBCI disclaimer, we are taking 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 benefits 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, oftentimes 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."¹³² 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 2020.¹³³ 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 advertisements 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 propose 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 would clarify 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 § 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. 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, our proposal amends the required SSBCI disclaimer content to clearly communicate the eligibility parameters to beneficiaries without misleading them. Specifically, at § 422.2267(e)(34), we are proposing three key changes to the regulation and two clarifications.

First, we are proposing to redesignate current paragraph (e)(34)(ii) as paragraph (e)(34)(iii) and add a new

paragraph (e)(34)(ii), in which we propose 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.B. of this proposed rule for a more detailed discussion of the definition of "chronically ill enrollee" and eligibility for SSBCI as part of our proposal 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 are proposing 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 are proposing it is the MA organization's discretion as to which 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 believe that five is a reasonable number of conditions for the MA organization to list, so that a beneficiary may have an idea of the types of conditions that may be considered for eligibility for the SSBCI, without listing so many conditions that a beneficiary ignores the information.

Second, we propose 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 are proposing 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 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

¹³² <https://content.naic.org/sites/default/files/State%20MA%20Marketing%20Authority%20Senate%20Letter%20.pdf>.

¹³³ 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, May 9, 2022).

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 they are 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, if the requirements we are proposing to add to § 422.102(f) for the item or service to be covered as an SSBCI are finalized, an MA organization would also need to meet those requirements to offer SSBCI (see section IV.B. of this proposed rule). 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 are not including those requirements from the proposal in section IV.B. of this proposed rule in the proposed expansion of the SSBCI disclaimer. Our proposed newly redesignated § 422.2267(e)(34)(iii) refers to the eligibility requirements and MA organization responsibilities in § 422.102(f) because we expect 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 proposed in section IV.B. of this proposed 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 (that is, the definition of a "chronically ill enrollee" and the coverage criteria of the MA organization for a specific SSBCI item or service) in order 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, not only on the fact 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 are not proposing to add such a requirement; however, MA organizations must accurately convey the required information listed in the proposed regulatory text at § 422.2267(e)(34)(i) through (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 are proposing 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 reiterate 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 propose 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 propose 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 believe additional clarification of current requirements is appropriate. In the introductory language at paragraph (e)(34), we propose 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, current paragraph (e)(34)(iii) (requiring the MA organization to include the SSBCI disclaimer in the material copy which mentions SSBCI benefits) would be revised and moved to new proposed paragraph (e)(34)(v). In this newly redesignated paragraph (e)(34)(v), we propose to clarify that MA organizations must include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. We also propose a slight adjustment in this paragraph to delete the redundant word "benefits" after "SSBCI."

In summary, 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 believe the revised disclaimer would diminish the ambiguity of when SSBCI are covered, thus reducing the potential for misleading information or misleading advertising. Our goal is 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 is of utmost importance in this proposal.

We are not scoring 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 welcome comment on our proposed amendments to § 422.2267(e)(34), and we thank commenters in advance for their feedback.

B. Agent Broker Compensation

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 Medicare Advantage (MA) plan that is intended to best meet beneficiaries' health care needs. In September 2008, CMS published the "Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs" interim final rule (73 FR 54226, 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/compliance/advisory-opinions/process/>.

In subsequent years, agents and brokers have become an integral part of the 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. CMS has also adopted updates to the agent and broker compensation requirements. It has become apparent that shifts in the MA industry and resulting changes in contract terms offered to agents and brokers for enrollment-related services and expenses, warrant further action to ensure CMS is complying with its statutory requirement to ensure 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 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 the compensation cap set by CMS to encourage agents and brokers to enroll individuals in their plan over a competitor's plans. 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) in exchange for enrollments. These payments, while being presented to the agents and brokers as innocuous 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 regulatory limits on compensation.

CMS has also received complaints from a host of different organizations, including State partners, beneficiary advocacy organizations, and MA plans. 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, not dissimilar to what prompted CMS to engage in the original agent and broker compensation requirements in 2008, where the amounts being paid for activities that do not fall under the umbrella of "compensation," are rapidly increasing. The result is that agents and brokers are presented with a new 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 MA 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, 27704–27902). 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 22234–22256), 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 Medicare Advantage 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 the call recording, 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 as a means to compensate over and above the CMS-set compensation limits on payment to agents and brokers. We also note that such payments appear to have no regional correlation, that is, they are generated across the country.¹³⁴ 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 a plan that is intended to best meet the beneficiary's health care needs.

Consequently, the rise in MA marketing complaints noted above

¹³⁴ <https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment/agent-broker-compensation>.

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” in excess of their compensation payment. Although CMS’s existing regulations already prohibit plans, and by extension their agents and brokers, from engaging in misleading or confusing communications with current or potential enrollees, additional limitations on payments to agents and brokers may be necessary to adequately address the rise in MA marketing complaints described here.

Additionally, while the proposals described in this proposed rule are focused on payments and compensation made to agents and brokers, CMS is also concerned about how payments from MA plans to third party marketing organizations (TPMOs) may further influence or obscure the activities of agent and brokers. In particular, CMS is interested in the effect of payments made to Field Marketing Organizations (FMOs), which is a type of TPMP that employs agents and brokers to complete MA enrollment activities and 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.”¹³⁵ In the time since CMS first began to regulate agent and broker compensation, we have seen the FMO landscape change from mostly small regionally-based companies to a largely consolidated group of large national private equity-backed or publicly-traded companies.

We have also observed that, similar to the additional payments made to agents and brokers, there has been a steep increase in administrative payments made to FMOs by MA organizations. Likewise, CMS is concerned that these quick increases in fees have resulted in a “bidding war” among 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 comments on our proposals here to help us develop additional regulatory action, we specifically request 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 proposed rule.

Finally, in addition to the undue influence that perks, add-on payments, volume bonuses and other financial incentives 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 plans are more able to shoulder the added costs being paid as compared to smaller, more locally based MA plans. Furthermore, we have received reports that some larger FMOs are more likely to contract with national 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 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 proposed regulatory changes included here also aim to deter

¹³⁵ 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>.

anti-competitive practices engaged in by MA organizations, agents, brokers, and TPMPs that prevent beneficiaries from exercising fully informed choice and limit competition in the Medicare plan marketplace among Traditional Medicare, MA plans, and Medigap plans.

In this proposed rule we are focusing on current payment structures among MA organizations, agents, brokers, and TPMPs, specifically FMOs, that may incentivize 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.

As noted above, section 1851(j)(2)(D) and 1851(h)(4)(D) of the Social Security Act directs 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 Medicare Advantage 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.”

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 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 are 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, 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 below).¹³⁶

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 commission and administrative payments]—sometimes much higher—for enrolling people in Medicare Advantage plans compared to Medigap.”¹³⁷

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. This would inherently create a conflict of interest for the agent. As the Secretary must “ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare

Advantage 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 an entity, 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 § 422.2267(d), separate and apart from any referral fee paid to the FMO.

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 intended 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 plans 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 Social Security 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.

In this rule we are proposing to: (1) 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 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 are also proposing to make conforming edits to the agent broker compensation rules at § 423.2274.

1. Limitation on Contract Terms

We propose 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 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 intend to prohibit would include, 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 organizations 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 organizations; 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.

We believe this proposal gives 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 seek comment on this proposal.

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 CY2023 national agent/broker FMV compensation caps are \$601 for each

¹³⁶ 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>.

¹³⁷ 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>.

MA initial enrollment, \$301 for a MA renewal enrollment, \$92 for each Part D initial enrollment, and \$46 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. We are concerned 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 ensure that CMS's 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 are proposing 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 paragraph (ii) of the definition of compensation at § 422.2274(a), and are regulated by the compensation requirements of § 422.2274(d)(1) through (3). We are also proposing 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 at section VI.B.3. of this proposed rule.

Further, we are proposing to change the caps on compensation payments that are currently provided in § 422.2274 to set rates that would be paid by all plans across the board. Under this proposal, agents and brokers would be paid the same amount either from the MA plan directly or by an FMO. We note that the 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 above, 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 would level the playing field for all plans represented by an agent or broker and promote 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's 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 them would enhance a beneficiary's ability to get the most out of their plan.

MA organizations are 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 propose 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 seek comment on this proposal.

3. Administrative Payments

As discussed above, CMS is proposing 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 are also proposing to remove the separate regulatory authority regarding "administrative payments" currently at § 422.2274(e)(1), and to amend § 422.2274(e)(2) to clarify that the portion of an agent's compensation for an enrollment may be calculated and updated independently. 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 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.¹³⁸ However, 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.¹³⁹ Compensation at these levels is not consistent with market value. 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."¹⁴⁰ 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, 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, CMS expects that this proposal would eliminate a significant method which some plans may have used to circumvent the regulatory limits on enrollment compensation. Furthermore, we believe 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

¹³⁹ <https://4239296.fs1.hubspotusercontent-na1.net/hubsfs/4239296/2023%20Plan%20Year%20Docs/2023%20HRA%20Instructions/Cigna%202023%20HRA%20Details.pdf>.

¹⁴⁰ 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/paoo/hra/hraawvguidance-reportfinal.pdf>.

¹³⁸ CDC, Interim Guidance for Health Risk Assessments and their Modes of Provision for Medicare Beneficiaries; <https://www.cms.gov/files/document/healthriskassessmentscdcfinalpdf>.

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 propose to adjust the FMV for compensation to take into account costs for certain appropriate administrative activities.

We recognize that this approach could have some drawbacks, particularly as this policy would, in effect, leave agents and brokers 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 about \$50 per month. This expense would require at least one enrollment commission per year to cover these costs, whereas it is currently permissible for an MA organization to pay for these costs directly, leaving the entire commission as income for the agent or broker. However, given the high volume of enrollees that use an agent or broker for enrollment services, we do not believe there to be a large risk of agents or brokers failing to cross that initial threshold to recoup their administrative costs.

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, 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 seek comment on this proposal. We are also proposing to increase the compensation rate described at § 422.2274(a) to add certain appropriate administrative costs. In particular, we believe that the administrative cost of the licensing and training and testing requirements at § 422.2274(b), and the recording requirements at § 422.2274(g)(2)(ii), may warrant an increase in the rate of compensation given the significant and predictable cost of these mandatory activities.¹⁴¹ Based on our fair market value analysis, we believe these activities would warrant increasing the base compensation rate by \$31,¹⁴² and be updated annually as part of the scheduled compensation rate update described at § 422.2274(a). Therefore, we propose to add, beginning in 2025, that FMV will 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.

We believe it is necessary to increase the rate for compensation by \$31, based on the estimated costs for training, testing, and call recording that would need to be covered by this single enrollment-based payment. We are proposing 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." We note that we are not proposing a proportionate increase to compensation for renewals and we considered this in determining the amount by which we are proposing to increase the rate for compensation for enrollments.

We seek comment on our proposal to increase the rate for compensation to account for necessary administrative costs that would be incorporated into this rate under our previous proposal. Specifically, CMS is requesting comment on the administrative costs

¹⁴¹ <https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment/agent-broker-compensation>.

¹⁴² Our calculations arriving at this number are further discussed in the COI in section X.B.10 titled ICRs Regarding Agent Broker Compensation (§ 422.2274).

that should be considered, and how else we might determine their value, as we consider the future of the compensation structure.

4. Agent Broker Compensation for Part D Plans

Finally, we also are proposing to apply each of the proposals described above to the sale of PDP plans by agents and brokers, 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 Medicare Advantage (MA) and Part D prescription drug plans that are intended to best meet beneficiaries' health care needs.

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 by \$31.

We also believe it is necessary to extend these regulations to the sale of PDPs to avoid shifting the incentives discussed at length above, 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 above. Therefore, for the same reasons discussed above regarding proposed changes to § 422.2274, we propose to make conforming amendments to § 423.2274.

We seek comment on this proposal, and specifically whether and to what extent modifications to these proposals should be made to account for differences between MA and Part D plan types.

VII. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

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. Cost plans under section 1876 of the Act are also included in the MA and Part D Star Ratings system, as codified at § 417.472(k). 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 proposals here would 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 applies 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 Foundation¹⁴³ of quality measures, which is a set of measures that are aligned across CMS programs. CMS is committed to aligning a 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 will reduce provider burden while also improving the effectiveness and comparability of measures. The Universal Foundation of quality measures will 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 will add additional aligned or program-specific measures. The set of measures will evolve over time to meet the needs of individuals served across CMS programs. We have submitted the Initiation and Engagement of Substance Use Disorder Treatment (IET) measure (Part C) (a Universal Foundation measure) to the 2023 Measures under Consideration process for review by the Measures Application Partnership prior to 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 Measures Under Consideration process for review by the Measures Application Partnership 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 D Star Ratings program.

In this proposed rule, we are also proposing to update the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure (Part D).

We are also proposing 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 CAI and 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, proposed changes would apply (that is, data would be collected and performance measured) for the 2025 measurement period and the 2027 Star Ratings.

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. In this rule, CMS is proposing a measure change to the Star Ratings program and an updated methodology for calculating scaled reductions of the Part C appeals measures for performance periods beginning on or after January 1, 2025, unless noted otherwise.

¹⁴³ <https://www.nejm.org/doi/full/10.1056/NEJMp2215539>.

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 NCQA and PQA.

1. Proposed Measure Update

a. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D)

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 Star Rating measure, which is defined as the percent of MTM program enrollees who received a CMR during the reporting period. The Part D MTM Program Completion Rate for CMR measure shows 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.¹⁴⁴

In the December 27, 2022 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” (87 FR 79452), hereafter referred to as 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 diseases¹⁴⁵ 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 12, 2023 final rule, “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” (88 FR 22120), hereafter referred to as 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, these 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, if the changes to eligibility for the MTM program in the December 2022 proposed rule (described above) are finalized in a future rule, in this proposed rule CMS proposes to move the MTM Program Completion Rate for CMR Star Rating measure to a display measure for at least 2 years due to substantive measure updates. For example, if such MTM program eligibility changes are finalized for CY 2025, our proposal in this rule would move the measure to the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings. There would be no legacy measure to calculate while the updated measure using the same measure specifications is on the display page because the MTM-eligible denominator population would have meaningfully increased due to changes in the program requirements. Therefore, 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 does not anticipate any additional burden associated with the measure update, as burden tied to the changes in the MTM eligibility criteria is already considered in estimates for the December 2022 proposed rule.

If the changes to eligibility for MTM programs described above and in the December 2022 proposed rule are not finalized, CMS would not make any substantive changes to the MTM Program Completion Rate for CMR measure—that is, we would also not finalize the proposal in this rule to update the Star Rating measure.

Table GB1 summarizes the updated MTM Program Completion Rate for CMR measure addressed in this proposed rule. The measure description listed in this table is a high-level description. The annual Star Ratings measure specifications supporting document, Medicare Part C & D Star Ratings Technical Notes, provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. The annual Star Ratings are produced in the fall of the prior year. For example, the 2027 Stars Ratings are produced in the

¹⁴⁴ 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/performance>.

¹⁴⁵ 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 (*).

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.

TABLE GB1. SUMMARY OF PROPOSED REVISED INDIVIDUAL STAR RATING MEASURE 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 D Measure								
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

* Effective as soon as the 2027 measurement year.

C. 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 16562–16564. 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. As provided under § 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 Announcement¹⁴⁶ 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 are proposing to remove and reserve the paragraphs at §§ 422.164(g)(1)(iii)(B), (F), and (I) and 423.184(g)(1)(ii). Paragraphs (g)(1)(iii)(B), (F), and (I) of § 422.164 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 propose 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)(1)(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 are proposing to modify, and in one case reserve, paragraphs (g)(1)(iii) introductory text, (g)(1)(iii)(A)(1) and (2), (g)(1)(iii)(H) and (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 are proposing 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 include minor grammatical changes to the verb tense. We are also proposing 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) is 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 provide for a new calculation to implement scaled reductions for the Part C appeals

¹⁴⁶ Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (*cms.gov*).

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 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 as set forth at § 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 partially favorable claims and the number of partially favorable service requests by enrollees/representatives

and non-contract providers) over a calendar year.¹⁴⁷ 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,

CMS is proposing to compare the total number of appeals received by the IRE, including all appeals regardless of their disposition (for example, including appeals that are dismissed for reasons other than the plan's agreement to cover the disputed services and withdrawn appeals), 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 1 to December 31st). We propose 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 proposed revisions to § 422.164(g)(1)(iii)(A):

Equation (1)

$$\text{Part C Calculated Error Rate} = 1 - \frac{\text{Total number of cases received by the IRE}}{\text{Total number of cases that should have been forwarded to the IRE}}$$

Equation (2)

$$\begin{aligned} \text{Total Number of Cases that should have been forwarded to the IRE} \\ = \text{Number of partially favorable reconsiderations} \\ + \text{Number of unfavorable reconsiderations} \end{aligned}$$

We propose 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 are proposing 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 are proposing 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.

We also propose to update § 422.164(g)(1)(iii)(A)(2) to change the data source in the case of contract consolidations so that the data

¹⁴⁷ Elements E through L in Subsection #4 on page 15 at <https://www.cms.gov/files/document/>

cy2023-part--technical-specifications-222023.pdf

are currently used to identify favorable and partially favorable reconsiderations.

described in paragraph (g)(1)(iii)(A)(1) are combined for consumed and surviving contracts for the first year after consolidation. In addition, we propose to delete the phrase “For contract consolidations approved on or after January 1, 2022” as unnecessary.

We are not proposing to update the steps currently described at § 422.164(g)(1)(iii)(C) through (E) and (G), (g)(1)(iii)(K)(1), and (g)(1)(iii)(L) through (N) to determine whether a scaled reduction should be applied to the two Part C appeals measures. We welcome feedback on this updated approach for making scaled reductions proposed at § 422.164(g)(1)(iii) introductory text, (g)(1)(iii)(A)(1) and (2), (g)(1)(iii)(H), (g)(1)(iii)(K)(2), and (g)(1)(iii)(O), the removal of the Part D related provisions at §§ 422.164(g)(1)(iii)(B), (F), and (I) and 423.184(g)(1)(ii), and removal of the provision at § 422.164(g)(1)(iii)(J).

D. 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 that CMS will establish an annual deadline by which such requests must be submitted. At §§ 422.164(h)(3) and 423.184(h)(3), CMS proposes 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. These requests would also have to be received by the annual deadline set by CMS. We intend that the requests could include CMS's review of Prescription Drug Event (PDE), diagnosis code, and enrollment data 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 sociodemographic status (SDS) risk adjustment for the three Medication Adherence measures, as finalized in the April 2023 final rule (88 FR 22265–22270), the final measure rates, which are calculated in July after the end of the measurement period, will 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 are proposing that sponsors' 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 propose 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. 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 intend

to announce the deadline for measurement year 2025 in the final rule, should this proposal be finalized. In subsequent years, we will 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 expect 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.

E. Categorical Adjustment Index (§§ 422.166(f)(2) and 423.186(f)(2))

We propose to calculate the percentage LIS/DE enrollees and percentage disabled enrollees used to determine the Categorical Adjustment Index (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 enrollees who receive a low-income subsidy or are dual eligible (LIS/DE) or have disability status within that contract. Currently, the percentage LIS/DE enrollees and percentage 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 propose to determine the percentage LIS/DE enrollees and percentage disabled enrollees for the surviving contract by combining the enrollment data across all contracts in the consolidation.

We propose to modify §§ 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 two 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 are proposing to restructure that regulation text into new paragraphs (f)(2)(i)(B)(2) through (4). We are proposing 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.

F. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

We are proposing how to calculate the health equity index (HEI) reward in the case of contract consolidations beginning with the 2027 Star Ratings. (The 2027 Star Ratings will 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 propose 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 will handle combining measures scores for consolidations, but do not address how CMS will handle the calculation of the

HEI when contracts consolidate since the HEI is not a measure. We propose 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 propose 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).

G. Quality Bonus Payment Rules (§ 422.260)

Sections 1853(n) and 1853(o) of the Act require CMS to make QBP 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 21490–91), § 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. We propose 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 propose 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 will be issued as directed by the Administrator. If finalized, this proposed amendment

would be implemented for all QBP appeals after the effective date of the final rule.

VIII. Improvements for Special Needs Plans

A. 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.¹⁴⁸

We propose 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

¹⁴⁸ 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>.

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 propose 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 16-B, section 40.2.1 of the Medicare Managed Care Manual 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 are proposing to use the term “physician” throughout proposed new § 422.52(f).

To further clarify the verification process, we also propose 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.¹⁴⁹ Both proposed options are discussed in the current guidance. We continue to believe that these procedures will allow the MA organization to efficiently serve

¹⁴⁹ CMS provides an outline of the Pre-enrollment Qualification Assessment Tool in section 40.2.1 of chapter 16-B of the Medicare Managed Care Manual (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.

special needs populations while maintaining the integrity of SNP offerings under the MA program.

As part of this process, we propose 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 guidance,¹⁵⁰ 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 proposes 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.

¹⁵⁰ This guidance can be found in chapter 16-B, Special Needs Plans, section 40.2 of the Medicare Managed Care Manual.

- 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 are also proposing 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 propose to codify at § 422.52(f)(1)(ii)(E) our longstanding

guidance¹⁵¹ 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 (*i.e.*, 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 propose 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 propose 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.

B. 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 "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" proposed rule, which appeared in the **Federal Register** on December 27, 2022 (87 FR 79452) ("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 for a more detailed discussion of the eligibility requirements for I-SNPs. (87 FR 79566 through 79568) See also chapter 16-B, section 20.3 of the Medicare Managed Care Manual.¹⁵² Our use of the term "facility-based I-SNP" in this proposed rule aligns with the proposed definition of "Facility-based Institutional special needs plan (FI-SNP)" in the December 2022 proposed 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 serve a vulnerable cohort of Medicare beneficiaries with well over 95 percent of facility-based I-SNP enrollees being eligible for both Medicare and Medicaid. Generally, facility-based I-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

¹⁵¹ 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.

¹⁵² <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf>.

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 facility-based I-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 facility-based I-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 facility-based I-SNPs have raised questions about whether our network standards are appropriate considering the nature of the facility-based I-SNP coverage model. The residential nature of this model creates inherent differences in patterns of care for facility-based I-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 would need to travel to a provider to receive health care services.

To address these concerns, CMS is proposing to adopt a new exception for facility-based I-SNP plans from the network evaluation requirements. This provision would apply only to facility-based I-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.¹⁵³ 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 facility-based I-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 would be the basis for an approval exception do not account for the provider network issues unique to facility-based I-SNPs that we propose to address in this rule. Therefore, we are proposing 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 are proposing that this exception be specific to facility-based I-SNPs. Under this proposal, facility-based I-SNPs would not be required to meet the current two prerequisites to request an exception from the network adequacy requirements in § 422.116 but would have alternate bases on which to request an exception.

First, CMS is proposing to broaden the acceptable rationales for an exception from the requirements in § 422.116(b) through (e) for facility-based I-SNPs. We are proposing that a facility-based I-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 are reorganizing 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). Second, we are proposing new considerations CMS will use when determining whether to grant an exception under § 422.116(f) that are specific to the proposed new acceptable rationales for an exception request. We are proposing to add a new paragraph (f)(2)(iv) to specify the proposed new considerations that will apply to the new exceptions for facility-based I-SNPs, which will be added to the existing considerations in § 422.116(f)(2).

Our proposal includes new bases on which only facility-based I-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 facility-based I-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, the proposed new exception is limited to contracts that include only facility-based I-SNPs.

The first proposed 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. For purposes of this first proposed new basis for an exception, the inability to contract means the MA organization offering the facility-based

¹⁵³ <https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance08302022.pdf>.

I-SNP could not successfully negotiate and establish a contract with a provider, including individual providers and facilities. This is broader than the existing condition for an exception that certain providers are unavailable for the MA plan. 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. Currently, 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 that, historically, facility-based I-SNP plans have encountered significant struggles contracting with the necessary number of providers to meet CMS network adequacy standards due to their unique care model. We propose to add this new basis for an exception request to § 422.116(f)(1)(ii)(A). CMS is also proposing that its decision whether to approve an exception for a facility-based I-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 facility-based I-SNPs receive care) will be based on whether the facility-based I-SNP submits evidence of the inability to contract with certain specialty types required under § 422.116 due to the way enrollees in facility-based I-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 facility-based I-SNP. CMS proposes to add this requirement in a new paragraph (f)(2)(iv)(A). Under this proposal, 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 facility-based I-SNPs. We solicit 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 are also proposing a second basis on which a facility-based I-SNP may

request an exception from the network adequacy requirements in § 422.116(b) through (e) if:

(1) 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) in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e).

(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) 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.

We believe it is appropriate to permit exceptions in these situations because enrollees in facility-based I-SNP plans 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 are proposing 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 are proposing regulation text to ensure that the exception for facility-based I-SNPs is used by and available only to facility-based I-SNPs. We are proposing a new paragraph (f)(3) at § 422.116 to require any MA organization that receives the exception provided for facility-based I-SNPs to agree to offer only facility-based I-SNPs on the contract that receives the exception. To support the provision outlined at § 422.116(f)(3), CMS also proposes 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 facility-based I-SNPs to their facility-based I-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 facility-based I-SNP to a contract, the exception we propose here would not be appropriate. We welcome 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 facility-based I-SNPs consistent with our rationale for it.

Under our proposal, facility-based I-SNPs would 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 facility-based I-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) would apply. We believe that our proposal appropriately balances the need to ensure access to covered benefits for enrollees in facility-based I-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 would not be appropriate or serve the best interests of the Medicare program or Medicare beneficiaries.

We request comment on this proposal.

C. 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 enrollment¹⁵⁴). 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, is a critical part of improving experiences and outcomes for dually eligible individuals. Exclusively aligned enrollment (EAE) occurs when enrollment in a parent organization's D-SNP is limited to individuals who are also enrolled in that organization's Medicaid managed care organization. Congress' advisory commissions have emphasized similar themes: the Medicare Payment Advisory Commission (MedPAC) has "long believed that D-SNPs should have a high level of integration so they have the proper incentives to coordinate care across Medicare and Medicaid."¹⁵⁵ The

¹⁵⁴ 42 CFR 422.2 (definition of "aligned enrollment").

¹⁵⁵ MedPAC response to Congressional request for information on dual-eligible beneficiaries, page 2, January 13, 2023.

Medicaid and CHIP Payment and Access Commission's (MACPAC's) "long-term vision is for all dually eligible beneficiaries to be enrolled in an integrated model"¹⁵⁶ and has noted that a key feature of integrated care is "financial alignment where a single entity receives a single payment to cover all Medicare and Medicaid services."¹⁵⁷

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 here represent an incremental step in that direction, 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),¹⁵⁸ highly integrated dual eligible special needs plans (HIDE SNPs),¹⁵⁹ and applicable integrated plans (AIPs).¹⁶⁰ These D-SNP types

¹⁵⁶ 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.

¹⁵⁷ MACPAC response to request for information on data and recommendations to improve care for dually eligible beneficiaries, page 3, January 13, 2023.

¹⁵⁸ 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.

¹⁵⁹ 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.

¹⁶⁰ 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

more meaningfully integrate Medicare and Medicaid services than coordination-only D-SNPs¹⁶¹ that are not also AIPs.

In this section we describe 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. 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.

of the following: home health services, medical supplies, equipment and appliances (DME), or nursing facility services.

¹⁶¹ 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 benefits either directly or through an affiliated Medicaid managed care plan.

TABLE HC1: ENROLLMENT SCENARIOS UNDER CURRENT RULES AND PROPOSED AMENDMENT—INDIVIDUAL PERSPECTIVE*(NOTE: This table does not include other applicable seps)*

Scenarios for Dually Eligible Individuals	Current Rules under Quarterly Dual 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 ¹⁶²
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

Our proposals create a new SEP and revise the duals/LIS SEP, but otherwise do not change the remaining SEPs. To highlight the changes in our proposals without overly complicating this table, we did not reference the other SEPs.

1. 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 a SEP for full-benefit dually eligible individuals under Part D. The SEP, subsequently referred to as the continuous dual SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by

¹⁶² We propose 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).

regulation.¹⁶³ The continuous dual 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 SEP related to enrollees changing plans frequently, hindering care coordination efforts by D-SNPs; plans having less incentive to innovate and

¹⁶³ Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (CMS-4085-F) (75 FR 19720 (April 15, 2010)).

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). We had considered limiting use of the SEP to once per calendar year, limiting use of the SEP to two or three uses per calendar year, or prohibiting use of the SEP for enrollment into non-integrated MA-PD plans, but allowing continuous use of the SEP to allow eligible beneficiaries to enroll into (a) integrated D-SNPs for dually eligible individuals or (b) standalone PDPs (83 FR 16515). We received a mix of concern and support from commenters on our proposals.

Ultimately, the April 2018 final rule amended the continuous dual 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). We noted that our changes struck a balance between allowing dually eligible individuals opportunities to change plans while also maintaining stability with care coordination and case management (83 FR 16515).

The quarterly dual 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, we have concerns with the quarterly dual SEP:

- *Marketing.* We finalized numerous policies to reduce aggressive marketing tactics in the April 2023 final rule,¹⁶⁴ but 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 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 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 SEP.

- *Complexity for States.* State Medicaid agencies have shown interest in opportunities to bring Medicare and Medicaid managed care enrollment policies into greater alignment and reduce complexity. The quarterly dual SEP has created some challenges related to aligning Medicare and Medicaid enrollment dates for dually eligible individuals seeking to enroll in integrated products. For example, California needed expenditure authority to waive § 438.56(e)(1) under a section 1115(a) demonstration to allow for a Medicaid MCO disenrollment to be delayed during the last calendar quarter to maintain exclusively aligned enrollment with a corresponding D–SNP. This expenditure authority would not have been necessary if the dual SEP was available to make elections

throughout the year. In the capitated financial alignment models of the Financial Alignment Initiative (FAI), we waived the quarterly dual 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. Without any accessible central data source on who has already used the quarterly dual SEP, it is not clear to options counselors (or sometimes to beneficiaries themselves) what enrollment options are truly available to dually eligible individuals at any given time.

To further protect Medicare beneficiaries, reduce complexity for States and enrollment counselors, and increasingly promote integrated care, we are proposing two SEP changes. Section 1860D–1(b)(3)(D) of the Act requires the Secretary to establish special enrollment periods 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.¹⁶⁵ 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 these authorities, we propose to amend § 423.38(c)(4)(i) to replace the quarterly dual 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.

Functionally, the 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, 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 propose 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.

In combination, our SEP proposals draw heavily from MedPAC's 2008 recommendation to Congress, which proposed eliminating dually eligible individuals' ability to enroll in MA–PD plans, except special needs plans with State contracts, outside of open enrollment. MedPAC also recommended dually eligible individuals be able to disenroll from an MA–PD plan and return to Traditional Medicare at any time of the year.¹⁶⁶

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–SNPs¹⁶⁷ or other MA plans only during

¹⁶⁴ 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 (CMS–4201–F) (88 FR 22122 (April 12, 2023)).

¹⁶⁵ Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (CMS–4085–F) (75 FR 19720 (April 15, 2010)).

¹⁶⁶ Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy," March 2008.

¹⁶⁷ Dual eligible special needs plans (D–SNPs) are defined at § 422.2. "Coordination-only" D–SNPs are

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.

We believe the proposed SEP changes would:

- Create more opportunity for dually eligible or LIS individuals to leave MA–PD plans if MA is not working well for them, by providing an opportunity to enroll in a standalone PDP, which results in disenrollment from the MA–PD plan and enrollment in Traditional Medicare.¹⁶⁸

- Reduce the incentive for most plans to deploy aggressive sales tactics targeted at dually eligible or LIS-enrolled individuals outside of the AEP. Based on our review of 2023 plans, approximately 5 percent of the plans that can currently enroll dually eligible individuals using the quarterly dual SEP would be available as options for dually eligible individuals using the proposed new monthly integrated care SEP.

- Increase transparency for Medicare beneficiaries and enrollment counselors—such as SHIPs—on opportunities to change plans, by eliminating the need to determine whether the current once-per-quarter SEP opportunity had already been used.

- Create more opportunities for enrollment into integrated D–SNPs through which an individual could receive Medicare and Medicaid services and care coordination from the same organization.

- Reduce the burden on States working to align Medicaid MCO enrollment to D–SNP enrollment, particularly for States transitioning their FAI demonstrations to integrated D–SNPs (all FAI demonstration States waived the implementation of the quarterly dual SEP as it proved too operationally challenging to implement for Medicare-Medicaid Plans).

- Strengthen incentives for MA sponsors to also compete for Medicaid managed care contracts.

While there are advantages to the new proposed SEP changes, we recognize there are potential challenges:

- In States with few or no integrated D–SNPs, dually eligible individuals would not be able to change MA–PD plans outside of the AEP, MA–OEP, or

other available SEPs, limiting their ability to change plans as their needs change. Choices outside of AEP, MA–OEP, or other available SEPs would similarly be limited in States where integrated D–SNPs only serve limited geographic regions.

- MA plans may have marginally less incentive to innovate and invest in meeting the needs of high-cost dually eligible enrollees in a situation where these enrollees may disenroll at any time. This could exacerbate the phenomenon of higher-cost dually eligible individuals disenrolling from MA.^{169 170 171}

- Some dually eligible individuals would be able to change between integrated care plans monthly, which could hinder care coordination and case management efforts by those plans.

- Finally, since LIS individuals without Medicaid are ineligible for integrated D–SNPs, our proposal would limit how the dual/LIS SEP can be used for these individuals compared to the current scope of the SEP. LIS eligible individuals without full Medicaid and partial-benefit dually eligible individuals would have the opportunity to disenroll from an MA–PD plan (to Traditional Medicare) in any month throughout the year, and could switch between standalone PDPs on a monthly basis, but—with few exceptions—could not use the new integrated care SEP to enroll in an MA–PD.¹⁷² These individuals could elect an MA–PD or non-AIP coordination-only D–SNP for which they are eligible only during the ICEP, the AEP, the MA–OEP (as applicable), or by using a different SEP. We estimate approximately one million partial-benefit dually eligible individuals and other LIS eligible individuals, or 7.5 percent of all individuals with LIS, would no longer be able to make quarterly MA–PD elections.¹⁷³ Dually eligible and other LIS-eligible individuals would also

¹⁶⁹ GAO Report to Congressional Requesters, Medicare Advantage Disenrollment, pages 19–20, June 2021.

¹⁷⁰ <https://www.gao.gov/assets/gao-17-393.pdf>.

¹⁷¹ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0272>.

¹⁷² There is no Federal prohibition on partial-benefit dually eligible individuals enrolling in HIDE SNPs. However, most States limit enrollment in HIDE SNPs to full-benefit dually eligible individuals.

¹⁷³ Section 11404 of the Inflation Reduction Act (IRA) amended section 1860D–14 of the Act to expand eligibility for the full LIS to individuals with incomes up to 150 percent of the Federal poverty level (FPL) beginning on or after January 1, 2024. See 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 (CMS–4201–F) (88 FR 22123 (April 12, 2023)).

continue to be eligible, if applicable, for other SEPs outlined in §§ 422.62(b) and 423.38(c), which include circumstances like enrolling into a 5-star plan, change in residence, or enrollment in PACE.¹⁷⁴

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. We are considering using 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). Establishing a different enrollment effective date could allow better alignment with Medicaid enrollment effective dates, for example, in situations where States are unable to 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. However, aligning with Medicaid enrollment effective dates may delay enrollment in integrated care plans and prevent dually eligible individuals from selecting an integrated D–SNP on a monthly basis.

We welcome comments on utilizing these flexibilities to establish a different enrollment effective date for the proposed integrated care SEP. See section VIII.E. for further discussion of alignment of enrollment effective dates and a request for comments on this topic.

We also welcome comments on the proposed changes to the dual SEP, the proposed integrated care SEP, and their combined impacts.

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

¹⁷⁴ 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 (CMS–4182–F) (83 FR 16516 (April 16, 2018)).

D–SNPs that neither meet the FIDE SNP nor HIDE SNP definition at § 422.2 and are not required to cover any Medicaid benefits.

¹⁶⁸ We note that enrollment in a standalone PDP would not result in automatic disenrollment from a Medicare MA-only Private Fee-for-Service plan unless that plan also offers Part D.

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.¹⁷⁵ Many States with Medicaid managed care programs select a limited number of Medicaid MCOs through a competitive procurement process. State approaches vary regarding eligibility for Medicaid MCOs that are part of the State's managed care program (for example, whether plans cover just dually eligible enrollees or additional Medicaid populations), service areas, and carved-in benefits for dually eligible enrollees. While there may be some overlap in plan parent organizations operating both Medicaid MCOs and D-SNPs within a State, it is not always the case.¹⁷⁶ Service areas are commonly misaligned between Medicaid MCOs and D-SNPs. States have the option to pursue EAE when it meets their own Medicaid managed care policy goals and objectives; however, placing responsibility solely on States to implement and facilitate EAE has often led to a complex market of D-SNPs, many of which only meet minimum integration requirements, as well as a complex set of Federal and State enrollment policies for States, plans, advocates, and beneficiaries to navigate.

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. Enrollment in D-SNPs has increased rapidly and now exceeds five million. We estimate that approximately 1.26 million were in aligned enrollment as of July 2022, and this number has also grown over time.¹⁷⁷ However, the majority of D-

SNP enrollment remains in unaligned plans where the individual is either in a non-AIP coordination-only D-SNP or in one parent organization's D-SNP and another parent organization's Medicaid MCO, and the increases in enrollment in such plans has exceeded the increases in enrollment for integrated D-SNPs.¹⁷⁸ Analysis by MedPAC in 2019 found that "14 percent of [D-SNP] enrollees qualify for full Medicaid benefits and are in D-SNPs that have a companion managed long term services and supports (MLTSS) plan run by the same parent company, but they are not enrolled in that MLTSS plan." As MedPAC noted, "some enrollees may not be required to enroll in an MLTSS plan, but for those who are, these cases of misaligned enrollment are unlikely to lead to any meaningful integration given the inherent challenges of coordinating the efforts of two separate managed care companies."¹⁷⁹

While 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, 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 of D-SNP options that often do not offer significantly different benefits or

eligible individuals were enrolled in managed care arrangements where the same organization covers both Medicare and Medicaid services. CMS utilized the underlying data to estimate that of the 1.75 million, 1.26 million were enrolled in a D-SNP and affiliated Medicaid MCO offered by the same organization. The remaining half million were enrolled in Medicare-Medicaid plans, PACE, and managed fee-for-service arrangements. The FY22 Medicare-Medicaid Coordination Office Report to Congress can be accessed here: <https://www.cms.gov/files/document/mmco-report-congress.pdf-0>.

¹⁷⁸ Velasquez, David E., E. John Orav, and José F. Figueroa. Enrollment and characteristics of dual-eligible Medicare and Medicaid beneficiaries in integrated care programs, Health Affairs 42, No. 5 (2023), 685.

¹⁷⁹ MedPAC Report to Congress, Promoting integration in dual-eligible special needs plans, Chapter 12, page 422, June 2019. Retrieved from https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.

networks, which creates confusion for plan selection and could lead to individuals choosing unaligned Medicare and Medicaid plans.

One State provides a useful (but not necessarily unique) example. In this State, for 2023, there are 47 D-SNP plan benefit packages (PBPs) offered through 24 different plan contracts. A few parent organizations' D-SNPs account for a large share of the plans in this State: UnitedHealth Group operates 15 D-SNP PBPs across six different MA contracts, Humana offers eight D-SNP PBPs across two MA contracts, and Centene offers five D-SNP PBPs across three MA contracts. A search of available options in Medicare Plan Finder (MPF) for a dually eligible individual in a zip code in this State yields 69 MA-PD options, including 19 D-SNPs. Of the 19 D-SNPs, five are offered by Centene, three are offered by Elevance, three are offered by UnitedHealth Group, and two are offered by Humana. The large number of D-SNPs operated by a relatively small group of parent organizations in this State illustrates the "choice overload" faced by dually eligible individuals, their families, advocates, and enrollment counselors.

Although Medicaid managed care in this State is mandatory for dually eligible individuals, and many of the same D-SNP parent organizations operate Medicaid MCOs in the State, there is currently no EAE required. Additionally, D-SNP and Medicaid MCO service areas are misaligned throughout the State, hindering meaningful integration and robust care coordination for enrollees despite a relatively small group of parent organizations. Further, the abundance of non-AIP coordination-only D-SNP options reduces the likelihood that a dually eligible individual would select a more integrated option. Additionally, numerous plan options in one service area increases the potential for marketing issues including agents and brokers targeting dually eligible individuals to switch into another plan.

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 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.

¹⁷⁵ See 42 CFR 438.2 for definitions of the terms managed care organization (MCO), prepaid ambulatory health plan, and prepaid inpatient health plan.

¹⁷⁶ MedPAC Report to Congress, Promoting integration in dual-eligible special needs, table 12-6, page 436, June 2019.

¹⁷⁷ The FY22 CMS Medicare-Medicaid Coordination Office Report to Congress indicates that as of July 2022, 1.75 million full-benefit dually

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 these authorities, we are proposing new regulations (at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii)) related to how MA organizations offer and enroll eligible individuals into D-SNPs. Proposed § 422.503(b)(8) would establish a new qualification for an MA organization (or new applicant to be an MA organization) to offer D-SNP(s) while proposed § 422.504(a)(20) would establish a new contract term for certain MA organizations; both are tied to the substantive limits we are proposing in § 422.514(h). Proposed § 422.514(h) would 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, proposed § 422.530(c)(4)(iii) would establish a new crosswalk 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 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 CMS believes MA organizations under the same parent organization share operational and administrative functions, we are proposing to apply the proposed regulations at the parent organization level.

We are proposing a corresponding new provision at § 422.530(c)(4)(iii) that would provide a new crosswalk 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). Currently, § 422.530(a)(2) does not allow enrollee crosswalks across different contracts or plan types. 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 expect MA organizations who offer D-SNPs to 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).

We believe that allowing this crosswalk would limit enrollee disruption if MA organizations non-renew D-SNPs to comply with our proposal. In addition, we believe this new crosswalk is consistent with preserving the evergreen nature of enrollee elections given the differences in the benefits being offered by the D-SNPs that are owned or controlled by the same parent organization are generally not meaningful beyond the scope of annual changes explained in the Annual Notice of Change. For example, in contract year 2023, there is one parent organization with three MA organizations that offer a total of 13 HMO D-SNP benefit packages in one State. Only five of those D-SNPs enroll full-benefit dually eligible individuals, and the benefits offered in each of the D-SNPs are substantively similar.

We are proposing the following exceptions to our proposals at §§ 422.504(a)(20) and 422.514(h)(1) and (2):

- 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 propose 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 as that MA organization's affiliated Medicaid MCO only when a SMAC requires it. 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. This exception allows for States that currently have different integrated D-SNP programs based on age or benefit design to continue to operate these programs and allows States the flexibility to design future integrated D-SNP programs with eligibility nuances should they so choose. This proposed 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.

- Numerous parent organizations operate both HMO and PPO D-SNPs in States where they also contract with a State as a Medicaid MCO, and the proposed regulation at §§ 422.504(a)(20) and 422.514(h)(1) and (2) would apply to both HMO and PPO D-SNPs.

However, as noted above, § 422.530(a)(2) does not allow enrollee crosswalks across different plan types, and we are not including any exception from that existing rule in the new crosswalk exception proposed at § 422.530(c)(4)(iii). To minimize enrollee disruption, our proposal 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. However, 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 propose 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 propose 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 propose 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). These proposals would apply regardless of any EAE requirements in State SMACs, unless the exception to accommodate State policy choices, described in proposed § 422.514(h)(3)(i), applies.

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.

TABLE HC2: 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 <u>has</u> an affiliated Medicaid MCO that enrolls <u>full-benefit</u> 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 <u>does NOT</u> have an affiliated Medicaid MCO that enrolls <u>full-benefit</u> 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 look to a hypothetical example of how the proposed regulations would likely play out in the market. For this example, Parent Organization Alpha

operates three MA organizations in Montgomery County. For the sake of this example, the service areas for all D-SNPs encompass Montgomery County,

and each of the D-SNPs enrolls both full-benefit and partial-benefit dually eligible individuals of all ages.

TABLE HC3: HYPOTHETICAL EXAMPLE—D-SNP CURRENT LANDSCAPE

Parent Organization Alpha			
MA Organization Gamma	MA Organization Omega		Medicaid MCO Omega (in Montgomery County)
HIDE HMO D-SNP Gamma 001	HIDE PPO D-SNP Omega	HIDE HMO D-SNP Omega 001	

We anticipate that under proposed § 422.514(h), for periods beginning on or after January 1, 2027, Parent Organization Alpha would have to choose one of the three D-SNPs offered by its MA organization subsidiaries to align with the Plan Omega Medicaid MCO. For this example, MA Organization Omega chooses HIDE D-SNP Omega 001 to serve as the D-SNP aligned with Medicaid MCO Omega and permitted to continue under proposed

§ 422.514(h). Under the proposed crosswalk authority at § 422.530(c)(4)(iii), MA Organization Omega and MA Organization Gamma would be able to move enrollees from Gamma 001 into Omega 001 on January 1, 2027. MA Organization Gamma could then convert HIDE D-SNP Gamma 001 to coordination-only D-SNP Gamma 001 and keep that plan open for partial-benefit dually eligible individuals, or elect to non-renew Gamma 001 and

keep only Omega 001 as the plan aligned with the Omega Medicaid MCO into which full-benefit dually eligible individuals may enroll so long as they are also enrolled in the Omega Medicaid MCO. Further, under proposed § 422.514(h)(3)(ii), MA Organization Omega could retain the HIDE PPO D-SNP, but it would be closed to new enrollment for full-benefit dually eligible individuals in Montgomery County.

TABLE HC4: HYPOTHETICAL EXAMPLE – POSSIBLE D-SNP LANDSCAPE AFTER POTENTIAL ACTIONS BY PARENT ORGANIZATION*

Parent Organization Alpha-under proposed rule		
MA Organization Omega		Medicaid MCO Omega (in Montgomery County)
HIDE PPO D-SNP Omega* Now frozen to new enrollment	HIDE HMO D-SNP Omega 001* now aligned with Medicaid MCO Omega for full-benefit dually eligible individuals: <ul style="list-style-type: none"> • 2027: new enrollment limited to individuals enrolled in (or in the process of enrolling in) Medicaid MCO Omega • 2030: 100 percent of enrollment aligned with Medicaid MCO Omega; unaligned enrollees would be disenrolled 	

*In Table HC4, MA organization has non-renewed Gamma 001.

Our proposals on enrollment limitations for non-integrated D-SNPs would apply based on an MA organization having an affiliated Medicaid MCO. However, we are considering 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). PIHPs and PAHPs are limited

in what they cover and do not have comprehensive risk contracts. Some States use PIHPs or PAHPs to deliver specific categories of services, like behavioral health, or a single benefit, such as non-emergency medical transportation, using a single contractor. The revenue for a PIHP or PAHP is usually less than the revenue for an MCO. As such, to the extent our proposal incentivizes an organization to end its Medicaid managed care

contracts to avoid our new contracting limitations, that incentive would be stronger for a PIHP or PAHP than an MCO. Therefore, we are concerned that applying our proposals to PIHPs and PAHPs could create incentives that are disruptive yet do not significantly further the goals of our proposals. We welcome comments on this issue.

If we finalize our proposals, we would consider updates to the systems and supports designed to aid individuals in

making Medicare choices. This would include MPF, HPMS, and other resources that help to outline available plan choices to individuals, SHIP counselors, and others. This may be especially important where dually eligible individuals have choices that would vary based on the type of plan and time of year. We would consider the best ways to show only those plans available to individuals and highlight options that align with Medicaid enrollment. We welcome recommendations on how the choice architecture could best support the proposals or objectives described in this section.

Overall, we believe 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 who are in aligned enrollment, and—over time—exclusively aligned enrollment (EAE), which would increase 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. The impact would be concentrated in those States that have Medicaid managed care but do not have EAE requirements already. In such States, to comply with the proposals, MA organizations that have multiple D–SNP PBPs available to full-benefit dually eligible individuals and that also offer (or have parent organizations that offer) Medicaid MCOs in the same service area would likely choose to consolidate their 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. Such MA organizations could operate non-AIP coordination-only D–SNPs both for service areas where they do not serve beneficiaries on the Medicaid side and for partial-benefit dually eligible individuals. (We believe that consolidation is more likely due to the potential administrative burden of offering multiple D–SNPs for which enrollment is restricted.)

- Reduce the number of D–SNP options overall, and thus 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 (especially among employed or captive agents affiliated with plans that do not offer integrated D–SNPs), thus lessening the assistance needed

from advocates and SHIP counselors to correct enrollment issues.

- Simplify provider billing and lower the risk of inappropriate billing, as more enrollees would be in D–SNPs with aligned enrollment.

- Promote integrated care and create more opportunities to provide truly integrated experience for beneficiaries by requiring plans to align enrollment (for example, D–SNPs can better coordinate care across Medicare and Medicaid when plans are aligned).

- In 2030, increase the number of D–SNPs with EAE, and therefore increase the number of D–SNPs that would be AIPs that are required to use unified appeals and grievance procedures and continuation of Medicare benefits pending appeal.

- Potentially lead to more States requiring D–SNP-only contracts (see § 422.107(e)) 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 (like HPMS access for oversight and information sharing, greater transparency on Star Ratings specific to D–SNP enrollees in their State, increased transparency on health care spending, among other benefits).¹⁸⁰

While there are many benefits to our proposals, we acknowledge there are certain challenges:

- Our proposals would reduce the number of D–SNP options for Medicaid MCO enrollees in some States. In general, we share MedPAC’s assessment that cases of misaligned enrollment are unlikely to lead to any meaningful integration. However, 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 this 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 welcome comments on our overall policy direction, specific proposals, and analysis of their likely effects.

D. 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

¹⁸⁰ MMCO memo on 42 CFR 422.107(e) available here: <https://www.cms.gov/files/document/stateopsintegratedcareprogs.pdf>.

to improve its functionality by implementing enhancements to MPF.

MPF users can find information on D-SNPs that also provide Medicaid benefits for dually eligible individuals. However, the extent to which MPF highlights those plans is currently limited. We are soliciting 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.

One important consideration is how MPF displays benefits offered by MA and Part D plans. Currently, MPF only displays 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.

However, 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 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.

For example, 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.

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 believe there is an opportunity to better inform dually eligible MPF users. For AIPs, we are 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 would limit this functionality to AIPs, because in such plans all enrollees—by definition—receive Medicaid benefits through the AIP.

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.

Displaying Medicaid benefits in MPF, even with the limitations described above, would present new operational challenges for CMS. We do not currently capture 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. (Medicaid benefit information is included in State Medicaid agency contracts (SMACs) that D-SNPs submit annually to CMS, but the information is not standardized and can be inconsistent and difficult to retrieve. Also, the current timing of SMAC submissions by the first Monday in July may not allow CMS enough time to review the SMACs and make the Medicaid benefits information available to MPF for an early October release.) Another way to potentially capture the necessary information would be for us to provide a mechanism by which D-SNPs can report it to us annually. We solicit comment on the practicality and means for accomplishing this. Our experiences with integrated PBPs in the Medicare-Medicaid Financial Alignment Initiative would inform our implementation, but enhancements to MPF would require effort and some opportunity cost. Nonetheless, we

believe we can better inform dually eligible MPF users about the benefits to which they are entitled and, in doing so, better integrate their experience across Medicare and Medicaid. With support from the Administration for Community Living and the National Council on Aging, the My Care My Choice website is currently available to showcase integrated care plan options (and more) for three States (California, Michigan, and Ohio).¹⁸¹ We are also interested in stakeholders submitting comments about any features from the My Care My Choice website that are particularly helpful for individuals in understanding and making plan choices.

Such enhancements to MPF would not require rulemaking. We are soliciting comments on the concepts described above to inform our decision about whether and how to implement changes to MPF along these lines.

E. 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 FAI, CMS delegated eligibility and enrollment functions for Medicare-Medicaid Plans (MMPs) to States by waiving regulations at 42 CFR part 422, subpart B, insofar as they were inconsistent with the passive enrollment process used for each demonstration and with limiting enrollment in MMPs to certain dually eligible individuals. Operationally, many States have leveraged their State Medicaid enrollment vendors to operationalize enrollment, eligibility, or both. Which functions FAI States have chosen to delegate to their enrollment vendors or keep in-house (for example, enrollment vendor call center, enrollment noticing, eligibility determinations and enrollment processing) vary depending on the State.

Within the context of the FAI demonstrations, the use of a State enrollment vendor serves multiple purposes:

¹⁸¹ The My Care My Choice website is available at: <https://www.mycaremychoice.org/en>.

- Effectuating Medicare and Medicaid enrollment simultaneously to avoid misalignment between enrollment start and end dates,

- Serving as an unbiased source of information about integrated managed care plans and coverage options, and

- Reducing the risk of real or perceived conflicts of interest when plans initiate enrollment directly.

Outside of the FAI, dually eligible individuals elect MA plans, including D-SNPs, by enrolling directly with the plan, or Third-Party Marketing Organizations, or via 1-800-Medicare and the Medicare Online Enrollment Center. 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. 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.

Based on this experience, we are assessing ways to:

- Promote enrollment in integrated D-SNPs and reduce the likelihood of misaligned Medicare and Medicaid managed care enrollment for beneficiaries,

- Work toward an integrated D-SNP enrollment process that is operationally practical for both 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 without creating barriers to enrollment into a plan of choice, and

- Streamline beneficiary messaging and communication related to enrollment.

1. Current Opportunity for Use of State Enrollment Vendors for Enrollment in Integrated D-SNPs

States can utilize Medicaid enrollment vendors for enrollment in integrated D-SNPs through requirements in the SMAC required by § 422.107. 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. 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 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 would have to compensate its enrollment broker for performing these functions. D-SNPs would be in the position to provide the necessary information and oversight of the enrollment mechanisms and activities. 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.

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, similar to the noticing and messaging that applies in the FAI demonstrations. States could choose which functions to direct the D-SNPs to contract with the enrollment vendor for via the SMAC. States could also choose to direct the D-SNPs via the SMAC to not elect use of the Medicare Online Enrollment Center.

States could require D-SNPs to transfer prospective enrollees to the State's enrollment vendor for eligibility confirmation, as MMPs are required to do under the FAI demonstrations (for example, via warm transfer, in which the D-SNP staff transfers the prospective enrollee to the State's enrollment vendor but passes on the relevant information about the prospective enrollee). The enrollment vendor or the D-SNP—depending upon the contractual arrangement—would then effectuate the enrollment or disenrollment for Medicare and Medicaid. States could also require plans to direct enrollees to their vendor for disenrollments. Currently, under FAI, MMPs cannot accept enrollment requests directly from an individual or process the request, but instead they must forward the request to the State or State's enrollment vendor within two business days.

Under an arrangement in which a State requires D-SNPs to contract with the State's enrollment vendor, D-SNPs would retain the responsibility to oversee any functions delegated to the State's enrollment vendor under § 422.504 provisions that require MA plans to oversee first tier, downstream, and related entities. However, as noted earlier, financial arrangements would need to be structured to avoid violating the independence and conflict of interest limitations that apply to enrollment brokers under section 1903(b)(4) of the Act and §§ 438.71(c) and 438.810.

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. As in the FAI demonstrations, the State's enrollment vendor would need to implement Medicare managed care eligibility and enrollment policies, such as Medicare special enrollment periods and Comprehensive Addition and Recovery Act provisions.

Finally, 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.

2. Medicaid Managed Care Enrollment Cut-Off Dates

One challenge of applying FAI enrollment processes outside the demonstration context is 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.

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. (For example, an application received on March 28 would be effective May 1 in some States.) 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. 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, particularly in instances where the D-SNP and Medicaid MCO are described as a single integrated organization.

We are interested 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 invite 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.

3. Comment Solicitation

We are seeking feedback on the feasibility of the approach to enrollment outlined above (requiring integrated D-SNPs to contract with State enrollment brokers), as well as any specific concerns about States implementing it.

We are soliciting comments on, but not limited to, the following topics:

- What challenges do individuals face when trying to enroll in integrated D-SNPs?

- What are States' reasons for having a specific Medicaid managed care enrollment cut off date in place?

- What type of operational or systems barriers do States and Medicaid managed care plans face to making changes to their Medicaid enrollment cut-off date to align with the Medicare managed care enrollment start date?

- What potential concerns would stakeholders 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? (For example, Medicare enrollment effective dates that align with Medicaid enrollment effective dates, even if they are not the first day of the first calendar month following the date on which the election or change is made.)

- Are there operational or systems barriers for States and Medicaid managed care plans to align disenrollment dates with Medicare?

- What concerns, if any, should we consider with States requiring D-SNPs to route enrollment through the State enrollment vendor via the SMAC? Are there 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?

- 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?

- What are States' current requirements and policies related to agents and brokers?

- Are there other aspects of the integrated enrollment and disenrollment processes in FAI that should apply to D-SNPs?

F. 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 believe we can further clarify our regulations.

We propose 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 propose 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.

G. 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), CMS 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 2022¹⁸² 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

¹⁸² CMS 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.

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;¹⁸³ 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). As described in the June 2020 final rule, we also considered two other approaches: (1) setting the threshold at the higher of 50 percent dually eligible enrollment or the proportion of dually eligible MA-eligible individuals in the plan service area plus 15 percentage points; and (2) setting a lower threshold for dually eligible enrollment at a point between 50 and 80 percent (85 FR 33807). In addition to 80 percent or higher being an indicator that the plan is designed to attract disproportionate dually eligible enrollment, we believed this threshold would be easier for MA organizations to determine prospectively and operationally easier for CMS to implement than a threshold that varied across each service area.

A number of commenters on the February 2020 proposed rule recommended that we set a threshold lower than 80 percent. These commenters expressed concern that a threshold of 80 percent could be “gamed” by MA organizations to keep enrollment of dually eligible individuals just under the ceiling. Some commenters recommended that CMS set the ceiling for dually eligible enrollment at 50 percent with a commenter citing MACPAC analysis showing faster growth in projected enrollment among

MA plans with dual eligible enrollment greater than 50 percent than among those greater than 80 percent. Another commenter recommended a threshold of 60 percent.

In the June 2020 final rule, we responded that we believed the 80-percent threshold was reasonable because, based on the 2019 MedPAC analysis on 2017 data, it far exceeded the share of dually eligible individuals in any given MA plan service area—no MA plan service area had more than 50 percent dually eligible beneficiaries—and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. We also 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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¹⁸³ See June 2019 MedPAC Report to Congress, Chapter 12 at http://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.

TABLE 1: TOTAL NUMBER OF NON-SNPS BY DUALY 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 2: TOTAL ENROLLMENT IN NON-SNPS BY PERCENT OF DUALY 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	26,231	3,091	246	29,568
2018	26,132	2,570	2,957	31,659
2019	9,204	8,171	16,459	33,834
2020	46,319	15,939	20,320	82,578
2021	54,185	29,738	23,652	107,575
2022	75,926	45,522	26,481	147,929
2023	105,534	92,100	53,334	250,968
Percent growth from 2017 to 2023	302%	2,880%	21,580%	749%

Source: CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023.

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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)¹⁸⁴ exceeded the rate of enrollment growth for all MA-PD plans (109 percent) over the

¹⁸⁴ CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023, as shown in Table 1.

same period of time.¹⁸⁵ 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

¹⁸⁵ 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.

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.¹⁸⁶

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.¹⁸⁷ 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).¹⁸⁸ 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 2017,¹⁸⁹ we found 128 non-SNP MA plans with enrollment in that range for 2023.¹⁹⁰

To address the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals, we propose lowering the D-SNP look-alike threshold from 80 percent to 60 percent incrementally over a two-year period. We propose 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 propose a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for contract year 2025. For contract year 2026, we propose 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 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 propose 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 propose 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 propose revisions to paragraph (d)(2) to apply the lower thresholds to non-SNP MA plan enrollment. Specifically, we propose 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.

We considered lowering the threshold to 50 percent, given the growth in the number of non-SNP MA plans between 50 and 60 percent dually eligible

¹⁸⁶ Ma, Y., Austin F., 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>.

¹⁸⁷ 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.

¹⁸⁸ CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

¹⁸⁹ 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.

¹⁹⁰ CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

individuals as a share of total enrollment. MedPAC's analysis of 2017 data and our analysis of 2023 data showed that there are some service areas where the entire Medicare population is around 50 percent dually eligible individuals and 50 percent non-dually eligible individuals. As such, lowering the threshold to 50 percent could prohibit plans that reflect the distribution of eligibility in that community. Also, it is less clear that a plan is designed to target dually eligible individuals and circumvent the statutory D-SNP requirements when a plan appeals equally to dually eligible individuals and non-dually eligible individuals. Although we propose to lower the threshold to 60 percent, we solicit comments on whether the 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 Annual Notice of Change (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 propose 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 propose 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 propose 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 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 provided all 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 at § 422.530(c)(2) to request to transition the entire enrollment of the MA contract (including the D–SNP look-alike) to another MA contract offered by another MA organization with the same parent organization as part of a contract consolidation of separate MA contracts. As part of reviewing a request for a crosswalk exception under § 422.530(c)(2), CMS reviews the contract consolidation to ensure compliance with the change of ownership regulations (§§ 422.550 through 422.553).

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) 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 propose 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 also considering 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 solicit 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 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. 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 same 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 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 also propose 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.

H. For D–SNP PPOs, Limit Out-of-Network Cost Sharing (§ 422.100)

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.¹⁹¹

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 2023.¹⁹² Four national MA sponsors account for over 98 percent of D–SNP PPO enrollment.¹⁹³

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 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.

Our review of D–SNP PPO out-of-network cost sharing shows that for some important services, the cost sharing applicable to out-of-network services far exceeds the Medicare FFS cost sharing for these Part A and B benefits. For example, as of 2023:

- *Primary care providers:* 59 percent of D–SNP PPOs charge out-of-network coinsurance above 20 percent, with most ranging from 30 to 40 percent.
- *Part B prescription drugs:* 53 percent of D–SNP PPOs charge an out-of-network coinsurance above 20 percent, with most ranging from 30 to 40 percent.

¹⁹¹ 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.

¹⁹² D–SNP PPO enrollment was at approximately 668,000 as of May 2023.

¹⁹³ The four sponsors are UnitedHealth Group (69 percent of national D–SNP PPO enrollment), Humana (23 percent), Centene (4 percent), and Elevance (2 percent).

- *DME*: 50 percent of D–SNP PPOs charge an out-of-network coinsurance above 20 percent, with most ranging from 30 to 50 percent.
- *Home health*: 41 percent of D–SNP PPOs charge an out-of-network coinsurance for home health services (original Medicare has no coinsurance). Out-of-network coinsurance ranged from 20 percent to 40 percent.
- *Dialysis*: Three percent of D–SNP PPOs charge an out-of-network coinsurance above 20 percent for dialysis.
- *Skilled Nursing Facility (SNF)*: 46 percent of D–SNP PPOs charge between 20 and 50 percent coinsurance for out-of-network SNF stays, considerably more than Traditional Medicare, which charges nothing for the first 20 days of a stay and a per diem charge for days 21–100.
- *Inpatient Hospital (Acute)*: 47 percent of D–SNP PPOs charged between 20 and 50 percent for an inpatient stay at an out-of-network acute care hospital, which can be substantially more than the Part A deductible in Traditional Medicare.
- *Inpatient Hospital (Psychiatric)*: 46 percent of D–SNP PPOs charge between 20 and 50 percent coinsurance for out-of-network inpatient psychiatric services, substantially greater than the inpatient deductible charged under Traditional Medicare.

By contrast, cost sharing for in-network services in these D–SNP PPOs largely tracks the cost sharing structure in Traditional Medicare. Seventy-nine percent charge a Part B deductible. Eighty-five percent charge 20 percent for professional services, like visits with primary care and specialist physicians, and 100 percent charge 20 percent coinsurance for Part B drugs and DME, consistent with Traditional Medicare. While this in-network benefit design is consistent with statutory and regulatory requirements for overall and service-specific limits under § 422.100(f)(6) (which sets specific cost sharing limits for certain in-network services tied to the maximum out-of-pocket (MOOP) limit used by the plan) and (j) (which identifies services for which in-network cost sharing must not exceed cost sharing in Traditional Medicare) for in-network benefits, it differs from non-D–SNP PPOs which generally provide greater reductions in in-network cost sharing (compared to Traditional Medicare cost sharing) as supplemental benefits.

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. This is especially true for those few States that, by policy, pay the full Medicare cost sharing amounts for all Medicare services, rather than for specific services in the Medicaid benefit.

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. (QMBs, in contrast, have applicable Medicare cost-sharing amounts covered by Medicaid based on coverage of cost-sharing for Medicare covered services.) Non-QMB full-benefit dually eligible individuals are protected from cost sharing under § 422.504(g)(1)(iii) if they use in-network providers, including providers not enrolled in Medicaid. The regulation imposes obligations on MA organizations to ensure that their contracted—that is, in-network—providers do not collect cost sharing from enrollees when the State is responsible for paying such amounts. However, this protection does not extend to out-of-network providers not 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.¹⁹⁴ In such a scenario, the provider may receive 70 or 60 percent of the Traditional Medicare rate for the services rather than the 80 percent that the provider would receive under Traditional Medicare (or as an in-network provider). We are concerned that this effective payment cut disincentivizes providers from serving dually eligible enrollees, which may compromise access to services for these enrollees. In addition, we are concerned that such disincentives undermine the promise of out-of-network access that is a key component of how D–SNP PPOs are marketed to potential enrollees.

In addition to the potential impact on States, safety net providers and dually

¹⁹⁴ 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 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.

eligible individuals of this cost sharing structure, 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 original 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.¹⁹⁵ 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.

For example, a provider in a State that capped its cost sharing payments at a Medicaid primary care rate that is 70 percent of the Medicare rate would receive just 70 percent of that Medicare rate when the provider is not in the PPO’s network and the PPO’s out-of-network cost sharing is 30 percent or higher. That provider would receive 80 percent of the Medicare rate under

¹⁹⁵ For more information on cost sharing protections applicable to dually eligible individuals, see: [https://www.cms.gov/medicare-medicare-coordination/medicare-and-medicare-coordination-office/qmb](https://www.cms.gov/medicare-medicare-coordination/medicare-and-medicare-coordination/medicare-and-medicare-coordination-office/qmb).

Traditional Medicare for the covered service.

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 original 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 are proposing 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. This proposal 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 propose 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 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 here as well.

We propose to apply cost sharing limits on out-of-network professional services because this category of services includes the physician and psychiatry services most utilized out-of-network in D–SNP PPOs. In addition, physician services are among the services for which Medicaid rates will most commonly either result in no payment of cost sharing due to limits on Medicaid rates or will increase State liability for cost sharing but still not result in total payment of at least 80 percent of the Medicare rate.¹⁹⁶

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.

¹⁹⁶ Only 14 States have Medicaid primary care rates that are greater than 80 percent of the Medicare rate. See: <https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/?currentTimeframe=0&sortModel=%7B%22collId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

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 propose 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:

- Cost sharing for chemotherapy administration services, including chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen, other Part B drugs, and renal dialysis services as defined at section 1881(b)(14)(B) of the Act, would be capped at the cost sharing applicable for those service under Traditional Medicare.

- For skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility (SNF) during the period for which cost sharing would apply under Traditional Medicare, cost sharing would be limited to the cost sharing amounts under Traditional Medicare when the MA plan establishes the mandatory MOOP catastrophic limit under § 422.101(d)(3). When the MA plan establishes the lower MOOP catastrophic limit, the cost sharing could not be greater than \$20 per day for the first 20 days of a SNF stay. When the MA plan establishes the intermediate MOOP catastrophic limit, the cost sharing could not be greater than \$10 per day for the first 20 days of a SNF stay.

- Regardless of the MOOP amount established by the MA plan, the per-day cost sharing for days 21 through 100 could not be greater than one eighth of the projected (or actual) Part A deductible amount.

- For home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP type, cost sharing could not be greater than Traditional Medicare. When the MA plan establishes the lower MOOP catastrophic limit, the cost sharing could not be greater than 20 percent coinsurance or an actuarially equivalent copayment.

- Cost sharing could not be greater than the applicable cost sharing under Traditional Medicare, when the MA plan establishes the mandatory MOOP catastrophic limit for the following specific service categories of durable medical equipment (DME): equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts.

For regional PPO D–SNPs, we propose to exclude paragraph (j)(1)(C)(2) and the last sentence of paragraph (j)(1)(E) regarding overall actuarial equivalence requirements to avoid conflict with section 1852(a)(1)(B)(ii) of the Act.

We propose applying out-of-network cost sharing limits to those services enumerated at § 422.100(f)(6) and (j)(1) because MA organizations and CMS have experience limiting cost sharing to Traditional Medicare for these categories of services when they are furnished in-network. In addition, this would establish alignment and consistency between the in-network and out-of-network cost sharing used by D–SNP PPOs for these services. We also note that section 1852(a)(1)(B)(iv) of the Act limits cost sharing for some of these services, including chemotherapy administration and dialysis, to cost sharing levels in Traditional Medicare, which CMS has implemented in § 422.100(j) to apply to in-network benefits. As noted above, these services are among those services for which D–SNP PPOs most often impose cost sharing greater than Traditional Medicare.

We are considering a requirement to limit all D–SNP PPO out-of-network cost sharing to no greater than Traditional Medicare, or using a limit specifically for physician services, including psychiatric and other mental health services, rather than using the cost sharing limits in § 422.100(f)(6). These are among the most commonly accessed services out-of-network in D–SNP PPOs, and these safety net providers are most likely to see reduced payment compared to their Traditional Medicare patients, which weighs in favor of requiring cost sharing to align with Traditional Medicare. Although we continue to consider these alternatives and request comment on them, we

decided to propose application of the cost sharing limits that are applicable for in-network coverage for specific benefit categories, some of which are capped at Traditional Medicare cost sharing and some of which are higher. We propose to take this measured approach on the one hand to impose cost sharing limits on those services where the limits would have the most impact—those services most used out-of-network in D–SNP PPOs and where the greater cost sharing has the most impact on provider payment and, for those dually eligible beneficiaries liable for cost sharing, ability to pay. We also believe this approach, at least initially, would mitigate any negative impact on MA organizations and D–SNP PPO enrollees as MA organizations redirect funds from other supplemental benefits to reduce cost sharing for these out-of-network services. However, we seek comment on whether there are additional out-of-network services for which cost sharing should be limited to the levels applicable in Traditional Medicare.

We considered proposing out-of-network cost sharing limits for D–SNP PPOs only for services for which the Medicaid payment of cost sharing did not result in a total payment that was at least equivalent to the payment under Traditional Medicare. That approach would address our concern about how high out-of-network costs sharing by D–SNP PPOs appears to circumvent the goal of section 1852(a)(2)(A) of the Act that the out-of-network providers that furnish covered services to enrollees in MA plans receive the amount that the provider would have received under Traditional Medicare. However, such an approach would create an overly complex and likely unworkable system of cost sharing limits that differed both by State (depending on whether State policy limited cost sharing for specific services), by service, and—in some cases—by individual provider. For example, a State may pay the full Medicare cost sharing for Part B drugs administered by an oncologist but set the rate for administration of those drugs at 50 percent of the Medicare rate, resulting in no payment of cost sharing. That would result in two parts of a single services—payment for chemotherapy drugs and administration of such drugs—being subject to different cost sharing limits. The services subject to cost sharing limits could also change over time as States changed the rates at which they reimbursed for such services.

We also considered proposing out-of-network cost sharing limits only for services furnished out of network to

QMBs because they are always protected from being billed cost sharing (see sections 1848(g)(3), 1866(a)(1)(A), 1902(n), and 1905(p)(3) of the Act). However, this would not allow for the MA organization to apply its benefit uniformly to all its members, as required by 42 CFR 422.100(d)(2)(i), unless the SMAC limits enrollment in the D–SNP PPO to QMBs. In addition, managing cost sharing benefits in a non-uniform way could be administratively burdensome for both MA organizations and providers or difficult to clearly and accurately explain to enrollees in the member materials.

Finally, 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 propose 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. Therefore, we do not believe this proposed rule creates substantial information collection requirements.

We do not expect any new burden to be associated with these proposed changes, as MA organizations are currently required to include information on MA cost sharing in their bids. Further, we do not expect any additional burden on CMS, as modifications to account for this proposed provision would be completed as part of normal business operations.

IX. Updates to Program of All-Inclusive Care for the Elderly (PACE) Policy

A. 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, 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. For example, 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, therefore, 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. Therefore, we propose to revise § 460.194(b) to specify that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. This proposal would give CMS and the SAA the flexibility to determine

how to use their oversight resources most effectively, which will be increasingly important as PACE continues to grow.

This proposal 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.

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 solicit comment on this proposal.

B. 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) through (iii)). In the January 2021 final rule (86 FR 6024), we 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 we 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 propose 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 propose to add the add the following language at § 460.121(b)(2). For all requests identified in this section, the interdisciplinary team must—

- Document the request; and
- Discuss the request during the care plan meeting and either—

++ Approve the requested service and incorporate it into the participant’s initial plan of care; or

++ Document their rationale for not approving the service in the initial plan of care.

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).

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).

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.

We are soliciting public comment (see section VII.D. of this preamble for further information) on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

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.html), which, at the time of publication of this proposed 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.

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
Insurance Sales Agent (Agent-Broker)	41-3021	37.00	n/a	n/a
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
Software and Web Developers, Programmers, Testers	15-1250	60.07	60.07	120.14
Software Developers	15-1252	63.91	63.91	127.82
Registered Nurse	24-1141	42.8	42.8	85.6

As indicated, except for Insurance Sales Agents, 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.

However, the mean wage for Insurance Sales Agent is being applied

to Agent-Brokers who work on behalf of Medicare Advantage plans. We are not adjusting their mean hourly wage for fringe benefits and other indirect costs because this proposed rule includes a proposal which accounts for payments for certain administrative activities while explicitly precluding others. These proposed payments would have their own annual update.

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.

For valuing time spent outside of work, there is logic to this approach but also to 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 use the lower limit as we consider it more accurate. The effect of this range will be footnoted in Table J5 and the summary table. Since the impact to beneficiaries is approximately \$54,000, increasing the wage by 50 percent would result in a roughly \$24,000 increase.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this proposed rule.

1. ICRs Regarding Network Adequacy in Behavioral Health (§ 422.116(b)(2) and (d)(2) and (5))

The following proposed changes will be submitted to OMB for review 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 proposing to amend the network adequacy requirements to 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 in § 422.116(d)(2). This new category can include, for network adequacy evaluation purposes, provider types including 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 propose 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 not subject to COI review.

Although there is a 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 proposed 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 proposal would only require that the proposed 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 of 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 \$4,929 (62 hr * \$79.50/hr).

2. ICRs Regarding Standards for Electronic Prescribing (§ 423.160 and 45 CFR 170.205 and 170.299)

In section III.B. of this proposed rule, we propose updates to the standards to be used for electronic transmission of prescriptions and prescription-related information for Part D covered drugs for Part D eligible individuals. This includes: (1) after a transition period, requiring the National Council for Prescription Drug Plans (NCPDP) SCRIPT standard version 202301, proposed for adoption at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071 for communication of a prescription or prescription-related information supported by Part D sponsors; (2) requiring use of NCPDP RTPB standard version 13 for prescriber RTBTs implemented by Part D sponsors beginning January 1, 2027; and (3) requiring use of NCPDP Formulary and Benefit (F&B) standard version 60, proposed for adoption at 45 CFR 170.205(u), and retiring use of NCPDP F&B version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors. These proposals update existing standards that have historically been exempt from the PRA, as explained in this section.

The initial electronic prescribing standards for the Medicare Part D program were adopted in the final rule “Medicare Program; Standards for E-

Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)” (Initial Standards final rule), which appeared in the April 4, 2008, **Federal Register** (73 FR 18917). The Initial Standards final rule implemented the first update to the electronic prescribing foundation standards in the Part D program that had been adopted in the final rule “Medicare Program; E-Prescribing and the Prescription Drug Program” (Foundation Standards final rule), which appeared in the November 7, 2005, **Federal Register** (70 FR 67567). The Initial Standards final rule adopted the updated the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 8.1 and retired the previous NCPDP SCRIPT standard version 5.0. With respect to ICRs in the Initial Standards final rule, CMS stated that as a third-party disclosure requirement subject to the PRA, Medicare Part D sponsors must support and comply with the adopted e-prescribing standards relating to covered Medicare Part D drugs, prescribed for Medicare Part D eligible individuals. However, the requirement that Medicare Part D sponsors support electronic prescription drug programs in accordance with standards set forth in this section, as established by the Secretary, does not require that prescriptions be written or transmitted electronically by prescribers or dispensers. These entities are required to comply with the adopted standards when they electronically transmit prescription or prescription-related information for covered transactions. Testimony presented to the [National Committee on Vital and Health Statistics] indicates that most health plans/[pharmacy benefit managers] currently have [electronic] prescribing capability either directly or through contract with another entity. Therefore, we do not believe that utilizing the adopted standards will impose an additional burden on Medicare Part D sponsors. Since the standards that have been adopted are already familiar to industry, we believe the requirement to utilize them in covered [electronic] prescribing transactions constitutes a usual and customary business practice. As such, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Subsequent rules which have updated electronic prescribing standards in the Medicare Part D program have not included any burden estimates. Specifically—

- The “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013” final rule, which appeared in the November 16, 2012, **Federal Register** (77 FR 68891). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP SCRIPT standard version 8.1 to version 10.6;

- The “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014” final rule, which appeared in the **Federal Register** December 10, 2013 (78 FR 74229). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP Formulary and Benefit (F&B) standard version 1.0 to 3.0; and

- 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** April 16, 2018 (83 FR 16640). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP SCRIPT standard version 10.6 to 2017071.

Rationale that further supports CMS’s longstanding approach to not estimate burden associated with updating electronic prescribing standards is described in the proposed 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 Benefit Programs, and the PACE Program” (November 2017 proposed rule), which appeared in the November 28, 2017, **Federal Register** (82 FR 56336). When describing the proposed update of the NCPDP SCRIPT standard from version 10.6 to 2017071 in the November 2017 proposed rule, CMS stated that we believe that transitioning to the new 2017071 versions of the transactions already covered by the current Part D [electronic] prescribing standard (version 10.6 of the NCPDP SCRIPT) will impose de minimis cost on the industry as the burden in using the updated standards is anticipated to be the same as using the old standards for the transactions currently covered by the program. We believe that prescribers and dispensers that are now prescribing [electronically] largely invested in the

hardware, software, and connectivity necessary to prescribe [electronically]. We do not anticipate that the retirement of NCPDP SCRIPT 10.6 in favor of NCPDP SCRIPT 2017071 will result in significant costs.

Similarly, Part D sponsors have been required support real-time benefit tools (RTBTs) since January 1, 2021, as finalized in the “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses” final rule, which appeared in the **Federal Register** May 23, 2019 (84 FR 23832). Because Part D sponsors have invested in the hardware, software, and connectivity necessary to utilize RTBTs, we believe that adopting the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13 will impose de minimis cost on the industry and that costs will be largely offset by the advantages and efficiencies associated with interoperability that a standard brings.

The operations associated with updates to standards that we propose in this proposed rule are analogous to the operations associated with updates to standards in the prior rules described. Therefore, the proposals in section III.B. of this proposed rule are exempt from the PRA.

3. ICRs Regarding to Improvements to Drug Management Programs (§§ 423.100 and 423.153)

The following proposed changes will be submitted to OMB for review 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 their clearance of our proposed 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 their approval of our final rule’s collection of information request. When ready, the expiration date can be found on [reginfo.gov](https://www.reginfo.gov).

Ordinarily, the proposed changes would be submitted to OMB for review 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 proposing to remove

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.E. of this proposed rule, we propose to amend regulations regarding Part D DMPs for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs). Specifically, we propose to amend the definition of “exempted beneficiary” at § 423.100 by replacing the reference to “active cancer-related pain” with “cancer-related pain.” This proposed change would 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” would result 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 ($[2 \text{ hr} \times \$124.44/\text{hr}] + [2 \text{ hr} \times \$38.70/\text{hr}] + [1 \text{ hr} \times \$229.52/\text{hr}]$). Therefore, the case management team’s average hourly wage is \$111.16/hr ($\$555.80/5 \text{ hr}$). In aggregate, we estimate annual burden with the proposed 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 (30,365 enrollees * 5 hr * \$111.16/hr); see case management row in Table J3. 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 J2. Thus, we calculate a savings of 27,033 hours (178,855 – 151,825) and \$3,004,655 ($\$19,955,671 - \$16,876,867$) with this current proposed burden; see case management row in Table J4 and note that in Table J4 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 proposed 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 J3. 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 J2. Thus, we calculate a savings of 1,066 hours (1,319 – 253) and \$41,254 ($\$51,045 - \$9,791$) with this current proposed burden; see the row for notification for enrollees in Table J4 and note that in Table J4 we list savings as a negative number.

Amending the definition of “exempted beneficiary” would also reduce 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 proposed 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 J3. 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 Table J2. Thus, we calculate a savings of 90 hours (597 – 507) and \$3,483 ($\$23,104 - \$19,621$) with this current proposed burden; see the row for notification to CMS in Table J4 and note that in Table J4 we list savings as a negative number.

Table J2, presents information from the current package, CMS–10141, with wages adjusted to 2022 wages.

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TABLE J2: CURRENTLY APPROVED BURDEN ESTIMATES WITH UPDATED WAGES

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time	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 J3 presents the estimated burden proposed in this rule which will be submitted with the new package, CMS-10874, which uses the currently approved burden from CMS-10141 as a baseline.

TABLE J3: ESTIMATED BURDEN FROM THIS PROPOSED RULE

Regulatory Citation	Subject	Number of Respondents	Number of Responses (PARBs after exclusions)	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Proposed Burden
423.153(f)(2)	Conduct Case Management (Annualized)	319	30,365	5	151825	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 proposed 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 J4, and will be submitted with the new package, CMS-10874.

TABLE J4: BURDEN CHANGES *

Regulatory Citation	Subject	Number of responses (PARBs after exclusion)	Time per response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Proposed Burden
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	(3,483.00)
Total				(28,186)	Varies	(3,049,392)

* Table J4 is obtained by subtracting from Table J3 (burden of proposed regulation), Table J2 (current burden). For example, for Case Management, $-27,030 = 151,825 - 171,855$.

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4. ICRs Regarding Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2))

In section III.F. of this proposal, we are proposing a limited number of changes to update regulatory text we originally proposed in section III.Q. Changes to an Approved Formulary of the December 2022 proposed rule. In the December 2022 proposed rule, we proposed to reorganize current regulatory text to incorporate and as necessary conform with longstanding sub-regulatory guidance and operations with respect to changes to an approved formulary and associated notice provisions. We also proposed to permit the immediate substitution of interchangeable biological products. The proposals discussed in section III.Q. of the December 2022 proposed rule have not been finalized and remain under consideration.

Specifically, in section III.F. of this proposed rule, we are now proposing to update the regulatory text proposed in December 2022 to the extent necessary 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 are proposing 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 are proposing a few technical changes, including in support of the above specified proposals.

In section VII.B.10. of the December 2022 proposed rule (87 FR 79680), we outlined ICRs regarding the proposed provision “Changes to an Approved Formulary.” We described the methodology used to quantify burden, labor, and non-labor costs incurred by Part D plan sponsors related to making changes to their approved Part D formularies. The information collection responses included: (1) submitting a negative change request to CMS; (2) updating the formulary in CMS’s Health Plan Management System (HPMS); (3) updating the formulary and providing online notice of changes on the plan website; and (4) providing direct written notice to affected enrollees. The burden estimates in the December 2022 proposed rule were based on actual formulary changes submitted to CMS since the “Changes to an Approved Formulary” proposals set out to codify existing guidance that Part D sponsors had already been following.

We are not revising the December 2022 proposed rule’s burden estimates for the purposes of this CMS-4205-P proposal which permits 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 2023,¹⁹⁷ but CMS has not seen a corresponding influx of non-maintenance negative change requests from Part D sponsors. 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.

We will continue to base our burden estimates on CMS’s internal data on formulary changes from a recent contract year, as described in section VII.B.10. of the December 2022 proposed rule and will consider comments received. We will revise our estimates, as appropriate, based on current data when finalizing the proposals from the December 2022 proposed rule. The changes will also 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

¹⁹⁷ 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>.

after the publication of the CMS–4205–F final rule.

5. ICRs Regarding Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

In section III.H. of this proposed rule, we discuss two proposals 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. Our proposals to improve access to MA encounter data include all the following:

- Adding “and Medicaid programs” to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii).
- 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 proposals aim to 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., explaining that we do not anticipate any significant impact to CMS.

As discussed in sections III.H. and XI., these proposed provisions would 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 analysis to support the Medicare program (including demonstrations). In addition, we interpret the regulation as permitting use and disclosure of the MA encounter data for quality review and improvement activities for Medicaid as well as Medicare.

When determining the potential burden of these proposals on States, we considered our existing data sharing program for States to request Medicare data for initiatives related to their dually

eligible population. We expect 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 would not need to complete and submit a new data agreement for MA encounter data; instead, they would 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 would 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 help States 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 this proposed rule, we do not anticipate a significant change in burden for States as a result of these proposals, which clarify and expand MA encounter data uses and timing of data release. We solicit comment on our analysis.

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 proposed changes will be submitted to OMB for review under

control number 0938–0753 (CMS–R–267).

As explained in section IV.B. of this rule, due to increased offering of SSBCI, we are proposing 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. 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 denials of SSCBI, 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).

7. ICRs Regarding Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111 and 422.2267)

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

As explained in section IV.C of this proposed rule, 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. Currently, there is no 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 proposing 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 proposed requirement would still 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. We propose 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 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, we are proposing that 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.

In estimating the burden of this provision, we first note 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:* We estimate a bulk rate mailing of \$0.12 for 1,000 notices, or \$0.00012. We particularly solicit stakeholder feedback on their experience in bulk rates. We note that the particular provision for which this estimate was provided in CMS–4201, DMP, had HIPPA requirements necessitating first class postage. However, notifications about the lack of use of supplemental benefits would be similar to EOBs which need not be sent by first class postage.

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. Thus, the expected price per page of mailing is \$0.01412 (\$0.007 for paper plus \$0.007 for toner plus 0.00012 for postage). The aggregate non-labor cost for 32 million mailings of one page would be \$451,840 (32,000,000 * \$0.01412). 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 but solicit stakeholder feedback. Thus, the total non-labor cost would be \$1,355,520 (3 pages * \$451,840/page).

8. ICRs Regarding New Requirements for the Utilization Management Committee (§ 422.137)

As discussed in section IV.D. of this proposed rule, we are adding new requirements related to the Utilization Management (UM) Committee established at § 422.137.

The following proposed changes will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

We are proposing 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).

The following proposed changes will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

We are proposing 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 would 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 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).

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

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).

9. ICRs Regarding Agent Broker Compensation (§ 422.2274)

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–273).

Currently, agents and brokers are compensated by MA plans at a base rate with a maximum of \$601 per enrollee, plus administrative payments. In section VI.B. of this proposed rule, we are proposing to raise the maximum compensation rate to a fixed amount that covers two basic activities that agents and brokers perform: (1) training and testing; and (2) other necessary administrative activities such as recording and transcription. The training and testing focus on the information that agents and brokers may or may not disclose about the Medicare program and the plans they represent. The training and testing involve the transmission of information to agents and brokers about Medicare rules.

Prior to stating our estimates, we emphasize that there are numerous data challenges in formulating an exact amount of compensation. Therefore, we especially invite stakeholder comments on all our assumptions and conclusions. More specifically, the estimates that follow address three areas where we have uncertainty: (1) the number of agent and brokers actively working in selling Medicare products; (2) the number of new enrollees in non-employer MA plans and PDPs; and (3) the percent of new enrollments effected by agent and brokers. Our assumptions and supportive data are presented in Table J5.

TABLE J5: THREE ESTIMATES USED IN THE ANALYSIS

Item	Estimate	Partially Supportive Data
Number of agent brokers selling Medicare	100,000	The Bureau of Labor Statistics occupational handbook lists about 340,000 insurance agents (including life insurance agents, auto insurance agents etc.). We assume one third are involved with health plans (https://www.bls.gov/oes/2022/may/oes413021.htm).
Number of new enrollees per year for non-employer MA plans and stand-alone prescription drug plans	2 million	Published CMS data (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenrolldata) 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.
Per cent of new enrollments effected by agent brokers	50%	We do not have any data on this. Furthermore, many agents work for themselves and do not have to report to CMS about the number of new enrollments they effect. Traditionally we have used 50% when we do not have data. Additionally, we are soliciting stakeholder comment in this area.

We now present estimates for the two activities listed previously: (1) training and testing per enrollee, and (2) other necessary administrative activities such as recording and transcription.

a. Cost of Training

CMS requires that agents be certified, as evidenced by attending training and passing certain tests, in order to sell Medicare products. Many agents and brokers and many plans prefer the use of a recognized certification organization such as AHIP (<https://www.ritterim.com/blog/what-is-ahip-certification-and-how-do-i-get-it/#pdp-ebook>) for training and testing. The AHIP training and certification costs \$175. However, some plans provide a discount of \$50; and some plans will pay for the training. The training allows three attempts at passing. If the agent or broker fails three times, some plans will not recognize their certification even if they eventually pass. For those plans that do recognize continued attempts, the agent must pay an additional \$175. Therefore, we believe it reasonable to set the average cost of training at \$125 and assume that most agents and brokers pass within their first three attempts (we lack data on this and invite stakeholder comment). We are treating the \$125 as a non-labor business expense (and invite comments on this assumption). Finally, we note that this \$125 fee, corresponds to \$12.50 per enrollee, since we estimate there are 2

million new enrollees, half of which (1 million enrollees) are affected by the 100,000 agent and brokers, implying that on average each agent and broker recruits 10 enrollees. Therefore, the \$125 cost when divided by the number of enrollees gives a \$12.50/enrollee cost (\$125/10).

b. Burden Associated With Transcription and Recording

We are estimating 30 minutes (0.5 hr) to account for the time and expense of recording and storing calls (and solicit stakeholder comment on this assumption). As already noted, based on the occupational title “Insurance Sales agents” we assume a mean hourly wage of \$37.00/hr. Thus, the fair market value (FMV) per enrollee for transcription and recording would be \$18.50 (\$37.00/hr * 0.5 hr).

c. Total Cost

Thus, the aggregate cost per enrollee is \$31 (\$18.50 for transcription and recording + \$12.50 for training and testing). The aggregate cost over all new enrollees would be \$31 million (\$31/enrollee × 1,000,000 new enrollees affected annually).

We have focused on new enrollments, since the cost of the administrative activities discussed is predominantly overhead not closely connected with actual enrollments, and we are more accurately able to track new enrollments, so they serve as a better basis for attaching these payments.

10. ICRs Regarding Adding Proposed New Rationale for an Exception From the Network Adequacy Requirements in § 422.116(b) Through (e)

The following proposed changes will be submitted to OMB for review 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 proposing to broaden our acceptable rationales for facility-based I–SNPs when submitting a network exception under § 422.116(f). The first proposed 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–SNP 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 regarding this proposal, we considered the one-time burden for MA organizations to update policies. The other burdens associated with this provision involve updates to the HPMS system, which is done by CMS and its contractors and not subject to COI review.

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 \$64 (0.8 hr * \$79.50/hr).

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)

At § 423.38(c)(4) we are proposing to 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. At § 423.38(c)(35), we propose a new integrated care SEP to allow dually eligible individuals to elect an integrated D-SNP on a monthly basis. The burden associated with the current quarterly dual/LIS SEP at § 423.38(c)(4) is currently approved by OMB under

control number 0938–0964 (CMS–10141).

The proposed changes related to a new integrated care SEP at § 423.38(c)(35) will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

In section VIII.C. of this proposed rule, we propose amending §§ 422.514(h), 422.503(b), 422.504(a), and 422.530(c). Proposed § 422.514(h) would require an MA organization's parent 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. The proposed regulation at § 422.514(h) would 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 at § 422.503(b)(8) would prohibit parent organizations from offering a new D-SNP when that D-SNP would result in noncompliance with the proposed regulation at § 422.514(h). Additionally, the proposed regulation at § 422.504(a)(20) would require compliance with § 422.514(h). To support parent organizations seeking to consolidate D-SNPs, we also propose § 422.530(c)(4)(iii) that would 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 proposed changes related to MA organizations that offer multiple D-SNPs in a service area (§§ 422.514(h), 422.503(b), 422.504(a), and 422.530(c)) with a Medicaid MCO will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

a. MA Plan Requirements and Burden

We are proposing to redesignate § 423.38(c)(35) as § 423.38(c)(36) and proposing a new integrated care special enrollment period (SEP) at § 423.38(c)(35) that 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. The proposed integrated care SEP at § 423.38(c)(35) would 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 would need one software engineer working 4 hours to update software and one business operations specialist working 4 hours 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. This will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

The proposed provisions at §§ 422.514(h) and 422.530(c)(4)(iii) would create burden for MA organizations where they offer multiple D-SNPs in a service area with a Medicaid MCO. Impacted MA organizations would 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 would need two software engineers working 4 hours to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours 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)]). This will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

b. Medicare Enrollee Requirements and Burden

Proposed amendments to § 423.38(c)(4) and (35) would 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 0938–0964 (CMS–10141). However, Medicare beneficiaries make enrollment choices currently, and we do not expect the overall volume of enrollment selections to materially change if our proposals are finalized. Therefore, we do not believe the proposals at § 423.38(c)(4) and (35) would impact the burden estimates that are currently approved under 0938–0964 (CMS–10141). Similarly, we are not proposing any changes to that collection's currently approved forms.

In the section XI. of this proposed 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 proposed changes will be submitted to OMB for review 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) (see section VIII.G. of this proposed rule).

As described in section VIII.G. of this proposed rule, we propose lowering the D-SNP look-alike threshold from 80 percent to 60 percent over a two-year period. We propose a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for CY 2025. For CY 2026, we are proposing 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 plans and CMS to operationalize these transitions over a two-year period.

We would maintain processes to minimize disruption for the enrollees in plans affected by this proposed change. We propose 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 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 would 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 propose 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 through plan year 2023, the vast majority of enrollees 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.

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 plans¹⁹⁸ that have enrollment of dually eligible individuals of 70 percent through 79.9 percent of total enrollment and 40 non-SNP MA plans¹⁹⁹ 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 have total enrollment of 53,334 enrollees and the 40 non-SNP MA plans have 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).²⁰⁰ 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

¹⁹⁸ These 30 non-SNP MA plans are located in Arizona, California, Connecticut, Idaho, Illinois, Louisiana, Nevada, New Hampshire, New Mexico, Oklahoma, Oregon, Pennsylvania, Tennessee, Vermont, and Virginia.

¹⁹⁹ These 40 non-SNP MA plans are located in Arkansas, California, Connecticut, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, and Tennessee.

²⁰⁰ The 2 non-SNP MA plans are located in New Hampshire and Vermont, neither of which have a D-SNP as of contract year 2023.

managed care plans and would be subject to § 422.514(d). As of January 2023, these 68 plans have total enrollment of 145,434 for contract year 2023. If these plans all have the same enrollment pattern in 2024, MA organizations would need to non-renew for plan year 2025 those 28 plans that exceed our proposed criteria to lower the threshold to 70 percent for plan year 2025.²⁰¹ Similarly, MA organizations with plans that exceed our proposed criteria to lower the threshold to 60 percent for plan year 2026 would need to non-renew 40 plans for plan year 2026.²⁰² Each MA organization would 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 2023, 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. Plan year 2023 was the only plan year when D-SNP look-alikes transitioned enrollees to Traditional Medicare rather than an MA plan under the same parent organization. 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. The changes required of MA organizations based on this proposed rule would impact D-SNP look-alikes and their enrollees (see section VIII.G. of this proposed 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 2023.

a. MA Plan Requirements and Burden

As indicated, the following proposed changes will be submitted to OMB for review under control number 0938-0753 (CMS-R-267).

²⁰¹ These 28 plans have total enrollment of 53,334 individuals as of January 2023.

²⁰² These 40 plans have total enrollment of 92,100 individuals as of January 2023.

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 proposed “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 2023, we believe 95 percent of D-SNP look-alikes for plan years 2025 and 2026 would 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 would 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 27 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). 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 would account for any additional work to confirm enrollees’ Medicaid eligibility for D-SNP look-alikes 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 to 2027 plan years is summarized in Table J6.

TABLE J6: BURDEN FOR TRANSITIONING D-SNP LOOK-ALIKE ENROLLEES INTO ANOTHER MA-PD

Year	Number of Plans	Time per Response (hr)	Total Time (hr)	Total Cost (using \$79.50/hr for a business operations specialist) (\$)
2025	27	2	54	4,293
2026	38	2	76	6,042
2027	12	2	24	1,908
Total	77	6	154	12,243
Average	25.667 (77/3)	2 (6/3)	51.334 (154/3)	4,081 (12,243/3)

Based on our experience through plan year 2023, 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 would already be 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.

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 would 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).

We expect 1 plan for plan year 2025 and 2 plans for plan year 2026 would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at

§ 422.514(e)(4), as we anticipate—based on our experience with transitions through plan year 2023—not all D–SNP look-alikes would 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 our proposal to lower the threshold for identifying D–SNP look-alikes from 80 percent to 60 percent would 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 proposed changes to the § 422.514(e) transition process, which would limit use of the § 422.514(e) transition process to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Under our proposal, 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 proposed threshold lowered to 70 percent and then 60 percent—could 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 could only be used for D–SNP look-alike transitioning enrollees into D–SNPs. We believe this proposed limit would 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 proposed limit on the § 422.514(e) transitions would be effective for plan year 2027 and subsequent years. We believe that these 12 D–SNP look-alikes would non-renew and transition their enrollment into a D–SNP or other MA–PD plan. The annual burden is summarized in Table J6. We welcome comment on these assumptions.

As indicated, the following proposed changes will be submitted to OMB for review 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 this rule proposes to revise as discussed in section VIII.C. of this proposed rule. Based on our experience with D–SNP look-alike

transitions through plan year 2023, we estimate that 99 percent of the 53,334 D–SNP look-alike enrollees (52,801 enrollees = 53,334 enrollees × 0.99) in the 30 non-SNP MA plans with dually eligible enrollment of 70 to 79.9 percent and 99 percent of the 92,100 D–SNP look-alike enrollees (91,179 enrollees = 92,100 enrollees × 0.99) 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 143,980 transitioning enrollees (52,801 enrollees + 91,179 enrollees), our experience with D–SNP look-alike transitions through plan year 2023 suggests that 14 percent would 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 7,392 enrollees (52,801 transitioning D–SNP look-alike enrollees * 0.14), would opt out of the new plan into which the D–SNP look-alike transitioned them. For plan year 2026, we estimate that 12,765 enrollees (91,179 transitioning D–SNP look-alike enrollees * 0.14), would 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 J7, summarizes the hour and dollar burden for added enrollments for years 2025 to 2027.

TABLE J7: BURDEN ON ENROLLEES FOR YEARS 2025-2027

Year	Number of Affected Enrollees	Time /Enrollee (hr)	Total Time (hr)	Total Cost (@ \$20.71/hr) (\$)*
2025	7,392	0.3333	2,464	51,029
2026	12,765	0.3333	4,255	88,121
2027	3,490	0.3333	1,163	24,085
Total	23,647	0.9999	7,882	163,235
Average	7,882 (23,647/3)	0.3333 (0.9999/3)	2,627 (7,882/3)	54,412 (163,235/3)

*Had we used \$29.76/hour the mean wage for occupational code 00-0000 representing all occupations, the burden would change from \$54,412 to \$78,189 an increase of \$23,777

As stated previously, we believe that in 2027 and subsequent years, 12 plans would be identified as D–SNP look-

alikes and therefore this proposed 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. The burden is summarized in Table J6. The average annual enrollee burden over 3 years is also presented in Table J6.

13. ICRs Regarding Update to the Multi-Language Insert Regulation (§§ 422.2267 and 423.2267)

The following proposed changes will be submitted to OMB for review 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 are the 15 most common non-English languages in the United States. 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.G. of this proposed rule, we are proposing to update §§ 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 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. Thus, under our proposal, MA organizations and Part D sponsors would send the Notice of Availability in English and the 15 most common non-English languages in a State instead of the current MLI in the 15 most common non-English languages nationally. This proposed policy is consistent with a proposed rule that OCR published in August 2022 (87 FR 47824). We also expect that this proposed policy would better align with the Medicaid translation requirements

at § 438.10(d)(2).²⁰³ We propose to modify 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.

We do not expect this proposed 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 the translated language for the Notice of Availability in the 15 most common non-English languages in a State or States. Also, the MA organizations and Part D sponsors are already distributing the MLI and, under this proposal, 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 would be a one-page document that would never be sent alone and therefore does not create additional postage costs.

We expect 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 proposed rule the plans under these MA organizations or Part D sponsors would need to send the Notice of Availability with translations in the 15 most common non-English languages in each State in which the plan operates. Based on plan year 2023 data, we estimate 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 estimate that these 20 parent organizations have approximately 220 MA organizations covering PBPs by State. Similarly, we estimate that the 20 Part D sponsors have approximately 50 parent organizations covering PBPs by State. We believe the parent

²⁰³ 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 proposed rule 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).

organizations would 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 expect 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 one business operations specialist working one hour to update plan policies and procedures and train staff in the first year with no additional burden in future years. For MA organizations, we estimate 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-specific languages is distributed with other communications and marketing materials. We estimate 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-specific languages is distributed with other communications and marketing materials. We estimate 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 will submit this burden to OMB for review under control number 0938–1421 (CMS–10802).

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 do not believe the burden will be greater than our estimate note previously. We welcome comment on our assumptions.

*C. Summary of Proposed Information
Collection Requirements and Associated
Burden*

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TABLE J8: 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 in Behavioral Health	0938-1346 (CMS-10636)	742	742	0.0833	62	79.50	4,929	0
423.153(f)(2)	DMP: Case Management	0938-TBD (CMS-10874)	319	(5,406)	5	(27,030)	111.16	(3,004,655)	(3,004,655)
423.153(f)(5-8)	DMP: Enrollee notification	0938-TBD (CMS-10874)	319	(6,393)	0.1667	(1,066)	38.70	(41,254)	(41,254)
423.153(f)(15)	DMP: CMS Notification	0938-TBD (CMS-10874)	319	(5,406)	0.0167	(90)	38.70	(3,483)	(3,483)
422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI, expectation of health improvement	0938-0753 (CMS-R-267)	10,000	10,000	8	80,000	85.60	6,848,000	6,848,000
422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI, Documentation	0938-0753 (CMS-R-267)	774	774	2	1,548	98.84	153,004	0
422.111 and 422.2267	Increased Utilization of Supplemental Benefits, Software Updates	0938-0753 (CMS-R-267)	774	774	4	3,096	127.82	395,731	0
422.111 and 422.2267	Increased Utilization of Supplemental Benefits, Policy Updates	0938-0753 (CMS-R-267)	774	774	1	774	79.50	61,533	0
422.111 and 422.2267	Increased Utilization of Supplemental Benefits, Mailings	0938-0753 (CMS-R-267)	774	32,000,000	Non Labor	Non Labor	Non Labor	1,355,520 (Non Labor)	1,355,520 (Non Labor)
422.137	UM Committee, update policies	0938-0964 (CMS-10141)	966	966	0.5	483	74.02	35,752	0
422.137	UM Committee, Annual Health Equity Analysis	0938-0964 (CMS-10141)	966	966	8	7,728	120.14	928,442	0
422.137	UM Committee, Website Posting	0938-0753 (CMS R 267)	966	966	0.1667	161	79.50	12,800	12,800
422.2274	Agent Broker C	0938-0753 (CMS R 267)	966	100,000	NA	NA	31	31,000,000	31,000,000

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422.116	I-SNPs	0938-1346 (CMS-10636)	10	10	0.0833	1	79.50	64	0
423.38(c)(35)	D-SNP; SEP Programmers	0938-0964 (CMS-10141)	113	113	8	904	Varies	93,709	0
422.514(h) and 422.530(c)(4)(iii)	D-SNP Combining Plans, Programmer	0938-0753 (CMS-R-267).	50	50	12	600	Varies	67,208	0
422.514(d) and (e)	D-SNP Look-Alikes, Transitioning to other MA PD, Plan Burden	0938-0753 (CMS-R-267).	25.667***	27	2	51.334	79.50	4,081	4,081
422.514(d) and (e)	D-SNP Look-Alikes, Transitioning to other MA-PD, Enrollee Burden**	0938-0753 (CMS-R-267).	7882	7,882	0.3333	2,627	20.71	54,412	54,412
422.2267 and 423.2267	Notice of Availability; Part C Update of Systems	0938-1421 (CMS-10802)	220	220	2	440	127.82	56,241	0
422.2267 and 423.2267	Notice of Availability; Part C Update of Policies	0938-1421 (CMS-10802)	220	220	2	440	79.50	34,980	0
422.2267 and 423.2267	Notice of Availability; Part D Update of Systems	0938-1421 (CMS-10802)	50	50	2	100	127.82	12,782	0
422.2267 and 423.2267	Notice of Availability; Part D Update of Policies	0938-1421 (CMS-10802)	50	50	2	100	79.50	7,950	0
Totals			32,136,318	INSERT	Varies	70,928	Varies	38,077,501	36,225,414

* Agent broker dollar burden includes both labor and non-labor components as explained in the narrative

** Had we used \$29.76/hour the mean wage for occupational code 00-0000 representing all occupations, the burden would change from \$54,412 to \$78,189 an increase of \$23,777

*** The three-place accuracy is necessary to synchronize Table J6 with Table J8. Had we rounded the annual costs would not sync.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pralisting>, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS-4205-P), the ICR's CFR citation, and the OMB control number.

XI. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this proposed 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 proposed 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 proposed 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 of a final rule. 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 proposed 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 proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review

(January 18, 2011), 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 major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). The total economic impact for this proposed rule exceeds \$200 million in several years. Therefore, based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the \$200 million or more in any one year and also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the

best of our ability presents the costs and benefits of the rulemaking.

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 proposed 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 proposed 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 proposed 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 proposed 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.

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 region-specific effects from this proposed rule.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by OMB.

C. 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 proposed in this rule. These policies

codify, modify, and update current guidance governing MA organization 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; and (3) 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*	Threshold for Small Business (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
Physician offices	621111	16
Hospitals	622	47
Skilled Nursing Facilities	623110	34

We are certifying that this proposed 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 proposed 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.

To the extent that the government's payments to plans for the bid plus the rebate exceeds costs in Traditional Medicare, those additional payments put upward pressure on the Part B premium, which is paid by all Medicare beneficiaries, including those in Traditional Medicare who do not have the additional health services available in many MA plans.

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 funding sources

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 proposed 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.

If an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees

a premium for that amount. Historically, at most 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. Since the number of plans bidding above the benchmark is 2 percent, this is not considered substantial for purposes of the RFA.

The preceding analysis only shows that MA plans, whether small or large, are not affected by this proposed rule since a significant number of them (all but at most 2 percent) will have their costs subsidized by the Government.

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;
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and
- SNFs, NAICS 623110.

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. In other words, the provisions of this proposed rule do not create a significant burden for providers.

Based on the previous discussion, the Secretary certifies that this proposed 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. However, the government additionally pays the plan an MA “beneficiary rebate” amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan’s quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also be paid by enrollee premiums to the extent that the MA rebate is not sufficient to cover those costs.) However, as 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.

It is possible that if the provisions of this proposed rule would otherwise cause MA plan bids to increase, plans will reduce their profit margins, rather than substantially change their benefit package. This may be in part due to market forces; a plan lowering supplemental benefits may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it may, in certain cases, be advantageous for a plan to reduce profit margins, rather than reduce supplemental benefits. Most likely an increase in bids would result in a combination of reduction in supplemental benefits and reduction in profit margins (not 100 percent one or the other). Part of the challenge in pinpointing the effects of an increase in bids 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 supplemental benefits.

We also note that we do not have definitive data on this. Plans do not report to CMS the strategies behind their bids. More specifically, when plans do reduce supplemental benefits, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes.

D. Anticipated Effects

Many provisions of this proposed 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 proposed 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 proposed rule in order to arrive at total impact.

1. Effects of Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

In section III.H. of this proposed rule, we discussed two proposals 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. Our proposals to improve access to MA data include the following:

- Adding “and Medicaid programs” to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii).
- 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 proposals aim to 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.H., these proposed provisions would 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. There is one area where this provision could impact the burden to CMS: CMS reviewing and fulfilling new MA encounter data requests. However, in the FY 2015 Hospital Inpatient Prospective Payment System (IPPS)/ Long-term Care Hospital Prospective Payment System (LTCH PPS) 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 proposed rule.

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.B.11 of this proposed rule. In this section, we describe the impacts of our proposed change to the dual/LIS SEP, new integrated care SEP, and contract limitations for non-integrated MA-PD plans.

These proposals would 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 proposing to 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 proposal would allow individuals to switch PDPs or leave their MA-PD plans for Traditional Medicare (with a standalone PDP) in any month. The proposed dual/LIS SEP would 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 propose a new integrated care SEP that would allow enrollment in any month into a FIDE SNP, HIDE SNP, or AIP for dually eligible individuals who meet the qualifications of such plans.

Proposed §§ 422.504(a)(20) and 422.514(h) would 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 corporate 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, that the MA organization’s D-SNPs must limit new enrollment to individuals enrolled in (or in the process of enrolling in) the D-SNP’s aligned Medicaid MCO. 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 dually eligible individuals in the same service area as that MA organization’s affiliated Medicaid MCO (with limited exceptions as described in section VIII.C. of this proposed rule). Further, beginning in plan year 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.

Full-benefit dually eligible individuals enrolled in a D-SNP that consolidate due to our proposals at §§ 422.504(a)(20) and 422.514(h) would be moved into a new plan. The impacted enrollees would 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 $1 - \text{rebate percentage}$) 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 DUALY 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 proposed 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 DUALY 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 proposed change to § 423.38(c)(4) and the proposed provision at § 423.38(c)(35) would 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 would require coding changes for the proposed amended dual/LIS SEP at § 423.38(c)(4) and proposed integrated care SEP at § 423.38(c)(35). The CMS call center 1-800-MEDICARE would need training on the proposed SEPs to be able to identify beneficiaries eligible

for the SEPs. The updates and changes would 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 would not create new burden in subsequent years.

The new provision at § 422.514(h)(3)(ii) would 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 would not create new burden for CMS since CMS would use its existing process to suppress these plans from Medicare Plan Finder.

The new provision at § 422.530(c)(4)(iii) allowing a crosswalk exception for plans consolidating their D-SNPs would 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 would 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 would cancel each other out.

3. Effects of Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2))

We do not estimate any impact on the Medicare Trust Fund as a result of the proposal to treat substitutions of biosimilar biological products other than interchangeable biological products as a maintenance change. 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. Several biosimilar biological products entered the market in 2023,²⁰⁴ but CMS has not seen a corresponding influx of non-maintenance negative change requests from Part D sponsors. 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. 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.

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 proposed 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. This would 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 data: (1) how many plans offer these supplemental benefits; (2) which supplemental benefits are not being utilized at all by some enrollees; (3) for each plan offering supplemental benefits, how many enrollees do and do not utilize these benefits; (4) how many more enrollees would utilize these benefits as a result of the notification; and (5) 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 visit 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.”²⁰⁵

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.

We solicit public comment on the economic cost and benefits of this proposal.

5. Agent Broker Compensation (§ 422.2274)

In this rule we are proposing 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 are also proposing to make conforming edits to the agent broker compensation rules at § 423.2274.

The proposed changes to the MA and Part D agent broker compensation regulations at 42 CFR 422.2274 and 423.2274 have potential economic effects on agents/brokers, plans, and Medicare beneficiaries. Since we lack the data to quantify these effects, we discuss them qualitatively. Agents and brokers may lose certain excess payments that would be prohibited under the proposed regulation; on the other hand, they would receive an increased FMV calculation for compensation per enrollment. A typical agent or broker might work on behalf of many insurance companies and their associated plans, including commercial, Medicare, Medicaid, Medigap etc. A reduction in net payment for Medicare Advantage enrollments may cause

²⁰⁴ 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>.

²⁰⁵ <https://www.cdc.gov/chronicdisease/resources/infographic/physical-activity.htm#>.

agents or brokers to reapportion their time and focus instead on other areas of the industry, resulting in decreased MA plan enrollment; however, we believe this impact would swiftly be offset by increased marketing and other adjustments made by the MA plans, as discussed below.

Another effect on agents and brokers from this provision is the requirement of uniform payment to agents and brokers and the resulting increased transparency. More specifically, agents and brokers who might have been receiving excess payments for targeting certain plans will no longer be financially incentivized to target these plans resulting in a more equitable distribution of efforts.

Plans are already spending a standard amount of \$601 per new enrollee on agents and brokers. We do not believe the increased compensations of \$31 extra (about a 5 percent increase) per agent per enrollee would have any significant financial impact on plans given the proposal to prohibit excess payments in the form of administrative payments.

On the other hand, if some agents and brokers withdraw or lower efforts for Medicare Advantage and Part D plans, resulting in possibly lower enrollment, plans may increase money allocated to outreach and advertising. Overall, we do not expect a decrease in enrollment because of the agent and broker compensation provisions since plans meticulously monitor enrollment trends and possess a variety of vehicles to counteract any significant changes. Indeed, in assessing the impact of the agent broker compensation provision it is important to emphasize that people join plans because of outreach from a wide variety of sources and therefore no single source is critical.

We solicit public comment on the economic cost and benefits of this proposal.

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 are proposing 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 are 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 QIOs to the MA plans will result in an increased burden. 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 ($8,029 \text{ hr} \times \$85.18/\text{hr}$).

We are 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.

E. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this proposed 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 proposing to lower 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 proposing the more incremental approach to minimize disruptions to dually eligible individuals and allow plans and CMS more time to operationalize these transitions.

We are considering and soliciting 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 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 solicit 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 would consider in adopting the alternative instead of

our proposal 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 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.

F. Accounting Statement and Table

As required by OMB Circular A-4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/) in Table K-4, we have prepared an accounting statement showing the costs and transfers associated with the provisions of this

proposed rule for calendar years 2025 through 2034. Table K4 is based on Tables K-5a and Table K5-b which list savings and costs by provision and year. Tables K4, K5a and K5b with costs listed as positive numbers and savings listed as positive numbers. As can be seen, the net annualized savings of this proposed rule is between \$150 and \$200 million per year. The net savings reflect a mixture of several provisions that save and cost. Minor seeming discrepancies in totals in Tables K4, K5a, and K5b reflect use of underlying spreadsheets, rather than intermediate rounded amounts. A breakdown of these costs of this proposed rule by provision may be found in Tables K5a and K5b.

TABLE K4: ACCOUNTING TABLE (\$ MILLIONS)*

Item	Annualized at 3%	Annualized at 7%	Period	Who is affected
Net Annualized Monetized Savings	176.3	155.0	CYs 2025-2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Savings	216.5	195.2	CYs 2025-2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Cost	40.2	40.2	CYs 2025-2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,

* The savings and cost are expressed with positive numbers. For example, at 3%, this proposed rule annually saves \$216.5 million but costs \$40.2 million resulting in a net savings of \$176.3 million.

The following Tables K5a and K5b summarize costs, and savings by provision and year, and forms a basis for the accounting Table K4. In Tables K5a and K5b, costs and savings are expressed as positive numbers (except in the row with header “Aggregate savings” where positive numbers reflect

savings and negative numbers reflect cost). The provisions increasing enrollment for D-SNPs Part C and Part D—effect the Medicare Trust Fund. In these rows, positive numbers reflect reduced dollar spending to the Trust Fund, that is savings. The savings (and costs) in these tables are true costs and

savings reflecting increases or decreases in consumption of services and goods. Tables K5a and K5b combine related provisions. For example, all provisions related to the utilization management committee in the COI summary table are combined into one-line item in the RIA.

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TABLE K5a: SAVINGS AND COSTS (millions \$) BY PROVISION AND YEAR (YEARS 2025 – 2029) *

	2025 Savings	2025 Costs	2025 Transfers	2026 Savings	2026 Costs	2026 Transfers	2027 Savings	2027 Costs	2028 Savings	2028 Costs	2029 Savings	2029 Costs
Total Savings	3.0			3.0			15.6		27.9		40.0	
Total Costs		41.8			39.9			39.9		39.9		39.9
Aggregate Total	(38.7)			(36.9)			(24.3)		(12.0)		0.0	
Savings of the Medicare Trust Fund												
Increased enrollment in D-SNPs, Part C							5.5		10.9		15.9	
Increased enrollment in D-SNPs, Part D							7.0		13.9		21.1	
Increased enrollment in D-SNPs, Paperwork		0.2			-			-		-		-
DMP	3.0			3.0			3.0		3.0		3.0	
SSBCI		7.0			6.8			6.8		6.8		6.8
Increased Utilization of Supplementary Benefits		1.8			1.4			1.4		1.4		1.4
UM Committee		0.9										
Enhanced Appeal Rights		0.7			0.7			0.7		0.7		0.7
Agent Broker		31.0			31.0			31.0		31.0		31.0
D-SNP Look-Alikes		0.1			0.1			0.1		0.1		0.1
Notice of Availability		0.1										

*Table K5a is continued in Table K5b.

TABLE K5b: SAVINGS AND COSTS (millions \$) BY PROVISION AND YEAR (YEARS 2030 – 2034)*

	2030 Savings	2030 Costs	2031 Savings	2031 Costs	2032 Savings	2032 Costs	2033 Savings	2033 Costs	2034 Savings	2034 Costs	Raw 10-Year Totals
Total Savings	408.7		423.4		442.5		472.4		496.3		2,329.80
Total Costs		39.9		39.9		39.9		39.9		39.9	401.3
Aggregate Total	368.7		383.5		402.5		432.5		456.3		1,931.6
Savings of the Medicare Trust Fund											-
Increased Enrollment in D-SNPs, 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		1,340.9
Increased Enrollment in D-SNPs, Paperwork		-		-		-		-		-	0.2
DMP	3.0		3.0		3.0		3.0		3.0		30.5
SSBCI		6.8		6.8		6.8		6.8		6.8	68.6
Increased Utilization of Supplementary Benefits		1.4		1.4		1.4		1.4		1.4	14.0
UM Committee											0.9
Enhanced Appeal Rights		0.7		0.7		0.7		0.7		0.7	6.8
Agent Broker		31.0		31.0		31.0		31.0		31.0	310.0
D-SNP Look-Alikes		0.1		0.1		0.1		0.1		0.1	0.6
Notice of Availability											0.1

*Continued from Table K5a.

NOTES:

1. Except for the row with "aggregate total", positive numbers in the cost columns reflect costs while positive numbers in the savings column reflect savings. The aggregate column subtracts the costs from the savings and therefore lists the difference as a negative number when the aggregate effect is a cost and as a positive when it is a savings.
2. Two of the 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.
3. When the aggregate of line items for a provision is below \$50,000, for example the paperwork burden of \$4,929 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.

G. Conclusion

In aggregate this proposed rule saves significantly. Two provisions reduce spending by the Medicare Trust Fund: (1) the effect on Part C plans from the provisions designed to increase enrollment D-SNPs; and (2) the effect on Part D plans from these D-SNP provisions. Over a 10-year period they reduce spending of the Medicare Trust Fund of \$28, \$961, and \$1,341 million respectively. The provisions for the Drug Management Program should reduce paperwork burden by \$3 million annually saving \$30 million over 10 years. The agent broker provision is expected to cost \$31 million and \$310 million over 10 years.

XII. Response to Comments

Because of the large number of public comments that we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document. In accordance with requirements this major rule has been reviewed by OMB.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 24, 2023.

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, 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), Incorporation by reference, 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.

45 CFR Part 170

Computer technology, Health, Health care, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Public health, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV and the Department of Health and Human Services proposes to amend 45 CFR part 170 as set forth below:

Title 42

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.

Subpart L—Medicare Contract Requirements

■ 2. 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), 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

■ 3. 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.

■ 4. Section 422.2 is amended by revising the definition of “Basic benefits” to 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.

* * * * *

- 5. Section 422.52 is amended by:
 - a. Revising paragraph (b)(2);
 - b. Redesignating paragraph (f) as paragraph (f) introductory text; and
 - c. Adding paragraph (f)(1) and reserved paragraph (f)(2).

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) * * *
 (1) For enrollments into a SNP that exclusively enrolls individuals that have severe or disabling chronic conditions (C-SNP), the organization must contact the applicant’s current physician 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 physician or physician’s office and obtain verification of the condition(s) prior to enrollment in a form and manner authorized by CMS from the applicant’s primary care provider or specialist treating the qualifying condition(s).

(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 in paragraphs (f)(1)(i)(A)(1) through (4) of this section:

(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 be signed by a physician 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 using medical information (medical history, current signs or symptoms, diagnostic testing, and current medications) provided by the enrollee's primary care physician or the specialist treating the chronic condition.

(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) To complete the PQAT, the C-SNP is required to have the individual's current physician (primary care physician or specialist treating the qualifying condition) or a physician employed or contracted by the plan 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. The enrollee's physician must sign the completed PQAT.

(2) [Reserved]

■ 6. Section 422.60 is amended by revising paragraph (a)(1) and adding paragraphs (a)(3) and (h) to 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 (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) *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.

■ 7. Section 422.62 is amended by revising paragraphs (a)(1)(i) and (a)(4) to 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.

* * * * *

■ 8. 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.

■ 9. 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, a 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 that 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.

- 10. Section 422.102 is amended by:
 - a. Revising paragraph (f)(1)(i)(A)(2);
 - b. Redesignating paragraph (f)(3) as paragraph (f)(4);
 - c. Adding a new paragraph (f)(3);
 - d. Revising newly redesignated paragraph (f)(4) introductory text and (f)(4)(iii) and (iv); and
 - e. Adding paragraph (f)(5).

The additions and revision 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 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.

(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:

* * * * *

(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 section and the objective criteria on which the written policies are based.

(iv) Document each determination that an enrollee is not eligible to receive an SSBCI and make this information available to CMS upon request.

(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 subpart F of this

part nor does it limit CMS's authority to review plan benefits and bids for compliance with all applicable requirements.

■ 11. Section 422.111 is amended by adding paragraph (l) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(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).

■ 12. Section 422.116 is amended by:

- a. Adding paragraph (b)(2)(xiv);
- b. In table 1 to paragraph (d)(2), adding an entry for "Outpatient Behavioral Health" following the entry for "Orthopedic Surgery";
- c. Adding paragraph (d)(5)(xv);
- d. Revising paragraph (f)(1) introductory text; and
- e. Adding paragraphs (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(l) of the Act), Mental Health Counselors (as defined in section 1861(m) of the Act), Opioid Treatment Programs (as defined in section 1861(j) 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.

* * * * *

(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

* * * * *

(d) * * *

(5) * * *

(xv) Outpatient Behavioral Health, described in paragraph (b)(2)(xiv) of this section.

* * * * *

(f) * * *

(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 (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; or

(ii)(A) A facility-based Institutional-Special Needs Plan (I-SNP) is unable to contract with certain specialty types required under paragraph (b) of this section 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.

■ 13. Section 422.125 is added to read as follows:

§ 422.125 Resolution of complaints in 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.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the MA organization must contact the individual who filed a complaint within 3 calendar days of the assignment date.

■ 14. Section 422.137 is amended by adding paragraphs (c)(5) and (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, 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.

(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) 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.

(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:

(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.

■ 15. Section 422.164 is amended by:

■ a. Revising paragraphs (g)(1)(iii) introductory text and (g)(1)(iii)(A);

■ b. Removing and reserving paragraphs (g)(1)(iii)(B) and (F);

■ c. Revising paragraph (g)(1)(iii)(H);

■ d. Removing and reserving paragraphs (g)(1)(iii)(I) and (J);

■ e. Revising paragraphs (g)(1)(iii)(K)(2) and (g)(1)(iii)(O); and

■ f. Adding paragraph (h)(3).

The revisions and addition read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(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 (H) and (K) through (O) of this section is applied.

* * * * *

(H) The Part C calculated error is determined using 1 minus the quotient of the total number of cases received by the IRE 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.

* * * * *

(K) * * *

(2) The number of cases not forwarded to the IRE is at least 10 for the measurement year.

* * * * *

(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.

* * * * *

(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.

* * * * *

■ 16. Section 422.166 is amended by revising paragraph (f)(2)(i)(B) and adding paragraphs (f)(3)(viii)(A) and (B) to read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(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

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.

* * * * *

■ 17. Section 422.260 is amended by revising paragraph (c)(2)(vii) to read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

* * * * *

(c) * * *
(2) * * *

(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.

* * * * *

■ 18. Section 422.310 is amended by:
■ a. Revising paragraphs (f)(1)(vi) and (vii);
■ b. Adding reserved paragraph (f)(3)(iv); and
■ c. Adding 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) * * *
(iv) [Reserved]

(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.

* * * * *

■ 19. Section 422.311 is amended by:
■ a. Revising paragraphs (a) and (c)(5)(ii)(B);
■ b. Removing paragraph (c)(5)(ii)(C);
■ c. Revising paragraph (c)(5)(iii);
■ d. Adding paragraph (c)(5)(iv);
■ e. Revising paragraphs (c)(6)(i)(A) and (c)(6)(iv)(B);
■ f. Adding paragraph (c)(6)(v);
■ g. Revising paragraph (c)(7)(ix);
■ h. Revising paragraphs (c)(8)(iii), (c)(8)(iv) introductory text, (c)(8)(iv)(A), and (c)(8)(vi); and
■ i. 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 paragraph (c)(7)(x) of this section.

* * * * *

(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.

■ 20. Section 422.502 is amended by:

■ a. Revising paragraphs (b)(1)(i)(A) through (C); and

■ b. Removing paragraphs (b)(1)(i)(E)(2)(A) and (B).

The revisions read as follows.

§ 422.502 Evaluation and determination procedures.

* * * * *

(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.

* * * * *

■ 21. 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).

* * * * *

■ 22. Section 422.504 is amended by revising paragraph (a)(15) and adding paragraphs (a)(20) and (21) to read as follows.

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) As described in § 422.125, 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 ISNPs to contracts described in § 422.116(f)(3).

* * * * *

■ 23. Section 422.510 is amended by adding paragraph (e) to read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(e) *Intermediate sanctions imposed with CMS termination.* If CMS makes a determination to terminate a MA organization's contract under paragraph (a) of this section, 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.

■ 24. 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 of this chapter) that enrolls dually eligible individuals as defined in § 423.772 of this chapter, 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 dually 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 enroll) 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 with the MA organization limits enrollment for certain groups into D–SNPs (such as by age group or other criteria), 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 dually 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 of this chapter.

(ii) If the MA organization, its parent organization or an entity that shares a parent organization with the MA organization offers more than one D–SNP of any type (HMOs and/or PPOs), and one or more of the plans is subject to paragraph (h)(1) of this section, the plan (or plans) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dually eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

■ 25. 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 doctor-patient relationship, information with respect to the following:

(2) The procedures related to and utilization of its services and items.
* * * * *

■ 26. 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.
* * * * *

■ 27. 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.
* * * * *

■ 27. Section 422.584 is amended by revising the paragraph (b) heading and adding paragraphs (b) introductory text and (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.
* * * * *

■ 28. Section 422.626 is amended by:

- a. Revising paragraph (a)(2); and
■ b. Removing paragraph (a)(3).

The revision reads 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.

* * * * *

■ 29. 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.

* * * * *

■ 30. Section 422.2267 is amended by:

- a. Revising paragraph (e)(31) and paragraph (e)(34) introductory text;
- b. Redesignating paragraph (e)(34)(iii) as paragraph (e)(34)(v);
- c. Redesignating paragraph (e)(34)(ii) as paragraph (e)(34)(iii);
- d. Adding a new paragraph (e)(34)(ii);
- e. Revising newly redesignated paragraph (e)(34)(iii);
- f. Adding paragraph (e)(34)(iv);
- g. Revising newly redesignated paragraph (e)(34)(v); and
- h. 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).* 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.

(i) 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 and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(ii) 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.

(iii) The notice must be provided with all required materials under this paragraph (e).

(iv) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(v) When used as a standalone material, the notice may include organization name and logo.

(vi) When mailing multiple required materials together, only one notice is required.

(vii) 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 (e)(34)(i) through (iii) of this section. MA organizations must—

* * * * *

(ii) List the chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the MA organization.

(A) If the number of condition(s) is five or fewer, then list all condition(s).

(B) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization.

(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 MA organization’s coverage criteria for a

specific SSBCI item or service 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 supplemental benefit 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) *Additional notice information.* 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.
- (5) Supplemental benefits listed consistent with the format of the EOC.
- (6) A customer service number, and required TTY number, to call for additional help.

■ 31. Section 422.2274 is amended by:

- a. In paragraph (a)—
- i. Revising paragraph (i) of the definition of “Compensation”; and
- ii. Revising the definition of “Fair market value (FMV)”; and
- b. Revising paragraphs (c)(5), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, and (e)(1) and (2).

The revisions 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) Payment of fees to comply with State appointment laws, training, certification, and testing costs.
- (F) Reimbursement for mileage to, and from, appointments with beneficiaries.
- (G) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.
- (H) 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.

(i) 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.

(ii) Beginning in 2025, the FMV will be increased to account for administrative payments included under the compensation rate, beginning at \$31 and updated annually in compliance with this section.

(iii) For subsequent years, FMV is calculated by adding the current year FMV and the produce 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 in accordance with § 422.312.

* * * * *

(c) * * *

(5) 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) 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, MA organizations may pay compensation at FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year, MA plans may pay compensation at a rate of 50 percent of FMV.

* * * * *

(e) * * *

(1) For plan years through 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 in 2025, administrative payments are included in the calculation of enrollment-based compensation.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 32. 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.

■ 33. Section 423.4 is amended by adding definitions for “Biosimilar biological product” and “Interchangeable biological product” in alphabetical order to read as follows:

§ 423.4 Definitions.

* * * * *

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.

* * * * *

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)).

* * * * *

■ 34. Section 423.32 is amended by adding paragraph (h) to read as follows:

§ 423.32 Enrollment process.

* * * * *

(h) *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.

■ 34. Section 423.38 is amended by:

- a. Revising paragraph (c)(4)(i);
- b. Redesignating paragraph (c)(35) as paragraph (c)(36); and
- c. Adding new paragraph (c)(35).

The revision and addition read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(4) * * *

(i) Except as provided in paragraph (c)(4)(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.

* * * * *

(35) The individual is 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, or an applicable integrated plan as defined in § 422.561 of this chapter.

* * * * *

■ 35. 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.

■ 36. Section 423.100 is amended by:

■ a. Adding in alphabetical order a definition for "Corresponding drug";

■ b. Revising paragraph (3) of the definition of "Exempted beneficiary"; and

■ c. Adding in alphabetical order a definition for "Maintenance change".

The additions and revision read as follows:

§ 423.100 Definitions.

* * * * *

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 * * *

(3) Is being treated for cancer-related pain; or

* * * * *

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 deemed unsafe by FDA or withdrawn from sale by the manufacturer 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.

* * * * *

■ 37. Section 423.120 (as proposed to be amended at 87 FR 79727, December 27, 2022) is amended by revising paragraph (e)(2)(i) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(e) * * *

(2) * * *

(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.

* * * * *

■ 38. 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 section, 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 complaints.* 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.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the Part D sponsor must contact the individual who filed a complaint within 3 calendar days of the assignment date.

■ 39. Section 423.153 is amended by: ■ a. Removing the phrase "paragraph (f)(8)(ii)" and adding in its place

“paragraphs (f)(8)(ii) and (iii)” in paragraph (f)(8)(i) introductory text;

- b. Revising paragraph (f)(8)(i)(A);
- c. Redesignating paragraph (f)(8)(ii) as paragraph (f)(8)(iii); and
- d. Adding a new paragraph (f)(8)(ii).

The revision and addition 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.

* * * * *

(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.

* * * * *

■ 40. Section 423.160 is amended by:

- a. Revising paragraphs (a)(2) and (3), (b), and (c); and

- b. Removing the section-level authority citation.

The revisions read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media (including entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider, such as a nursing facility, that in turn forwards the prescription to a dispenser), must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3)(i) Entities transmitting prescriptions or prescription-related information must utilize the NCPDP SCRIPT standard, consistent with paragraph (b)(1) of this section, in all instances other than temporary/transient network transmission failures.

(ii) Electronic transmission of prescriptions or prescription-related

information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communication problems that would preclude the use of the NCPDP SCRIPT Standard adopted by this section.

(iii) Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

* * * * *

(b) *Standards*—(1) *Prescriptions, electronic prior authorization, and medication history.* The communication of a prescription or prescription-related information must comply with a standard in 45 CFR 170.205(b) (incorporated by reference, *see* paragraph (c) of this section) for the following transactions, as applicable to the version of the standard in use:

- (i)(A) GetMessage.
- (B) Status.
- (C) Error.
- (D) RxChangeRequest and RxChangeResponse.
- (E) RxRenewalRequest and RxRenewalResponse.
- (F) Resupply.
- (G) Verify.
- (H) CancelRx and CancelRxResponse.
- (I) RxFill.
- (J) DrugAdministration.
- (K) NewRxRequest.
- (L) NewRx.
- (M) NewRxResponseDenied.
- (N) RxTransferInitiationRequest.
- (O) RxTransfer.
- (P) RxTransferConfirm.
- (Q) RxFillIndicatorChange.
- (R) Recertification.
- (S) REMSInitiationRequest and REMSInitiationResponse.
- (T) REMSRequest and REMSResponse.
- (U) RxHistoryRequest and RxHistoryResponse.
- (V) PAInitiationRequest and PAInitiationResponse.
- (W) PARRequest and PARResponse.

(X) PAAppealRequest and PAAppealResponse.

(Y) PACancelRequest and PACancelResponse.

(Z) PANotification.

(ii) [Reserved]

(2) *Eligibility.* Eligibility inquiries and responses between the Part D sponsor and prescribers and between the Part D sponsor and dispensers must comply with 45 CFR 162.1202.

(3) *Formulary and benefits.* The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), April 2012 (incorporated by reference, *see* paragraph (c) of this section) or comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors. Beginning January 1, 2027, transmission of formulary and benefit information between prescribers and Medicare Part D sponsors must comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section).

(4) *Provider identifier.* The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(5) *Real-time benefit tools.* Part D sponsors must implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Beginning January 1, 2027, Part D sponsors' RTBT must comply with a standard in 45 CFR 170.205(c) (incorporated by reference, *see* paragraph (c) of this section).

(c) *Incorporation by reference.* The material listed in this paragraph (c) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C.

552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Centers for Medicare & Medicaid Services (CMS) and at the National Archives and Records Administration (NARA). Contact CMS at: CMS 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786-4132 or (877) 267-2323; email: *PartDPolicy@cms.hhs.gov*. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*. The material may be obtained from National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; phone: (480) 477-1000; email: *info@ncdpdp.org*; website: *www.ncdpdp.org*.

(1) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published April 2012.

(2) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017.

(3) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2023011, published April 2023, (Approval Date for American National Standards Institute [ANSI]: January 17, 2023).

(4) National Council for Prescription Drug Programs Real-Time Prescription Benefit Standard, Implementation Guide Version 13, published July 2023 (Approval Date for ANSI: May 19, 2022).

(5) National Council for Prescription Drug Programs Formulary and Benefit Standard, Implementation Guide Version 60, published April 2023 (Approval Date for ANSI: April 12, 2023).

■ 40. Section 423.184 is amended by:
■ a. Removing and reserving paragraph (g)(1)(ii); and

■ b. Adding paragraph (h)(3).

The addition reads as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(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.

* * * * *

■ 41. Section 423.186 is amended by revising paragraph (f)(2)(i)(B) and

adding paragraphs (f)(3)(viii)(A) and (B) to read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(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 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.

* * * * *

■ 42. Section 423.503 is amended by revising paragraph (b)(1)(i)(A) and (C) to read as follows:

§ 423.503 Evaluation and determination procedures.

* * * * *

(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.

* * * * *

■ 43. Section 423.505 is amended by revising paragraph (b)(22) 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.

* * * * *

■ 44. Section 423.509 is amended by adding paragraph (f) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *

(f) *Intermediate sanctions imposed with CMS termination.* If CMS makes a determination to terminate a Part D sponsor's contract under paragraph (a) of this section, 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.

■ 45. 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.

* * * * *

46. 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.

* * * * *

47. Section 423.584 is amended by revising the paragraph (b) heading and adding paragraphs (b) introductory text and (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.

* * * * *

■ 48. 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.

* * * * *

■ 49. 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). This is a model communications material through which Part D sponsors must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the Part D sponsor provides language assistance services and appropriate auxiliary aids and services free of charge.

(i) 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 and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(ii) 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. Part D sponsors may also opt to translate the notice in any additional languages that do not meet the 5-percent service area threshold, where the Part D sponsor determines that this inclusion would be appropriate.

(iii) The notice must be provided with all required materials under this paragraph (e).

(iv) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(v) When used as a standalone material, the notice may include organization name and logo.

(vi) When mailing multiple required materials together, only one notice is required.

(vii) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

■ 50. Section 423.2274 is amended by:

- a. In paragraph (a):
■ i. Revising paragraph (i) of the definition of "Compensation"; and
■ ii. Revising the definition of "Fair market value (FMV)"; and
■ b. Revising paragraphs (c)(5), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, and (e)(1) and (2).

The revisions 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) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(F) Reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) 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.

(i) Beginning January 1, 2021, the national FMV is 81.

(ii) Beginning in 2025, the FMV will be increased to account for administrative payments included under the compensation rate, beginning at \$31 and updated annually in compliance with this section.

(iii) 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 of this chapter.

* * * * *

(c) * * *

(5) 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) 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, Part D sponsors may pay compensation at FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year, Part D sponsors may pay compensation at a rate of 50 percent of FMV.

* * * * *

(e) * * *

(1) For plan years through 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 in 2025, administrative payments are included in the calculation of enrollment-based compensation.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 51. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f).

■ 52. 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 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 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.

■ 53. 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.

* * * * *

■ 54. Section 460.194 is amended by revising paragraph (b) to read as follows:

§ 460.194 Corrective action.

* * * * *

(b) At their discretion, CMS or the State administering agency may monitor the effectiveness of corrective actions.

* * * * *

Title 45

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 55. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj-11; 42 U.S.C. 300jj-14; 5 U.S.C. 552.

■ 56. Section 170.205 is amended by:

- a. Revising paragraph (b);
- b. Adding paragraph (c);
- c. Adding a reserved paragraph (t); and
- d. Adding paragraph (u).

The revision and additions read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(b) *Electronic prescribing—(1) Standard.* National Council for Prescription Drug Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071 (incorporated by reference in § 170.299). The Secretary's adoption of this standard expires on January 1, 2027.

(2) *Standard.* NCPDP SCRIPT Standard, Implementation Guide, Version 2023011 (incorporated by reference in § 170.299).

(c) *Real-time prescription benefit—(1) Standard.* NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13 (incorporated by reference in § 170.299).

(2) [Reserved]

* * * * *

(t) [Reserved]

(u) *Formulary and benefit—(1) Standard.* NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60 (incorporated by reference in § 170.299).

(2) [Reserved]

■ 57. Section 170.299 is amended by revising paragraph (k) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(k) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; phone (480) 477-1000;

email: *info@ncdpd.org*; website: *www.ncdpd.org*.

(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071 (Approval Date for ANSI: July 28, 2017); IBR approved for § 170.205(b).

(2) NCPDP SCRIPT Standard, Implementation Guide, Version 2023011, April 2023, (Approval Date for

ANSI: January 17, 2023); IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, July 2023 (Approval Date for ANSI: May 19, 2022); IBR approved for § 170.205(c).

(4) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60, April 2023 (Approval Date

for ANSI: April 12, 2023); IBR approved for § 170.205(u).

* * * * *

Xavier Becerra

Secretary, Department of Health and Human Services.

[FR Doc. 2023-24118 Filed 11-6-23; 4:15 pm]

BILLING CODE 4120-01-P