0-01-P]

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-4201-P]

RIN 0938-AU96

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology, 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, medication therapy management, marketing and communications, health equity, provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, identification of overpayments, formulary changes, and other programmatic areas. This proposed rule would also codify regulations implementing section 118 of Division CC of the Consolidated Appropriations Act, 2021, section 11404 of the Inflation Reduction Act, and includes a large number of provisions that would codify existing sub-regulatory guidance in the Part C, Part D, and PACE

programs. This proposed rule would also amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an identified overpayment.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 13, 2023.

ADDRESSES: In commenting, please refer to file code CMS-4201-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

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

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4201-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-4201-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:

Catherine Gardiner, (410) 786-7638 – General Questions.

Katie Parker, (410) 786-0537 – Parts A and B Overpayment Provision

Carly Medosch, (410) 786-8633 – Part C and Cost Plan Issues.

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

Nathan Jessen, (608) 520-1837 – Part D Issues.

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

Kelley Ordonio, (410) 786-3453 – Parts C and D Payment Issues; Parts C and D Overpayment Provisions.

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

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

Melissa Seeley, (212) 616-2329 – D-SNP 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 Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

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

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C), Medicare Cost Plan, and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). This proposed rule includes a number of new policies that would improve these programs as well as codify existing Part C and Part D sub-regulatory guidance. This proposed rule would also amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an identified overpayment.

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

- The Inflation Reduction Act (IRA) of 2022.
- The Consolidated Appropriations Act (CAA), 2021.
- The Bipartisan Budget Act (BBA) of 2018.
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018.

B. Summary of the Major Provisions

1. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

In this rule, we are proposing a health equity index (HEI) reward for the 2027 Star Ratings to further incentivize Parts C and D plans to focus on improving care for enrollees with social risk factors (SRFs); as part of this change, we are also proposing to remove the current reward factor. This proposal supports CMS efforts to ensure attainment of the highest level of health for all people. We are proposing to reduce the weight of patient experience/complaints and access measures to further align efforts with other CMS quality programs and the current CMS Quality Strategy, as well as to better balance the contribution of the different types of measures in the Star Ratings program. We are also proposing to remove the Part C Diabetes Care – Kidney Disease Monitoring and the stand-alone Medication Reconciliation Post-

discharge measures; add the Part C Kidney Health Evaluation for Patients with Diabetes and the updated Colorectal Cancer Screening and Care for Older Adults – Functional Status Assessment measures; add the Part D Concurrent Use of Opioids and Benzodiazepines, Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measures; and update the Part D Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. We are proposing to remove guardrails (that is, bi-directional caps that restrict upward and downward movement of a measure's cut points for the current year's measure-level Star Ratings compared to the prior year's measure-threshold specific cut points) when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures; modify the Improvement Measure hold harmless policy; add a rule for the removal of Star Ratings measures; and remove the 60 percent rule that is part of the adjustment for extreme and uncontrollable circumstances (also called the disaster adjustment). We are also proposing a series of technical clarifications related to the disaster adjustment, Quality Bonus Payment (QBP) appeals processes, treatment of ratings for contracts after consolidation, weighting of measures with a substantive specification change, and addressing the codification error related to use of Tukey outlier deletion. These changes would apply (that is, data would be collected and performance measured) for the 2024 measurement period and the 2026 Star Ratings, except for the removal of the Part C Diabetes Care – Kidney Disease Monitoring measure, which would apply for the 2022 measurement period and the 2024 Star Ratings; the HEI reward, which would include data from the 2024 and 2025 measurement periods and apply for the 2027 Star Ratings; and the risk adjustment based on sociodemographic status characteristics to the three adherence measures, which would be implemented for the 2026 measurement period and the 2028 Star Ratings.

2. Medication Therapy Management (MTM) Program (§ 423.153)

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).

Part D sponsors currently have significant flexibility in establishing their MTM eligibility criteria within the established framework. CMS has observed decreasing eligibility rates and near-universal convergence among Part D sponsors to the most restrictive criteria currently permitted. Due to the increasing cost threshold and variations in the targeting criteria implemented by sponsors, Part D enrollees with more complex drug regimens who would benefit most from MTM services are often not eligible. In addition, enrollees with equivalent patient profiles may or may not be eligible for MTM depending on the criteria their plan requires.

After an extensive analysis to identify potential disparities in MTM program eligibility and access, CMS is proposing changes to the MTM targeting criteria at § 423.153(d)(2) to promote consistent, equitable, and expanded access to MTM services. The combination of proposed changes includes: (1) requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current 9 core chronic diseases[1] 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

[1]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 (*).

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). The proposed changes would reduce eligibility gaps so that more Part D enrollees with complex drug regimens at increased risk of medication therapy problems would be eligible for MTM services. They would also better align MTM eligibility criteria with statutory goals to reduce medication errors and optimize therapeutic outcomes for beneficiaries with multiple chronic conditions and taking multiple Part D drugs, while maintaining a reasonable cost criterion.

In this rule, we are also proposing to codify longstanding CMS guidance that a beneficiary is unable to accept an offer to participate in the comprehensive medication review (CMR) only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. We are also proposing other technical changes to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth.

3. Strengthening Translation and Accessible Format Requirements for Medicare Advantage, Part D, and D-SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267)

Sections §§ 422.2267(a)(2) and 423.2267(a)(2) require MA organizations, cost plans, and Part D sponsors to translate required materials into any non-English language that is the primary language of at least 5 percent of individuals in a plan benefit package service area. In addition, 45 CFR 92.102(b) requires plans to provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. However, CMS has learned from oversight activities, enrollee complaints, and stakeholder feedback that enrollees often must make a separate request each time they would like a material in an alternate language or need auxiliary aids or services.

In addition, an increasing number of dually eligible individuals are enrolled in managed care plans where the same plan covers both Medicare and Medicaid services. In some cases, Medicaid standards for Medicaid managed care plans require translation of plan materials into a language not captured by the Medicare Advantage requirements.

We are proposing to specify in Medicare regulations that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a *standing basis* in any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area or accessible format using auxiliary aids and services upon receiving a request for the materials or otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services. We are also proposing at §§ 422.2267(a)(3) and 423.2267(a)(3) to extend this requirement to individualized plans of care for special needs plans. We are also proposing to require that fully integrated dual eligible special needs plans (FIDE SNPs), highly integrated dual eligible special needs plans (HIDE SNPs), and applicable integrated plans (AIPs) as defined at § 422.561, translate required materials into any languages required by the Medicare translation standard at § 422.2267(a) plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

4. Health Equity in Medicare Advantage (MA) (§§ 422.111 and 422.112)

CMS is 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.[2] To that end, we are proposing the following regulatory updates.

First, current regulations require MA organizations to ensure that services are provided in a culturally competent manner. The regulation provides examples of populations that may

[2]https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/

require consideration specific to their needs. In this proposed rule, we propose to further clarify the broad application of our policy. Specifically, we propose to amend the list of populations to include people: (1) with limited English proficiency or reading skills; (2) of ethnic, cultural, racial, or religious minorities; (3) with disabilities; (4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (6) who live in rural areas and other areas with high levels of deprivation; and (7) otherwise adversely affected by persistent poverty or inequality.

Next, CMS currently provides best practices for organizations to use in developing their provider directories, including incorporating non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. In this rule, we propose to codify these best practices by requiring organizations to include providers' cultural and linguistic capabilities (including American Sign Language, ASL) in their provider directories. If finalized, this change would improve the quality and usability of provider directories, particularly for non-English speakers, limited English proficient individuals, and enrollees who use ASL. We are also proposing to require organizations to identify certain providers waived to treat patients with medications for opioid use disorder (MOUD) in their provider directories.

In addition, as the use of telehealth becomes more prevalent, there is evidence of disparities in telehealth access due in part to low digital health literacy, especially among populations who already experience health disparities. Low digital health literacy is one of the most significant obstacles in achieving telehealth equity, and many older adults with low digital health literacy experience gaps in access to the health care they need. This is concerning for the MA program because its enrollee population includes older adults who are age 65 or older, which is why we are proposing to address the issue by requiring MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low

digital health literacy to assist with accessing any medically necessary covered telehealth benefits.

Finally, MA organizations' existing quality improvement (QI) programs are an optimal vehicle to develop and implement strategies and policies designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved. To support these efforts, we propose to require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees. MA organizations may implement activities such as improving communication, developing and using linguistically and culturally appropriate materials (to distribute to enrollees or use in communicating with enrollees), hiring bilingual staff, community outreach, or similar activities. We believe adopting this proposed requirement for MA organizations as part of their required QI programs will align with health equity efforts across CMS policies and programs.

5. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, 422.138, and 422.202).

In recent years, CMS has received numerous inquiries regarding MA organizations' use of prior authorization and its effect on beneficiary access to care. We are proposing several regulatory changes to address these concerns regarding prior authorization. First, we propose that prior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary based on standards specified in this rule. Second, we propose that an approval granted through prior authorization processes be valid for the duration of the approved course of treatment and that plans provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA plan. Third, we propose that MA plans

must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations as interpreted by CMS. Further, we propose that MA plans cannot deny coverage of a Medicare covered item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. We propose that when there is no applicable coverage criteria in Medicare statute, regulation, NCD, or LCD, MA organizations may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available to CMS, enrollees, and providers.

Finally, to ensure prior authorization is being used appropriately, we propose to require that all MA plans establish a Utilization Management Committee to review all utilization management, including prior authorization, policies annually and ensure they are consistent with current, traditional Medicare's national and local coverage decisions and guidelines. These proposed changes will help ensure enrollees have consistent access to medically necessary care, without unreasonable barriers or interruptions.

6. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

In accordance with our statutory authority to review marketing materials and application forms and to develop marketing standards under sections 1851(h), 1851(j), 1860D-1(b)(1)(vi), and 1860D-4(l) of the Act, as well as the statutory requirements in sections 1852(c) and 1860D-4(a) of the Act requiring MA organizations and Part D sponsors disclose specific types of information to enrollees, we are proposing several changes to 42 CFR parts 422 and 423, subpart V, to strengthen beneficiary protections and improve MA and Part D marketing. These changes include: notifying enrollees annually, in writing, of the ability to opt out of phone calls regarding MA and Part D plan business; requiring agents to explain the effect of an enrollee's enrollment choice on their current coverage whenever the enrollee makes an enrollment decision; requiring agents to share key pre-enrollment information with potential

enrollees when processing telephonic enrollments; simplifying plan comparisons by requiring medical benefits be in a specific order and listed at the top of a plan's Summary of Benefits; limiting the time that a sales agent can call a potential enrollee to no more than six months following the date that the enrollee first asked for information; limiting the requirement to record calls between third-party marketing organizations (TPMOs) and beneficiaries to marketing (sales) and enrollment calls; clarifying that the prohibition on door-to-door contact without a prior appointment still applies after collection of a business reply card (BRC) or scope of appointment (SOA); prohibiting marketing of benefits in a service area where those benefits are not available, prohibiting the marketing of information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell; requiring MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS; modifying the TPMO disclaimer to add SHIPs as an option for beneficiaries to obtain additional help; placing discrete limits around the use of the Medicare name, logo, and Medicare card; prohibit the use of superlatives (for example, words like "best" or "most") in marketing unless the material provides documentation to support the statement, and the documentation is for the current or prior year; and, clarifying the requirement to record calls between TPMOs and beneficiaries, such that it is clear that the requirement includes virtual connections such as video conferencing and other virtual telepresence methods.

7. Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116)

As part of the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule, which appeared in the January 12, 2022 **Federal Register** (87 FR 1842) (hereinafter referred to as the January 2022 proposed rule), we solicited comments from stakeholders regarding

challenges in building MA behavioral health networks and opportunities for improving access to services. 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.

To strengthen our network adequacy requirements and reaffirm MA organizations' responsibilities to provide behavioral health services, we propose to: (1) add Clinical Psychology Licensed Clinical Social Worker, and Prescribers of Medication for Opioid Use Disorder as specialty types that will be evaluated as part of the network adequacy reviews under § 422.116, and make these new specialty types eligible for the 10-percentage point telehealth credit as allowed under § 422.116(d)(5); (2) amend our general access to services standards in § 422.112 to include explicitly behavioral health services; (3) codify, from existing guidance on reasonable wait times for primary care visits, standards for wait times that apply to both primary care and behavioral health services; (4) clarify that some behavioral health services may qualify as emergency services and, therefore, must not be subject to prior authorization; and (5) extend current requirements for MA organizations to establish programs to coordinate covered services with community and social services to behavioral health services programs to close equity gaps in treatment between physical health and behavioral health.

8. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

CMS requires notification to MA enrollees when a provider network participation contract terminates. CMS is proposing to revise § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also proposing to revise § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

9. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries through the Limited Income Newly Eligible Transition (LI NET) Program (§§ 423.2500-423.2536)

CMS has operated the LI NET demonstration since 2010. The LI NET demonstration provides transitional, point-of-sale coverage for low-income beneficiaries who demonstrate an immediate need for prescriptions, but who have not yet enrolled in a Part D plan, or whose enrollment is not yet effective. LI NET also provides retroactive and/or temporary prospective coverage for beneficiaries determined to be eligible for the Part D low-income subsidy (LIS) by the Social Security Administration (SSA) or a State. In this proposed rule, we propose regulations to make the LI NET program a permanent part of Medicare Part D, as required by the Consolidated Appropriations Act, 2021 (CAA).

10. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c))

The proposed regulatory provisions would amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an "identified overpayment" and will align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act, which provides that the terms "knowing" and "knowingly" have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). Specifically, in this regulation we propose to remove the existing "reasonable diligence" standard and adopt by reference the False Claims Act definition of "knowing" and "knowingly" as set forth at 31 U.S.C. 3729(b)(1)(A). Under the proposed rule, an MA organization, Part D sponsor, provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment, or acts in reckless disregard or deliberate ignorance of the overpayment.

11. Changes to an Approved Part D Formulary – Immediate Substitutions (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

Current regulations permit Part D sponsors to immediately remove from the formulary a brand name drug and substitute its newly released generic equivalent. Part D sponsors meeting the requirements can provide notice of specific changes, including direct notice to affected beneficiaries, after they take place; do not need to provide a transition supply of the substituted drug; and can make these changes at any time including in advance of the plan year. Consistent with these requirements, we propose to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

12. Expanding Eligibility for Low-Income Subsidies (LIS) Under Part D of the Medicare Program (§§ 423.773 and 423.780)

Section 11404 of the 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. In addition, the IRA allows for individuals to qualify for the full subsidy based on the higher resource requirements currently applicable to the partial LIS group. This change will provide the full LIS subsidy for those who currently qualify for the partial subsidy, and we are proposing to implement this change in this regulation.

C. Summary of Costs and Benefits

TABLE 1

Provision	Description	Impact
a. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)	We propose several measure changes and methodological clarifications and enhancements to the Part C and Part D Star Ratings as described in section V. In addition to proposing to establish an HEI reward as a replacement for the current reward factor and to reduce the weight of patient experience/complaints and access measures, we are proposing to: modify the improvement measure highest rating hold harmless provision so it applies only to contracts with 5 stars for their highest rating, remove the cut point guardrails, add a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, remove the 60 percent rule for extreme and uncontrollable circumstances, clarify existing rules around administrative review process for QBP determinations, and clarify additional aspects of the existing Star Ratings calculations.	The HEI reward provision, which would replace the current reward factor, is expected to result in net savings of between $680 million in 2028 and $1.05 billion in 2033, resulting in a ten-year savings estimate of $5.13 billion. The patient experience/complaints and access measure weight provisions are expected to result in net savings of between $330 million in 2027 and $580 million in 2033, which results in a ten year savings estimate of $3.28 billion. For the improvement measure hold harmless provision, net savings are estimated to be between $2.08 billion in 2027 and $3.52 billion in 2033, resulting in a ten-year savings estimate of $19.3 billion. The net impact of all of the Star Ratings proposed provisions is $24.97 billion in savings over ten years accounting for 0.37% of the private health baseline.

Provision	Description	Impact
b. Medication Therapy Management (MTM) Program (§ 423.153)	We propose changes to the MTM targeting criteria to: (1) Require Part D sponsors to include all core chronic diseases in their targeting criteria, codify the current 9 core chronic diseases in regulation, and add HIV/AIDS for a total of 10 core chronic diseases. (2) Lower the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and require sponsors to include all Part D maintenance drugs. (3) Revise the cost threshold methodology based on the average annual cost of 5 generic Part D drugs ($1,004 in 2020).	We estimate that these proposed changes would increase the number and percentage of Part D enrollees eligible for MTM services from 4.5 million (9 percent) to 11 million (23 percent). The increase in MTM program enrollment is estimated to cost approximately $336 million annually for required MTM services. We cannot definitively score this proposal because there may be other administrative costs attributable to MTM, which is not a specific line item that can be easily extracted from plan bids. Also, there is evidence that MTM services may generate overall medical savings, but we cannot quantify those savings at this time.

Provision	Description	Impact
c. Strengthening Translation Requirements for Medicare Advantage, Cost plans, Part D, and D-SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267)	We propose to require that: (1) MA organizations, cost plans, and Part D sponsors provide materials to enrollees on a *standing basis* in any non-English languages that is the primary language of at least 5 percent of the individuals in that service area and/or accessible formats using auxiliary aids and services; and (2) fully integrated D-SNPs (FIDE SNPs), highly integrated D-SNPs (HIDE SNPs) and applicable integrated plans (AIPs) translate both Medicare and Medicaid materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.	(1) We estimate the proposal to require MA organizations, cost plans, and Part D sponsors to establish a process to provide materials to enrollees on a standing basis would cost $10.4 million. We expect that implementing a standing request process would reduce future costs to MA organizations, cost plans, and Part D sponsors by decreasing rework of sending two sets of information, one in the incorrect language or format and the other in the correct format. (2) We estimate it would cost $2.1 million for FIDE SNPs, HIDE SNPs, and AIPs to translate one set of materials into one additional language. Any additional documents needing translation would be a one-time cost with a smaller cost to update the documents in future contract years.

Provision	Description	Impact
d. Health Equity in Medicare Advantage (MA) (§§ 422.111 and 422.112)	We propose to: (1) clarify the broad application of our policy that MA services be provided in a culturally competent manner, (2) require each provider's cultural and linguistic capabilities and notations for certain MOUD-waivered providers be included in all MA provider directories, (3) require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits, and (4) require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees.	(1) Expanding the list of populations is proposed for purposes of clarity, and is not expected to have any economic impact on the Medicare Trust Fund. (2) Codifying providers' cultural and linguistic capabilities and notations for certain MOUD-waivered providers as required provider directory data elements is not expected to have any economic impact on the Medicare Trust Fund. (3) Our proposal requiring MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy is expected to have an unknown economic impact on the Medicare Trust Fund. (4) Aligning MA QI programs with health equity efforts across CMS policies and programs is not expected to have any economic impact on the Medicare Trust Fund.

Provision	Description	Impact
e. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Mandate Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137 and 422.138422.4)	We propose to: 1) require MA plans to follow Traditional Medicare coverage NCDs, LCDs, statutes and regulations when making medical necessity determinations, 2) require plans to provide a public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, 3) require that an approval granted through PA processes must be valid for the duration of a prescribed course of treatment and that plans are required to provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA plan, switches from Traditional Medicare to an MA plan, or is new to Medicare, and 4) require MA organizations to establish a committee, led by the Medical Director, that reviews utilization management, including PA, policies annually and keeps current of LCDs, NCDs, and other Traditional Medicare coverage policies.	(1) Require MA plans to follow Traditional Medicare coverage guidelines when making medical necessity determinations. The impact is difficult to quantify. (2) Requires plans to post a public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations. (3) Requires PA approval to be valid for the duration of the approved course of treatment and is not expected to have economic impact on the Medicare Trust fund. (4) Require MA organizations to establish a committee (similar to a P&T committee), led by the Medical Director, that reviews utilization management, including PA, policies annually and keeps current of LCDs, NCDs, and other Traditional Medicare coverage policies. This is qualitatively beneficial for enrollees and is not expected to have economic impact on the Medicare Trust fund.

Provision	Description	Impact
f. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)	We propose several changes to strengthen beneficiary protections and improve MA and Part D marketing. Examples include notifying enrollees annually, in writing, of the ability to opt out of plan business; requiring agents to explain the effect of an enrollee's enrollment choice on their current coverage; clarifying that the prohibition on door-to-door contact still applies solely based on collection of a business reply card (BRC) or scope of appointment (SOA); prohibiting marketing of benefits in a service area where those benefits are not available, prohibiting the marketing of savings available based on a comparison of typical expenses borne by uninsured individuals; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell; requiring plans and sponsors to have an oversight plan that monitors agent/broker activities and reports non-compliance to CMS; adding SHIPs to the TPMO disclaimer as an option for beneficiaries to obtain additional help; placing discrete limits around the use of the Medicare name, logo, and Medicare card; prohibit the use of superlatives unless the material provides documentation to support the statement; and, clarifying the requirement to record calls between TPMOs and beneficiaries includes virtual connections such as Zoom and Facetime.	We recognize the impact of these provisions to be primarily one of changes to Plans' policy and procedure documents. We have tallied the one-time costs of these changes to be $172,593 ($76.20/hr * 2265 hr). We believe there would be an impact of time and cost to Plans for the requirement to report non-compliant agents and brokers to CMS. We are unable to estimate that cost at this time, however, and have solicited comment on how we could accurately do so.

Provision	Description	Impact
g. Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116)	We propose to add Clinical Psychology Licensed Clinical Social Worker, and Prescribers of Medication for Opioid Use Disorder, as specialty types that will be evaluated using the time, distance and minimum provider standards in our network adequacy reviews; amend our access to services standards to include behavioral health services; codify minimum access wait time standards (from current example wait times for primary care) to apply to both primary care and for behavioral health services; clarify that behavioral health services may qualify as emergency services and therefore not be subject to prior authorization when furnished as emergency services; and require plans to establish behavioral health care coordination programs to ensure enrollees are offered the behavioral health services to which they are entitled to close gaps in behavioral health treatment.	We estimate negligible costs for this proposal.
h. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)	CMS requires notification to enrollees when a provider network participation contract terminates. CMS is proposing to revise § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also proposing to revise § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.	This proposal is not expected to have any economic impact on the Medicare Trust Fund.

Provision	Description	Impact
i. Limited Income Newly Eligible Transition (LI NET) Program	We propose to make the longstanding demonstration program a permanent part of Medicare Part D, as directed by the CAA.	The projected costs, estimated by OACT, are the same as what the government would have incurred if the demonstration continued. Further, the costs of the payments provided for under this program will continue, as under the demonstration, to be covered through the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance (SMI) Trust Fund. The provision is estimated to cost the Medicare Trust Fund $95 million over 10 years. There is an additional 10 year paperwork burden of $2.6 million.
j. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§ 401.305(a)(2))	We propose to remove the "reasonable diligence" standard and adopt by reference the "knowledge" standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1).	We do not have a basis for estimating the impact on new Parts A, B, C and D overpayment recoveries.
k. Changes to an Approved Part D Formulary - Immediate Substitutions	We propose to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.	We estimate no significant impact to the Medicare Trust Fund or other paperwork burden as a result of this specific proposal.
l. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)	We propose to implement section 11404 of the IRA to expand eligibility for the full LIS subsidy group to individuals currently eligible for the partial LIS subsidy beginning on or after January 1, 2024	We estimate that this change will increase Medicare spending by $2.3 billion over 10 years.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022

A. Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments (§§ 422.503(e), 422. 504, 422.510 and 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 2022 and subsequent years, as provided in § 422.514(d)(1), CMS will not enter into a contract for a new non-SNP MA plan that projects, in its bid submitted under § 422.254, that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a State plan under Title XIX. For plan year 2023 and subsequent years, as provided in § 422.514(d)(2), CMS will not renew a contract with a non-SNP MA plan that has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a State plan under Title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

We established these contract limitations to address the proliferation and growth of D-SNP look-alikes, which raised concerns related to effective implementation of requirements for D-SNPs established by section 1859 of the Act (including amendments made by the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) and the Bipartisan Budget Act of 2018 (Pub. L. 115-123)). We adopted the regulation to ensure full implementation of requirements for D-SNPs, such as contracts with State Medicaid agencies; a minimum integration of Medicare and Medicaid benefits; care coordination through health risk

assessments (HRAs); evidence-based models of care. In addition, we noted how limiting these D-SNP look-alikes would address beneficiary confusion stemming from misleading marketing practices by brokers and agents that misrepresent to dually eligible individuals the characteristics of D-SNP look-alikes. 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 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). We are proposing amendments to close unforeseen loopholes in the scope of the regulation adopted to prohibit D-SNP look-alikes.

1. Applying Contracting Limitations for D-SNP Look-Alikes to MA Plan Segments

As written at § 422.514(d) and (e), the contracting limitations for D-SNP look-alikes are based on analysis at the MA plan level. Section 1854(h) of the Act authorizes MA organizations to segment an MA plan and apply the uniformity requirements for MA plans at the segment level, provided that the segments are comprised of one or more MA payment areas. As implemented in §§ 422.2 (defining "MA plan"), 422.100(d), 422.254, and 422.262, MA plans may include multiple segments in an MA plan in which different benefit designs, cost-sharing, and premiums are available; bids are submitted at the segment level if an MA plan is segmented and evaluation of compliance with MA requirements is done at the segment level where appropriate. See § 422.100(f)(6) providing for evaluation of cost-sharing at the segment level for segmented plans. In effect, each segment of an MA plan is like a plan itself. We discussed in the Medicare Program; Medicare+Choice Program (65 FR 40170, 40204 through 40205) final rule, which appeared in the **Federal Register** on June 29, 2000 (also known as the June 2000 final rule) how the authority in section 1854(h) of the Act for an MA organization to segment an MA plan has practical implications that are similar to offering multiple plans. One or more segments

can be part of the same MA plan even though the Medicare Part C benefits, cost-sharing, premiums, and marketing materials can differ. For example, MA plan benefit package H1234-567 could offer multiple segments distinguished by three additional digits, such as H1234-567-001, H1234-567-002, and H1234-567-003. Since adopting § 422.514(d), we have seen MA plans where a specific segment looks like a D-SNP look-alike and would be subject to the contracting prohibitions in § 422.514(d) if the segment were treated as an MA plan. As finalized, § 422.514(d) does not clearly apply to a segment within an MA plan. However, we believe that by applying the D-SNP look-alike contracting limitations only at the MA plan level without applying it to segments of plans, our existing regulation has an unintended and unforeseen loophole through which D-SNP look-alikes could persist, contrary to the stated objectives in our prior rulemaking.

Based on January 2022 Monthly Membership Report (MMR) data, we identified 47 non-SNP MA plans that meet the criteria outlined at § 422.514(d)(2) when we performed our analysis at the plan level. If we were to apply the § 422.514(d)(2) criteria at the MA plan segment level, segments of three additional non-SNP MA plans would be identified as D-SNP look-alikes. The segments in those three plans collectively have approximately 3,000 enrollees. While the number of non-SNP MA plans at the segment level is currently small, this number could grow in the future and provide an opportunity for MA organizations to circumvent the D-SNP look-alike contracting limitations at § 422.514(d). For example, in our analysis of proposed D-SNP look-alike transitions for contract year 2023, two D-SNP look-alikes in contract year 2022 are proposing to transition a combined total of approximately 7,800 D-SNP look-alike enrollees into two new non-SNP MA plan segments, which could create two new D-SNP look-alike segments for contract year 2023.

We propose adding a new paragraph at 42 CFR 422.514(g) to provide that § 422.514(d) through (f) apply to segments of the MA plan in the same way that those provisions apply to MA plans. As a result, CMS will not contract with or renew a contract with a plan segment where the

MA plan or segment is not a D-SNP and the enrollment thresholds in paragraph (d)(1) or (d)(2) are met. This proposal, to treat a segment of an MA plan as an MA plan, would be consistent with CMS' annual review of MA plan bids and Medicare cost-sharing, in which each MA plan segment submits a separate bid pricing tool and plan benefit package like an unsegmented MA plan and CMS separately evaluates these submissions for compliance with MA requirements.

As discussed in the June 2020 final rule, CMS implements the contracting prohibition in § 422.514 at the plan level. Where an MA plan is one of several offered under a single MA contract and the MA organization does not voluntarily non-renew the D-SNP look-alike, CMS will sever the D-SNP look-alike from the overall contract using its authority under § 422.503(e) to sever a specific MA plan from a contract and terminate the deemed contract for the look-alike plan (85 FR 33812). However, CMS does not currently have clear regulatory authority to sever a segment from an MA plan to terminate a contract that has only a segment of an MA plan. CMS adopted the severability regulation at § 422.503(e) in the Medicare Program; Establishment of the Medicare+Choice Program interim final rule (63 FR 35103, hereafter known as the June 1998 interim final rule) as part of implementing the statutory authority for MA contracts to cover more than one MA plan. Without amending § 422.503(e), CMS would need to sever the entire MA plan that has the D-SNP look-alike segment such that other segments in that MA plan would be subject to the contracting prohibition and not renewed under § 422.514(d) as proposed to be amended here if the MA organization failed to comply with § 422.514(d). Instead, we propose to amend § 422.503(e) to allow for CMS to sever a segment from an MA plan and allow the remaining segments of that MA plan to continue along with any other MA plans offered under the same contract. We propose to rely on our authority to adopt MA standards under section 1856(b)(1) of the Act and our authority to adopt additional contract terms when necessary and appropriate, and not inconsistent with the MA statute, under section 1857(e)(1) of the Act. Our primary impetus for this proposal relates to D-SNP look-alikes, but our proposal at § 422.503(e) is not specific to D-SNP look-alikes; because each segment of an MA plan is like a plan itself,

we believe severability should apply similarly at the plan and segment level. We also propose to amend § 422.504(a)(19) to adopt a new contract term that MA organizations agree not to segment an MA plan in a way that results in a D-SNP look-alike. In conjunction with the proposed amendments to § 422.514(g) to apply the prohibitions on contracting with D-SNP look-alikes to segments of an MA plan, the amendments to § 422.503(e) would allow CMS to eliminate existing D-SNP look-alike segments and the amendments to § 422.504(a)(19) would allow CMS to prevent new D-SNP look-alikes.

2. Applying Contracting Limitations for D-SNP Look-Alikes to Existing MA Plans

We identified a second loophole during our analysis of contract year 2023 MA plan bids to identify any new MA plans that meet the contract limitation at § 422.514(d)(1). An existing (that is, renewing) MA plan that did not meet the criteria in § 422.514(d)(2) (using January 2022 MMR data as provided in paragraph (e)(3)) projected in its contract year 2023 bid that the MA plan would have 80 percent or higher enrollment of dually eligible individuals in 2023. Because this MA plan is not a new MA plan for contract year 2023, the contract prohibition in § 422.514(d)(1) did not apply. To prohibit similar situations in the future, we propose to amend § 422.514(d)(1) to apply it to both new and existing (that is, renewing) MA plans that are not D-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. We propose to revise paragraph (d)(1) to provide that CMS does not enter into or renew an MA contract for plan year 2024 and subsequent years when the criteria in paragraphs (d)(1)(i) and (ii) are met. We are proposing to begin this prohibition with 2024 because we expect that 2024 will be the first plan year after the final rule adopting this proposal. Pending finalization of this proposal, § 422.514(d)(1) will continue to prohibit contracts with new MA plans that meet the criteria. As contracts for 2022 and 2023 have been awarded as of the time this proposed rule is issued, the earliest our proposed revision to expand the scope of § 422.514(d)(1) can apply is 2024.

3. Contract Limitations for D-SNP Look-Alikes as a Basis for MA Contract Termination (§ 422.510(a)(4))

Finally, we propose an amendment to § 422.510(a)(4), which outlines the bases for termination of an MA contract. Specifically, we propose to add language at § 422.510(a)(4) to add a new paragraph (a)(4)(xvi) that permits CMS to terminate an MA contract when the MA organization meets the criteria in § 422.514(d)(1) or (d)(2). This proposed amendment is consistent with how § 422.514(d) provides that CMS will not enter into or renew an MA contract in certain circumstances. In our view, § 422.514(d) is sufficient authority for the non-renewal, that is termination, of MA contracts when § 422.514(d) applies. However, we believe that adopting a specific provision in § 422.510(a)(4) will avoid any inadvertent ambiguity on this topic and make it clear that the procedures outlined in § 422.510, including notices, timeframes, and appeal rights, apply when CMS does not renew an MA contract based on application of § 422.514(d).

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes (§ 423.38)

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L 108-173) established a Part D – Voluntary Prescription Drug Benefit program for Medicare-eligible individuals. The MMA added section 1860D–1(b)(3)(C) of the Act, which authorized the Secretary to establish Part D special enrollment periods (SEP) for Medicare-eligible individuals to enroll in a Part D plan based on exceptional circumstances – that is, an individual may elect a plan or change his or her current plan election when the individual meets an exceptional condition as determined by the Secretary.

The SEPs for exceptional conditions were historically included in our manual instructions rather than through regulation. In 2020, we codified a number of SEPs that we had adopted and implemented through subregulatory guidance as exceptional circumstance SEPs, including the SEP for Individuals Who Enroll in Part B During the Part B General Enrollment Period (GEP)

(85 FR 33909). This SEP, as codified at § 423.38(c)(16), allowed individuals who are not entitled to premium-free Part A and who enroll in Part B during the GEP for Part B (January–March) to enroll in a Part D plan. This SEP begins April 1st and ends June 30th, with a Part D plan enrollment effective date of July 1st. This SEP effective date aligns with the entitlement date for Part B for individuals who enroll in Part B during the GEP.

Currently, when an individual enrolls in Part B during the GEP, their Part B enrollment entitlement date is July 1st, regardless of when during the GEP they enrolled. Division CC, title I, subtitle B, section 120 of the Consolidated Appropriations Act, 2021 (CAA) Pub. L 116-260 modified section 1838(a)(2) of the Act, to address the beginning of the entitlement for individuals enrolling during their GEP pursuant to section 1837(e) of the Act. As added by the CAA, section 1838(a)(2)(D)(ii) of the Act requires that, for an individual who enrolls in Part B during the GEP on or after January 1, 2023, entitlement begins the first day of the month following the month in which the individual enrolled. For example, if an individual enrolls in Part B in February 2023 (during the GEP), their Part B coverage will begin on March 1st.

Based on Medicare enrollment statutory changes made by the CAA described previously, we are proposing to revise the start and end date for the SEP for Individuals Who Enroll in Part B During the Part B GEP to align with the Part B entitlement dates for someone who enrolls in Part B using the GEP that starts January 1, 2023. Accordingly, we are also proposing to revise the effective date of the individual's Part D plan enrollment, which is always July 1st under the current parameters of this Part D SEP. That is, we are proposing to modify § 423.38(c)(16) to provide that on or after January 1, 2023, an individual who is not entitled to premium-free Part A and who enrolls in Part B during the GEP is eligible to use the SEP for Individuals Who Enroll in Part B During the Part B GEP to request enrollment in a Part D plan, and that this SEP will begin when the individual submits the application for Part B, and will continue for the first 2 months of enrollment in Part B. Further, we propose to modify § 438.38(c)(16) to provide that where an individual uses this Part D SEP to request enrollment in a Part D plan, the Part D plan

enrollment would be effective the first of the month following the month the Part D plan sponsor receives the enrollment request. For example, an individual who enrolls in Part B on February 10th for a Part B entitlement date of March 1st can use the Part D SEP to request enrollment in a Part D plan during the period from February 10th to April 30th. If the individual submitted an enrollment request for a Part D plan on February 10th and the enrollment is accepted, the effective date of their Part D coverage would be March 1st. Note that an individual's Part D enrollment effective date cannot be prior to the Part A and/or Part B entitlement date, and the individual must also meet other Part D plan eligibility criteria as described in § 423.30(a). Per current practice, the Part D plan would need to confirm that the individual had enrolled in Part B (or Part B and premium Part A) prior to the individual's Part D enrollment effective date. The Social Security Administration (SSA) will have to first process the individual's Part B application and submit that information into SSA systems, which, in turn, would be populated in the CMS enrollment systems, for a Part D plan to have access to that entitlement information.

We expect this proposed change in enrollment and effective dates using this Part D SEP would simplify the enrollment process and reduce the potential for gaps in prescription drug coverage. Also, we believe it will be easier for beneficiaries to understand the effective date of their Medicare coverage using this Part D SEP, as we are proposing that the Part D effective date will be the first of the month following the month the beneficiary submits an enrollment request, which aligns with most Part D enrollment and SEP timeframes. Although the current SEP for Individuals Who Enroll in Part B During the Part B GEP lasts for 3 calendar months, and the proposed timeframe for use of this SEP would be shorter, the proposed timeframe aligns with most of our other Part D SEPs. In addition, this proposed timeframe would provide the individual the opportunity for a Part D plan enrollment effective date that is within 63 days of the Part B entitlement. For individuals who have maintained creditable drug coverage prior to enrolling in Part B, this proposed SEP timeframe will help to ensure that an individual would not incur a Part D late enrollment penalty (LEP). For example, if an individual enrolls in Part B in

February and is entitled to Part B effective March 1st, they could enroll in a Part D plan for an effective date of March 1st, April 1st or May 1st, depending on whether the Part D plan sponsor received the enrollment request in February, March or April, respectively. Any of these Part D plan effective dates would provide Part D coverage to an individual who maintained creditable coverage prior to enrolling in Part B in February within the 63-day timeframe to avoid the penalty. Proposing this exceptional condition SEP also supports President Biden's April 5, 2022 Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage, which, among other things, requires agencies to examine policies or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage, and also examine policies or practices that strengthen benefits and improve access to healthcare providers.

This proposal would revise the timeframes for use of the Part D SEP described in § 423.38(c)(16) based on the change in effective date for GEP enrollments made by section 120 of the CAA. These proposed revisions are needed to align the timeframe for use of this Part D SEP based on new Part B GEP enrollment effective date parameters.

Because an individual may elect a Part D plan only during an election period, Medicare Part D sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible. Our proposal would not add to existing enrollment processes, so we believe any burden associated with this aspect of enrollment processing would remain unchanged from the current practice, and would not impose any new requirements or burden.

All information impacts of this provision have already been accounted for under OMB control number 0938-1378 (CMS-10718). We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

C. Alignment of Part C and Part D Special Enrollment Periods with Medicare Exceptional Condition Enrollment (§§ 422.62 and 423.38)

Section 1851(e)(4)(D) of the Act authorizes the Secretary to create special enrollment periods (SEPs) for an individual to disenroll from an MA plan or elect another MA plan if the individual meets an exceptional condition provided by the Secretary. This authority was originally codified at § 422.62(b)(4) in the June 1998 interim final rule as a general SEP for CMS to apply on an ad hoc basis. (63 FR 35073)

As noted previously, section 1860D–1(b)(3)(C) of the Act authorizes the Secretary to establish Part D SEPs for Medicare-eligible individuals to enroll in a Part D plan if they meet certain exceptional circumstances. This authority was originally codified at § 423.38(c)(8)(ii) (70 FR 4529). The MMA also added section 1860D-1(b)(1)(B) of the Act which provides that in adopting the Part D enrollment process, the Secretary "shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA-PD plan under the following provisions of section 1851."

Historically, we had included in our regulations those MA and Part D SEPs that have been specifically named in the statute, and established SEPs for exceptional conditions in our subregulatory guidance. In the June 2020 final rule, we codified, at §§ 422.62(b) and 423.38(c), respectively, the MA and Part D SEPs that we had adopted and implemented through subregulatory guidance as exceptional condition SEPs (85 FR 33796). Codifying these SEPs provided transparency and stability to the MA and Part D programs by ensuring that these SEPs are known to plans and beneficiaries.

As required by section 1851(a)(3) of the Act (for the MA program) and section 1860D-1(a)(3)(A) of the Act (for the Part D program) and described in §§ 422.50(a)(1) and 423.30(a)(1)(i), eligibility for MA or Part D plan enrollment requires that an individual first have Medicare Parts A and B for MA eligibility and either Part A or B for Part D eligibility. Individuals who are entitled to premium-free Part A are generally auto-enrolled when they are

first eligible, if they are already receiving retirement or disability benefits from the SSA or Railroad Retirement Board, or they may submit an application to enroll in premium-free Part A at any time after meeting the requirements for entitlement. Under normal conditions, individuals who want to enroll in premium Part A, Part B, or both, must submit a timely enrollment request during their Initial Enrollment Period (IEP), the GEP, or an existing SEP for which they are eligible. Those who fail to enroll during their IEP may face a lengthy penalty for late enrollment (life-long for Part B) and a potential gap in coverage. Prior to the enactment of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L 116-260), CMS did not have broad authority to create SEPs based on exceptional conditions for enrollment into Medicare Parts A and B. However, Division CC, title I, subtitle B, Section 120 of the CAA established section 1837(m) of the Act to authorize the Secretary to establish Part B SEPs for individuals who are eligible to enroll in Medicare and meet such exceptional conditions as the Secretary provides. Per section 1818(c) of the Act, the provisions of section 1837 of the Act, excluding subsection (f) thereof, applies to the premium Part A program. This authority to adopt exceptional conditions SEPs for premium Part A and Part B is effective January 1, 2023. The ability to grant SEPs for exceptional conditions is an important tool that will allow CMS to provide relief to individuals who missed an opportunity to enroll in Medicare due to circumstances that were outside of their control, ensure continuous health coverage, and avoid late enrollment penalties on the premium Part A or Part B premiums. CMS finalized new exceptional condition SEPs under section 1837(m) of the Act in 42 CFR 406.27 and 407.23 for Medicare parts A and B, respectively, in a final rule that was published in the **Federal Register** on November 3, 2022, titled "Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules" (87 FR 66454). These SEPs would be available to individuals who have missed an enrollment period due to an exceptional condition that is specified in the final rule. Specifically, individuals who miss an IEP, GEP, or another SEP, such as the Group

Health Plan SEP, due to a specified exceptional condition, would be eligible to enroll in Medicare premium Part A or Part B using the new SEPs.

Based on Medicare enrollment changes made by the CAA described previously, we are proposing to add corresponding exceptional condition SEPs for MA and Part D enrollment, as authorized under sections 1851(e)(4)(D) and 1860D–1(b)(3)(C) of the Act, to align with the new Medicare premium Part A and B exceptional condition SEPs that CMS has finalized in 42 CFR 406.27 and 407.23. These new Medicare Part C and D SEPs would be based on an individual's use of a Medicare premium Part A or Part B exceptional conditions SEP. That is, individuals who use an exceptional condition SEP to enroll in premium Part A and/or Part B will be provided an opportunity to enroll in a MA or Part D plan, provided that the individual meets applicable eligibility requirements for the plan.

We are proposing at § 422.62(b) to redesignate current paragraphs (26) as (27) and add a new paragraph (26) to provide an SEP for individuals to enroll in a MA plan or MA plan that includes Part D benefits (MA-PD plan), when they use a Medicare exceptional condition SEP to enroll in premium Part A and/or Part B. We are also proposing at § 423.38(c) to redesignate current paragraph (34) as (35) and add new paragraph (34) to provide an SEP for individuals to enroll in a stand-alone Part D prescription drug plan (PDP) when they use a Medicare exceptional condition SEP to enroll in premium Part A or Part B.

The proposed new MA SEP would begin when the individual submits the application for premium Part A and Part B, or only Part B, and would continue for the first 2 months of enrollment in Part A (premium or premium-free) and Part B. Similarly, the proposed new Part D SEP would begin when the individual submits their premium Part A or Part B application and would continue for the first 2 months of enrollment in premium Part A or Part B. The MA or Part D plan enrollment would be effective the first of the month following the month the MA or Part D plan receives the enrollment request. For example, an individual who enrolls in premium Part A or Part B using an exceptional conditions SEP, as codified in 42 CFR §§ 406.27 and

407.23, on July 10th for an entitlement ate of August 1st, can use the MA or Part D exceptional circumstance SEP to request enrollment in a MA or Part D plan during the period from July 10th to September 30th. If the individual submitted an enrollment request for an MA or Part D plan on July 10th and the enrollment is accepted, the effective date of their MA or Part D coverage would be August 1st.

An individual's MA or Part D plan enrollment effective date cannot be prior to the Part A and/or Part B enrollment date, and the individual must also meet other MA or Part D plan eligibility criteria as described in §§ 422.50(a) or 423.30(a), respectively, in order to use the new MA or Part D SEP we are proposing. Per current practice, the MA or Part D plan would need to confirm that the individual had enrolled in premium Part A and/or Part B, as applicable, using one of the new SEPs for exceptional conditions prior to the individual's MA or Part D enrollment effective date. The SSA will have to first process the individual's premium Part A and/or Part B application and submit that information into SSA systems, which, in turn, would be populated in the CMS enrollment systems, for an MA or Part D plan to have access to that enrollment information.

Providing an opportunity for Part D enrollment at the time of Medicare premium Part A or Part B enrollment using an exceptional condition SEP will help ensure that an individual will have timely access to Part D drugs, within the timeframe of 63 days[3] established in regulation at § 423.46(a), to prevent a Part D late enrollment penalty from being assessed. For example, if an individual enrolls in premium Part A or Part B using an exceptional condition SEP in July and is entitled to premium Part A and/or Part B effective August 1st, they could enroll in a Part D plan for an effective date of August 1st, September 1st, or October 1st, depending on whether the Part

[3]42 CFR 423.46(a) states that, a Part D eligible individual must pay the late penalty described under § 423.286(d)(3), except as described at § 423.780(e), if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:
(1) The individual was eligible to enroll in a Part D plan.
(2) The individual was not covered under any creditable prescription drug coverage.
(3) The individual was not enrolled in a Part D plan.

D plan sponsor received the enrollment request in July, August, or September respectively. Any of these Part D plan effective dates would provide an individual with Part D coverage within the 63-day timeframe of Medicare eligibility to avoid the penalty. This is an important beneficiary protection, especially for those individuals who have to bear the cost of paying a premium for Part A.

This proposed MA exceptional condition SEP will allow beneficiaries who are enrolled in premium Part A and in Part B to exercise their option to receive their healthcare from an MA plan, instead of Original Medicare, as soon as the individual is enrolled in both Parts A and B, without waiting for the annual coordinated election period. Proposing exceptional condition SEPs for MA and Part D also supports President Biden's April 5, 2022 E.O. on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage, which, among other things, requires agencies to examine policies or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage, and also examine policies or practices that strengthen benefits and improve access to healthcare providers.

Because an individual may elect an MA or Part D plan only during an election period, MA organizations and Part D sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible. Our proposal would not add to existing enrollment processes, so we believe any burden associated with this aspect of enrollment processing would remain unchanged from the current practice, and would not impose any new requirements or burden.

Consequently, this provision will not have added impact. All burden impacts of these provisions have already been accounted for under OMB control number 0938-1378 (CMS-10718). We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees.

Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

D. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program (§§ 423.2500 through 423.2536)

1. Background on the LI NET Demonstration and Introduction to the Proposals

a. Background on the LI NET Demonstration

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D prescription drug benefit, which became effective on January 1, 2006. Prior to 2006, beneficiaries who were eligible for both Medicaid and Medicare (dual eligible) received prescription drug benefits through Medicaid. When the MMA went into effect, dual eligible beneficiaries began receiving their prescription drug benefits through Medicare Part D.

From the beginning of Part D, CMS recognized the need to provide both immediate and retroactive coverage for full benefit dual eligible (FBDE) beneficiaries who were newly identified by either CMS or a State. Prior to 2010, CMS automatically enrolled newly identified beneficiaries eligible for the Part D low-income subsidy (LIS) into a Part D plan with a premium at or below the low-income benchmark ("benchmark" plans), which have no or reduced premiums for LIS-eligible beneficiaries. Each benchmark plan receiving these beneficiaries was required to grant retroactive coverage to the beginning of a beneficiary's LIS-eligible status or their last uncovered month, whichever date was later. At the time, there were around 300 Part D benchmark plans, and each needed to develop the capacity to provide transitional and retroactive coverage for these beneficiaries. Conducting retroactive claims adjudication and providing point-of-sale coverage was not efficient for Part D sponsors and accordingly, in 2010, CMS established the Medicare Part D Demonstration for Retroactive and Point of Sale Coverage for Certain Low-Income Beneficiaries, also known as Medicare's Limited Income Newly Eligible Transition (LI

NET demonstration). The LI NET demonstration consolidates administration of transitional and retroactive Part D coverage for eligible beneficiaries to a single Part D sponsor.

Part D coverage under the LI NET demonstration differs from coverage under traditional Part D plans in that the LI NET demonstration provides point-of-sale coverage for beneficiaries who demonstrate an immediate need for prescriptions, and also provides retroactive and/or temporary coverage for beneficiaries determined to be eligible, or likely to be eligible, for the Part D LIS by the Social Security Administration (SSA) or a State. The LI NET demonstration provides temporary, transitional Part D prescription drug coverage for LIS-eligible beneficiaries, including beneficiaries who are eligible for the Part D LIS but who are not yet enrolled in a Part D drug plan, or are enrolled in a plan but for whom coverage has not yet taken effect.

The purposes of the demonstration are to provide the following:

- More efficient prescription drug coverage and claims reimbursement for newly eligible low-income beneficiaries, including periods of retroactive eligibility;
- More efficient prescription drug coverage and claims reimbursement for individuals who are not enrolled in a PDP and whose LIS status is not yet established in CMS' systems, but who arrive at a pharmacy with an immediate need for their prescription. This may occur, for instance, when a State has determined that a beneficiary is eligible for Medicaid but that information does not yet appear in CMS' systems;
- A seamless transition for LIS-eligible beneficiaries from LI NET into a qualifying PDP with basic prescription drug coverage absent a beneficiary's choice otherwise; and
- More efficient prescription drug coverage and claims reimbursement for LIS-eligible beneficiaries who are losing existing coverage in a PDP. For example, a beneficiary could be terminated for moving out of the service area of their current PDP. The beneficiary would be automatically enrolled into LI NET for that month and the following month, with enrollment into a qualifying PDP with basic prescription drug coverage that would become effective at the end of the LI NET enrollment absent the beneficiary's choice otherwise.

b. Introduction to the Proposals to Implement LI NET as a Permanent Program

Division CC, title I, subtitle B, section 118 of the Consolidated Appropriations Act 2021 (CAA) (Pub. L. 116-260) modified section 1860D-14 of the Act by redesignating subsection (e) of section 1860D-14 as subsection (f) and by establishing a new subsection (e) Limited Income Newly Eligible Transition Program. New subsection (e)(1) requires the Secretary to "carry out a program to provide transitional coverage for covered Part D drugs for LI NET eligible individuals…" no later than January 1, 2024. This directive in section 118 of the CAA makes LI NET a permanent program within Part D, beginning in 2024.

The proposed rulemaking to establish the LI NET program is consistent with President Biden's Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021) and Executive Order 14085 on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government (December 13, 2021). LI NET ensures that low-income beneficiaries transitioning from Medicaid to Medicare do not experience a gap in coverage for their prescription medications. Executive Order 14085 calls for the Federal Government to design and deliver services with "a focus on the actual experience of the people whom it is meant to serve" and "deliver services more equitably and effectively, especially for those who have been historically underserved." We have designed the proposed LI NET program with beneficiary needs foremost in mind, ensuring continuous drug coverage and access for eligible low-income individuals.

LI NET policies, infrastructure, and operations have evolved over the past 12 years to balance providing needed coverage with responsible stewardship of taxpayer dollars and efficiency in administering the program. The LI NET demonstration has proven successful in providing low-income individuals transitional Part D coverage. Approximately 8 million low-income individuals received the benefits of the LI NET program under the demonstration, with over 100,000 beneficiaries enrolled in LI NET in any given month. It has become a program that beneficiary advocacy groups rely on when supporting low-income individuals and connecting

them with services. LI NET works directly with over a dozen advocacy groups and 51 State Health Insurance Assistance Programs (SHIPs), which collectively work with LIS beneficiaries to remove access barriers and provide health insurance counseling.

We believe the LI NET demonstration has become a reliable, stable program that has been successful in providing transitional and retroactive Part D coverage to millions of beneficiaries. In developing our proposals for implementing the permanent LI NET program, we have taken into consideration our experience under the LI NET demonstration. Where appropriate, we discuss the policies and practices under the LI NET demonstration that inform our proposals for how to implement aspects of the LI NET program that are not directly specified by the statute.

We rely on the premise that Part D regulations apply to the LI NET program and to the LI NET sponsor as part of the Part D program and as a type of Part D sponsor, except for when the statute requires us to deviate or when existing regulations would not apply. For example, as discussed further in this proposed rule, because the LI NET sponsor is required to have an open formulary, existing Part D requirements on formulary development would not be applicable.

Our proposals to make LI NET a permanent program start with § 423.2500. In § 423.2500(a), we propose the basis of the LI NET program would be based on section 1860D-14 of the Act. We propose in § 423.2500(b) the scope of the LI NET program, which would begin no later than January 1, 2024. Under this program, eligible individuals would be provided transitional coverage for part D drugs. Section § 423.2504 sets forth the LI NET eligibility and enrollment proposals and § 423.2508 proposes LI NET benefits and beneficiary protections. Next, we propose in § 423.2512 the requirements to be an LI NET sponsor and § 423.2516 proposes how the Part D sponsor administering LI NET in partnership with CMS will be selected and the requirements set forth in the LI NET contract to provide services and coverage. Section 423.2518 provides a proposal for intermediate sanctions in the event of contract violations. Section 423.2520 proposes how an LI NET contract would be non-renewed

or terminated. Section 423.2524 lays out our proposals for bidding and determining the LI NET payment rate. Finally, § 423.2536 enumerates the Part D requirements we propose waiving for LI NET.

We propose to align sunsetting the demonstration seamlessly with the start of the LI NET program under this section. Specifically, the LI NET demonstration would continue to operate until December 31, 2023, and the LI NET program would start to operate on January 1, 2024 according to the regulations that we finalize.

2. Eligibility and Enrollment

a. Eligibility

Section 1860D–14(e)(2) of the Act provides that an individual is eligible for LI NET coverage if they: (A) meet the requirements of section 1860D-14(a)(3)(A)(ii) and (iii) of the Act; and (B) have not yet enrolled in a prescription drug plan or an MA–PD plan, or, who have so enrolled, but with respect to whom coverage under such plan has not yet taken effect. This means that to be eligible, the individual would need to be a full-benefit dual-eligible individual or low-income subsidy (LIS) eligible individual as defined at § 423.773 and--

- Not yet be enrolled in a prescription drug plan or an MA-PD plan; or
- Be enrolled but their coverage has not yet taken effect.

Under these requirements, LI NET would be available to all categories of individuals who are LIS-eligible, including:

- Full Subsidy-Full Benefit Dual Eligible (FBDE) individuals, including institutionalized beneficiaries and beneficiaries receiving home and community-based services;
- Full Subsidy-Non-FBDE Individuals, including those who have applied or are eligible for QMB/SLMB/QI or SSI, with income and resource thresholds at or below the amounts set by CMS each year; and
- Partial Subsidy Individuals, including those who have applied and have income and resource amounts below the thresholds set by CMS each year.

We propose to codify at Subpart Y the LI NET eligibility requirements set forth in section 1860D–14(e)(2) of the Act. We propose to establish in paragraph (a) of new § 423.2504 two categories of individuals eligible to enroll in LI NET that encompass the previously noted categories of low-income individuals recognized by Part D. The first category, which we term "LIS-eligible" in proposed paragraph (a)(1), would be composed of individuals whose low-income status has been confirmed either through CMS's data in our system of record or because the individual can demonstrate their current or future low-income status. The second category, which we term "immediate need" in proposed paragraph (a)(2), would consist of individuals whose low-income status has not been confirmed, because CMS's data do not yet reflect the individual's low-income status, but the individual has indicated that they are eligible for the LIS.

We refer to the individuals in the category established in proposed paragraph (a)(2) as "immediate need" because they present at a pharmacy or to the LI NET sponsor in immediate need of a prescription and have no Part D coverage. Ideally, these beneficiaries would be able to show documentation of their pending LIS status, such as a letter received from the State showing the beneficiary's LIS status. However, we do not believe an absence of documentation in hand at the point-of-sale should be a barrier to entry to LI NET for immediate need individuals. This is because our experience in the demonstration is that 80 percent of immediate need individuals do have their eligibility confirmed,[4] and we would not want to turn away these individuals who imminently require access to their prescription drugs. Under the LI NET demonstration, individuals can indicate the likelihood of their low-income status by providing the evidence they have, which can include verbal explanations of why they consider themselves eligible.

We propose in § 423.2504(a)(2) to grant immediate access to covered Part D drugs at the point-of-sale for individuals whose eligibility as defined at § 423.773 cannot be confirmed at the

[4]Of the 80 percent of immediate need LI NET beneficiaries whose LIS status is ultimately confirmed, for 89 percent confirmation was within 10 days, and for 97 percent confirmation was within 21 days. In the demonstration, beneficiaries whose LIS status is not able to be confirmed within 21 days continue to be enrolled in LI NET for two months, but they can no longer fill prescriptions after 21 days.

point-of-sale. Under proposed paragraph (a)(2)(i), immediate need individuals may provide documentation to the LI NET sponsor to confirm LIS eligibility. Documentation could include, but would not be limited to--

- A copy of the beneficiary's Medicaid card that includes their name and eligibility date;
- A copy of a letter from the State or SSA showing LIS status;
- The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call;
- A copy of a State document that confirms active Medicaid status;
- A screen-print from the State's Medicaid systems showing Medicaid status; or
- Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy's patient profile.

Under proposed paragraph (a)(2)(ii), if an immediate need individual's LIS status cannot be confirmed within a period of 2 months, that individual would not be automatically enrolled into a Part D plan. This is the same as current practice under the LI NET demonstration. We solicit comment on the proposal to align the 2 months of enrollment with the ability to fill prescriptions for these immediate need beneficiaries.

We propose in § 423.2504(a)(2)(i) that immediate need beneficiaries whose eligibility cannot be confirmed can continue to fill prescriptions throughout their 2-month enrollment in LI NET. We believe this ensures access to LI NET benefits and is an administratively simple approach as compared with alternative ideas, such as the approach under the demonstration of keeping immediate need beneficiaries with uncertain eligibility enrolled in LI NET but unable to fill prescriptions. We propose in § 423.2504(a)(2)(ii) that if, by the end of an immediate need individual's enrollment in LI NET, neither CMS's systems nor the beneficiary's provision of documentation confirms low-income status, then that individual would not be auto-enrolled into a qualifying standalone Part D plan following their LI NET coverage.

b. Enrollment

Section 1860D-14(e) of the Act does not specify a process for enrollment into the LI NET program. Therefore, in forming our proposed enrollment process, we look to the process used in the demonstration. Under the LI NET demonstration, there are four ways for eligible individuals to be enrolled into the demonstration. They are as follows:

Automatic enrollment. Individuals who are LIS-eligible but do not yet have Part D coverage, and those individuals who have selected a Part D plan but whose enrollment has not taken effect, are enrolled by CMS into the LI NET demonstration unless the beneficiary has affirmatively declined enrollment in Part D.

Point of sale enrollment. Immediate need individuals whose claims are submitted by the pharmacy at the point-of-sale and billed to LI NET are enrolled into the LI NET demonstration by the LI NET sponsor.

Direct reimbursement request. Individuals who are LIS-eligible and who submit receipts for reimbursement for claims paid out of pocket are retroactively enrolled into the LI NET demonstration by the LI NET sponsor, with 36-month retroactive coverage for full dual eligible individuals and those who receive supplemental security income (SSI) benefits.

LI NET application form. Beneficiaries who are not enrolled into LI NET through auto-enrollment, point-of-sale enrollment or via an approved direct reimbursement request may submit an application form to the LI NET sponsor with supporting documentation demonstrating their LIS status. The LI NET sponsor will periodically check for eligibility and enroll applicants once eligibility is confirmed.

The majority of LI NET beneficiaries are enrolled into the LI NET demonstration automatically by CMS; about 90 to 95 percent of LI NET beneficiaries are those we identify in our systems and enroll into the demonstration. To do this, CMS “sweeps” our data monthly to identify all beneficiaries who are--

- Eligible for LIS;

- Eligible for Part D;
- Not enrolled in a Part D plan or receiving the Retiree Drug Subsidy (RDS) or coverage through Veterans Affairs;
- Have not opted-out of Part D enrollment for any reason (for example, because they declined it);
- Not incarcerated, are lawfully present in the US, and do not live in another country; and
- Are not enrolled in a Part C plan that disallows concurrent enrollment in a Part D plan.

Beneficiaries identified in the monthly sweep are automatically enrolled into the LI NET demonstration for that month and the following month. CMS then prospectively enrolls the beneficiary into a traditional Part D plan, with coverage under that plan taking effect immediately after the LI NET coverage ends. This population of beneficiaries includes those who may be gaining Part D eligibility or LIS status but have not made an election into a Part D plan.

A smaller number of beneficiaries, about five to ten percent of LI NET beneficiaries, enroll in the LI NET demonstration outside of the sweeps process. Some enroll at the point-of-sale, as described previously. An even smaller number of beneficiaries contact the LI NET sponsor directly to enroll in the LI NET demonstration. Individuals can submit a request for reimbursement to the LI NET sponsor. If the person is LIS-eligible, the LI NET sponsor enrolls them into the LI NET demonstration and reimburses them for out-of-pocket costs during the duration of their retroactive enrollment. As with an individual who is enrolled at the point-of-sale, the start date of LI NET enrollment would be the first of the month the request is received. There may be individuals who do not have an immediate need for medication and believe they are eligible for LI NET. These individuals can fill out an application form, which allows the LI NET sponsor to periodically check their eligibility and enroll them into LI NET if they become eligible.

Consistent with the enrollment processes under the demonstration, we propose in § 423.2504(b) to codify the ways in which individuals can be enrolled into LI NET: auto-enrollment, point-of-sale for immediate need individuals, direct reimbursement, and LI NET enrollment form.

In § 423.2504(b)(1), we propose that individuals who are LIS-eligible and whose auto-enrollment into a Part D plan (as outlined in § 423.34(d)(1)) has not taken effect will be automatically enrolled by CMS into the LI NET program unless they have affirmatively declined enrollment in Part D per § 423.34(e). LIS-eligible beneficiaries who have made the decision to opt out of enrollment in Part D must take a proactive step to contact CMS for us to record that decision in our systems by placing a flag on the beneficiary's record. Beneficiaries may opt out of Part D enrollment if they have other insurance or do not want to participate as a matter of principle. We assume that a beneficiary who opts out of Part D enrollment would also want to opt out of transitional coverage under the LI NET program. Therefore, proposed § 423.2504(b)(1) would provide that when a beneficiary affirmatively declines enrollment in Part D per § 423.34(e), that would also entail opting out of LI NET enrollment.

In defining "transitional coverage" for LI NET, the statute sets forth requirements for the duration of LI NET coverage under section 1860D-14(e)(3). Section 1860D-14(e)(3)(A) of the Act establishes that "immediate access to covered part D drugs at the point of sale during the period that begins on the first day of the month such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection (a)(3)(A) and ends on the date that coverage under a prescription drug plan or MA–PD plan takes effect with respect to such individual." The starting point of enrollment into LI NET for these types of LIS-eligible beneficiaries, whether they are automatically enrolled or immediate need individuals, is required by statute but the duration of time they prospectively remain enrolled in LI NET is not specified. Under the demonstration, we have typically capped non-retroactive coverage in LI NET to 2 months. Consistent with the statute and with our operations under the demonstration, in § 423.2504(c),

we propose that LI NET enrollment begins on the first day of the month an individual is identified as eligible under § 423.2504 and ends after 2 months.

Section 1860D-14(e)(3)(B) of the Act sets a limit on how far back retroactive LI NET coverage can extend. Full-benefit dual eligible individuals (as defined in section 1935(c)(6)) and recipients of supplemental security income (SSI) benefits under title XVI) are eligible for up to 36 months of retroactive coverage. In proposed § 423.2504(c)(2), retroactive LI NET coverage would begin on the date an individual is identified as full-benefit dual or an SSI benefit recipient, or 36 months prior to the date such individual enrolls in (or opts out of) Part D coverage, whichever is later. This duration of time is similar to retroactive coverage under the demonstration, which provides for a maximum retroactive period of 36 months for Full Subsidy LIS eligible individuals.[5] As with LI NET beneficiaries without retroactive coverage, we propose that LI NET coverage would end with enrollment into a Part D plan or opting out of Part D coverage.

We propose in § 423.2504(d) that enrollment in LI NET would end on the date that coverage under Part D takes effect, consistent with section 1860D-14(e)(3) of the Act. In the case of immediate need beneficiaries for whom LIS-eligibility is not confirmed and who are not enrolled into a PDP, enrollment would end 2 months after the immediate need enrollment begins. No matter the method of enrollment, we propose that the minimum duration of LI NET enrollment is 2 months unless the beneficiary elects to disenroll from LI NET or to enroll in a Part D plan. For example, an individual whom we auto-assign into LI NET starting April 1, 2024 would remain in LI NET for April and May 2024 before being enrolled into an appropriate Part D plan starting June 1, 2024.

We provide two beneficiary examples to further explain how LI NET enrollment and

[5]The LI NET demonstration provides an exception to the 36-month maximum period of retroactive enrollment if there is a Medicaid determination within the last 90 days that confers Medicaid eligibility going back further than 36 months. In these situations, LI NET enrollment under the demonstration goes back to the start of Medicaid eligibility. We are not proposing an exception to the 36-month limit on retroactive coverage in this rulemaking as the statute does not provide for such an exception.

disenrollment would work under our proposals:

Example 1: Beneficiary Kristy is a full-benefit dual eligible and arrives at a pharmacy on May 5, 2024, with documentation showing that her LIS application is pending. She would have immediate coverage in LI NET for May and June 2024. If, in the course of adjudicating her LIS application, it is discovered that she was actually LIS-eligible dating back to January 2016, Kristy would be retroactively enrolled in LI NET as of July 1, 2021, which is the later of 36 months prior to the date she is enrolled in a Part D plan or the date she was first LIS eligible (since January 2016 is more than 36 months prior to her Part D plan enrollment, her retroactive coverage under LI NET is capped at 36 months prior to such enrollment). Kristy's LI NET coverage would end June 30, 2024, upon her enrollment into a benchmark PDP starting July 1, 2024, unless she makes the choice to opt-out.

Example 2: The Social Security Administration notifies CMS in February 2024 that Beneficiary Ravi was eligible for both Medicare and SSI starting in November 2022. CMS provides Ravi retroactive Medicare drug coverage from November 2022, which is the later of 36 months prior to enrollment in a Part D plan or the date Ravi was first LIS eligible, through March 2024. After March 2024, if Ravi does not actively enroll in a plan of their choosing, CMS would randomly enroll them into a benchmark PDP with an April 1, 2024 effective date.

As noted previously, our goal in the proposals is to match current eligibility and enrollment policy in effect in the demonstration and the Part D program, to the extent the statute permits. We seek comment on whether revised or additional regulations are required to achieve accurate, streamlined, and beneficiary friendly eligibility determinations and enrollment in the LI NET program.

3. Benefits and Beneficiary Protections

Section 1860D-14(e)(4)(B)(i) of the Act requires the LI NET program to provide eligible beneficiaries with access to all Part D drugs under an open formulary. The statute, at clauses (ii) and (iii) of section 1860D-14(e)(4)(B) of the Act, also requires the LI NET program to permit all

pharmacies that are determined by the Secretary to be in good standing to process claims under the program, and to be consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication. These requirements are consistent with how the LI NET demonstration has operated, and we propose to codify the requirement that the LI NET program provide access to all Part D drugs under an open formulary in § 423.2508(a). We propose in § 423.2508(b) to require the LI NET sponsor to permit all pharmacies that CMS determines to be in good standing to process claims under the program, whether or not the pharmacy is a network or out-of-network (OON) pharmacy for the LI NET sponsor. Under the demonstration, we consider a pharmacy, including retail, mail-order, and institutional pharmacies, to be "in good standing" when it is licensed and does not have a fraud, waste, or abuse determination against it. For the permanent LI NET program, we propose that a pharmacy would be in good standing if it is licensed, has not been revoked from Medicare under § 424.535, does not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act and from Medicare under section 1156 of the Act (unless the OIG waives the exclusion, which the OIG has authority to do in certain specified circumstances), and does not appear on the preclusion list as defined in § 423.100. A pharmacy will appear on the preclusion list if it:

- Is currently revoked from Medicare, is under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program, including LI NET;
- Has engaged in behavior for which CMS could have revoked the entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program, including LI NET; or
- Has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program, including LI NET.

In § 423.2508(c), we propose requirements we consider necessary to improve patient safety and ensure appropriate dispensing of medication consistent with subpart D of the Part D regulations. Existing Part D requirements related to appropriate dispensing, patient safety, electronic dispensing, quality improvement organization (QIO) activities, compliance, and accreditation would improve patient safety and appropriate dispensing. Specifically, we propose to apply the following provisions to the LI NET program and LI NET sponsor, as appropriate:

- § 423.153(b) and (c) for dispensing and point-of-sale safety edits.
- § 423.154 for appropriate dispensing of prescription drugs in long-term care facilities.
- § 423.159, requiring an electronic prescription drug program.
- § 423.160, excepting the requirements pertaining to formulary standards in § 423.160(b)(5), setting forth standards for electronic prescribing.
- § 423.162, for quality improvement organization (QIO) activities.
- § 423.165, regarding compliance deemed on the basis of accreditation.

We solicit comment on whether any of these provisions would not be compatible with the LI NET program proposed in this rulemaking.

Section 1860D-14(e)(4)(B)(iv) of the Act provides the Secretary the authority to establish requirements for the LI NET coverage provided to LI NET eligible individuals. We draw upon our experience under the demonstration to propose cost sharing and appeals policy for LI NET in sections § 423.2508(d) and (e), respectively.

We propose in § 423.2508(d)(1) that LI NET beneficiaries under § 423.2504(a)(1) (that is, beneficiaries whose LIS-eligibility is established and who have not yet enrolled in a prescription drug plan or MA-PD plan, or who have enrolled in a prescription drug or MA-PD plan but coverage under such plan has not yet taken effect) would pay the applicable cost sharing for their low-income category as established in the yearly Announcement of Calendar Year Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Rate Announcement publication specified in § 422.312). Under the demonstration, LI NET

beneficiaries pay the reduced cost-sharing aligned with the LIS categories defined in the Part D program. Because there is already the existing statutory requirement for CMS to update the parameters for the LIS benefit each year using statutory indexing methods, and because CMS and pharmacy systems are already set up to reflect the appropriate cost-sharing based on the LIS category of the individual, we believe it is reasonable to calculate and charge cost-sharing in alignment with the Part D LIS categories. For immediate need beneficiaries, we propose in § 423.2508(d)(2) these individuals would by default pay the cost-sharing associated with the category of non-institutionalized FBDE individuals with incomes above 100 percent of the Federal poverty level and full-subsidy-non-FBDE individuals (that is, Category Code 1). Of the four LIS eligibility categories, this category has the highest level of cost-sharing. Proposed § 423.2508(d)(2) would further provide that if the beneficiary is later confirmed to belong to a different LIS category, the beneficiary would be refunded by the LI NET sponsor for the difference between the cost sharing they paid versus what they would have paid in their confirmed LIS category. This approach allows for the least government liability for individuals whose LIS eligibility is unable to be confirmed while still allowing prescription drug access for immediate need individuals.

We propose in § 423.2508(e) that LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of the Part D regulations. The established processes would adequately adjudicate LI NET beneficiary concerns. This approach of using existing processes avoids needing to devote resources to establishing separate grievance, coverage determinations. Furthermore, consistency with other Part D contracts as it relates to grievances, coverage determinations, and appeals would be simplest for LI NET sponsors.

4. LI NET Sponsor Requirements

Section 1860D-14(e)(4)(A) of the Act specifies that, as determined appropriate by the Secretary, the LI NET program is to be administered through a contract with a single

administrator. Since the beginning of the demonstration, CMS has had one Part D sponsor serve as the sole contractor for administering the program. We have found that this approach supports our goal of administrative simplicity by making it unnecessary for each individual plan sponsor to check eligibility and conduct a retroactive enrollment/reimbursement process. In our experience, the benefits of having a single Part D sponsor administer LI NET include the following:

- Providing a single point of contact for beneficiaries and pharmacies attempting to have their claims paid.
- Providing a single point of contact for State Medicaid agencies submitting Medicaid eligibility and attempting to reconcile and coordinate claims.
- Simplifying the filing of retroactive beneficiary claims.

There may be circumstances in which CMS may want to consider contracting with more than one Part D sponsor to administer LI NET. Though we have had stability in LI NET in terms of only having the single LI NET sponsor for the duration of the demonstration, we recognize the need for some protections should it become necessary for another entity to take over as LI NET sponsor and assume responsibility for providing LI NET coverage. The downside of consolidating LI NET functions into a single sponsor is the potential for beneficiary impact should there be a reason that the single LI NET sponsor no longer continues its functions. We believe that this potential of beneficiary impact is mitigated by our proposals to non-renew or terminate the LI NET contract, which are discussed in greater detail in section II.D.5. of this proposed rule, titled "Contractor Selection and Contracting Guidelines." Accordingly, while we propose at new § 423.2512 that the program will be operated by "one or more" Part D sponsors, we intend to initially continue with the current practice of operating the program through a single sponsor because we determined the benefits outweigh potential beneficiary impacts, which have not come to bear since the start of the demonstration in 2010.

We propose to establish at § 423.2512 the requirements the LI NET sponsor must meet when administering the LI NET program.

- Because LI NET may enroll beneficiaries from across the nation, we propose to specify at § 423.2512(a)(1) that the LI NET sponsor(s) would be selected from among the Part D sponsors with a national presence, with an established contracted pharmacy network in all geographic areas of the United States in which LIS is available, which as of the date of this proposed rule is the 50 States and the District of Columbia. Because LIS is not available in the territories, CMS would not require the LI NET sponsor to have network pharmacies in territories. LI NET beneficiaries could still access LI NET benefits while in the territories if needed, however, through out-of-network pharmacies.

- We find that some experience as a Part D sponsor should be a pre-requisite for being an LI NET sponsor, and propose at § 423.2512(b) that any candidates to be an LI NET sponsor have a minimum of 2 consecutive years contracting with CMS as a Part D sponsor.

- We propose at § 423.2512(c) some technical and operational requirements of the LI NET sponsor. In § 423.2512(c)(1) and (c)(2) we propose that the LI NET sponsor have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees and the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees. In § 423.2512(c)(3), we propose requiring the LI NET sponsor to identify, develop, and implement outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program. Under the demonstration, CMS enrolls over 90 percent of LI NET beneficiaries into the LI NET plan and we expect CMS would continue to be responsible for most enrollees in a permanent LI NET program. For the beneficiaries who are not auto-enrolled, outreach is important so that stakeholders like the states, SHIPs, and pharmacies to have awareness and knowledge about the LI NET program. Under the demonstration, the LI NET

sponsor routinely conducts outreach in consultation with CMS to inform stakeholders about the program. We propose to adopt this approach for the permanent LI NET program.

As discussed further in this section of this rule, we propose to waive requirements under §§ 423.128(d)(2)(ii), 423.128(d)(2)(iii), and 423.128(d)(4). We also propose in § 423.2512(c)(4) that the LI NET sponsor be required to establish and manage a toll-free customer service telephone line and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf, for purposes that include but are not limited to: handling inquiries about services under the LI NET program, providing the status of eligibility or claims, and having the ability to accept documentation for evidence of eligibility.

Reimbursement to beneficiaries with retroactive coverage is provided for in section 1860D-14(e)(3)(B) of the Act, as the "amounts that would have been paid under this Part had such individual been enrolled in a prescription drug plan or MA–PD plan." This entails establishing a process for beneficiaries to request and receive such reimbursement. In the demonstration we provide a means for beneficiaries who receive retroactive coverage to submit a direct member out-of-pocket reimbursement request for Part D covered drugs for any past month(s) in which they were entitled to retroactive coverage under LI NET. The LI NET sponsor provides reimbursement to eligible beneficiaries based on the submitted cost minus any applicable copayments. Once the LI NET sponsor receives a written reimbursement request, they follow timeframes that are consistent with those Part D sponsors are already accustomed to in § 423.636(a)(2) when they authorize payment for a benefit due to a reversal in their coverage determination. That is, under the demonstration, the LI NET sponsor has 14 calendar days to reply with whether the claim is eligible for reimbursement, including the reason for denying the request if applicable. If the request for reimbursement is granted, the LI NET sponsor issues the reimbursement no later than 30 days after it determines the claim is eligible for reimbursement. As these timelines have proved workable under the demonstration, we propose in

§ 423.2512(c)(5) that the LI NET sponsor meet these deadlines related to direct reimbursement in the permanent LI NET program.

In § 423.2512(c)(6), we propose requiring the LI NET sponsor to adjudicate claims from out-of-network pharmacies according to the LI NET sponsor's standard reimbursement for their network pharmacies. As the LI NET sponsor must provide access to all Part D drugs under an open formulary, we believe there is the need for some protection against unreasonably high drug costs for OON claims in LI NET. Other Part D sponsors have the option to deny such claims, or to pay OON claims according to their standard reimbursement for their network pharmacies (with beneficiaries paying any difference between the cost of the OON claim the negotiated price). Because this restraint on unreasonable drug costs borne by the Medicare Trust Funds would not otherwise be present for LI NET, we believe a limit on how much the LI NET sponsor can be reimbursed for OON claims is needed.

5. Selection of LI NET Sponsor and Contracting Provisions

Section 1860D-14(e)(6) of the Act authorizes us to implement LI NET without regard to laws relating to the making, performance, amendment, or modification of contracts of the United States as we may determine to be inconsistent with the furtherance of the purpose of Title XVIII. Thus, CMS is not required to follow the Federal Acquisition Regulation (FAR) or the contracting authority used under the Part D program. Neither is CMS required to contract with every qualified plan sponsor to provide LI NET Part D coverage, as we are required to do for qualified plan sponsors providing non-LI NET Part D coverage. If we followed the same approach for LI NET, we could have many points of contact for beneficiaries and pharmacies attempting to have their retroactive claims paid and multiple points of contact for State Medicaid agencies submitting Medicaid eligibility and attempting to reconcile and coordinate claims. This approach would not serve the purpose of providing smooth, transitional coverage for Part D drugs for LI NET eligible individuals through the LI NET program, which is a Part D program under Medicare in Title XVIII.

Using the authority in section 1860D-14(e)(6) of the Act, we propose to follow the contracting approach set forth in proposed § 423.2516 to select the LI NET sponsor for the 2024 plan year and onwards.

In § 423.2516(a), we propose that CMS would appoint a Part D sponsor that meets the requirements at § 423.2512 to serve as the LI NET sponsor. To determine this appointment, we propose that CMS may choose to conduct discussions with potentially eligible entities to establish mutual interest and ability to administer the program. This circumstance could arise if, for example, CMS needs additional information in any particular year to learn more about a Part D sponsor's ability to administer the LI NET program. Under the demonstration, there is a multi-year contract approved by the Office of Management and Budget, and each year CMS and the LI NET sponsor have executed an addendum to the contract that included such information as the payment rates and risk corridors as determined in the final bid. As we consider options for establishing regulations to implement the permanent LI NET program, we find it is appropriate that we bring the LI NET contractor into closer alignment with other contracts in the Part D program by executing an LI NET contract with a Part D plan sponsor each plan year that contains, among other information, payment information for that year. Our expectation is that unless circumstances shift to prompt a change, the existing LI NET sponsor would continue in that role in the succeeding year. Therefore, in § 423.2516(b), we propose selection criteria CMS may use in appointing an LI NET sponsor based on some features of the LI NET program that are related to a Part D sponsor's ability to successfully administer the program. These are--

- Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.34;
- Pharmacy access as outlined in § 423.120;
- Past performance consistent with § 423.503(b), including Star Ratings (as detailed in § 423.186), and previous intermediate sanctions (as detailed in § 423.750); and

- Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536.

As we are proposing that Part D requirements apply to the LI NET program unless waived, we intend for § 423.505 to apply to LI NET, with the exception of § 423.505(k)(6), which we propose to waive in proposed § 423.2536(g). For example, the contract between the LI NET sponsor and CMS would be required to contain provisions in which the LI NET sponsor agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments (see § 423.505(a) and (b)(2)). As another example, consistent with § 423.505(b)(22), the LI NET contract would be required to include a provision in which the LI NET sponsor agrees to use the CMS complaint tracking system to address and resolve complaints received by CMS against the sponsor. Per § 423.505(k), the LI NET contract would also require the LI NET sponsor to submit certifications of data that determine payment as applicable, such as for enrollment and payment information, claims data, bid submission information, DIR data, and overpayments. The only certification the LI NET sponsor would not submit is the one pertaining to data for price comparison under § 423.505(k)(6); we believe this certification is unnecessary given that the LI NET plan is not one for which beneficiaries shop and thus would not be comparing against other plan options based on price considerations. We intend to exclude LI NET from Medicare Plan Finder, consistent with past practice under the demonstration. Therefore, it would not make sense to require certification to data for price comparison purposes, and we propose to waive this requirement in § 423.2536(g).

In § 423.2516(c), we propose that the term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per proposed § 423.2524(c)) to determine payment rates for the upcoming year. This approach has worked well during the demonstration and we see no reason to propose a different approach for the permanent program.

If the LI NET sponsor violates its contract, we propose in § 423.2518 that CMS would have the authority to impose intermediate sanctions as outlined in subpart O of the Part D regulations, just as we would for any other Part D sponsor.

In § 423.2520(a) we propose that if the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS would notify the LI NET sponsor by January 1 of the year before the next contract year. We propose that CMS could non-renew for any reason, without cause, and the LI NET sponsor would not have a right to appeal the non-renewal. To provide CMS the authority to non-renew the LI NET contract with that particular sponsor for any reason with no appeal, we propose in § 423.2536(e) waiving the appeals requirements in Subpart N except for those relevant to a contract termination. As there has only been a single LI NET sponsor for the duration of the demonstration, and we are anticipating a single LI NET sponsor for the permanent LI NET program, we do not want to assume the risk of the appeals process not providing finality by the time an LI NET sponsor would need to begin preparing the LI NET bid. Even if we required the appeals process to be complete by the April timeframe and while the appeal was pending moved forward with selection process, we would be cutting into or needing to forgo entirely the transition time of 3 months we propose in § 423.2520(b) to ensure seamless transition of the LI NET program. Proposing to assume these risks would not further the purpose of the LI NET program being ready and available to provide immediate, current, and retroactive coverage for LI NET enrollees. We note that non-renewal, whether at the election of CMS or the LI NET sponsor, would not have an impact on the sponsor's eligibility to be selected as the LI NET sponsor in future years. As discussed in section II.D.4. of this proposed rule, we intend to initially contract with a single Part D sponsor to administer the LI NET program. Unlike beneficiaries in traditional Part D plans, beneficiaries enrolled in LI NET would not have the option of simply

choosing to enroll in LI NET under a different sponsor. For these reasons, ample notice is needed if the LI NET sponsor does not intend to continue as the LI NET sponsor in the following year. We anticipate that CMS would be able to provide the same amount of notice to the LI NET sponsor if we were contemplating changing the LI NET sponsor for the following year. A decision to non-renew the LI NET contract with a particular Part D sponsor would not bar or prohibit that sponsor from being considered to be the LI NET sponsor in a future year. Any CMS decisions regarding LI NET sponsor selection would have no bearing on a Part D sponsor proceeding with the application process for other, non-LI NET, Medicare prescription drug plans.

In § 423.2520(b), we propose that after a notice of non-renewal, CMS would select a successor LI NET sponsor from among the other eligible entities (as detailed in proposed § 423.2516). Similar to how our multi-year contracts with our contractors require an outgoing contractor to coordinate with any successor contractor during a transition period, proposed § 423.2520(b) would require the outgoing LI NET sponsor to coordinate with the successor LI NET sponsor appointed by CMS for a period of no less than 3 months to ensure seamless transition for LI NET enrollees, including timely transfer of any data or files. All data, files, written materials, and LI NET work products would be considered CMS's property. During the transition period, the outgoing and incoming LI NET sponsors would work together to develop a transition plan, including setting up a training schedule and a schedule of events for a smooth changeover.

There may be exigent circumstances of risk to beneficiaries in which a more immediate termination is warranted. Referencing portions of CMS's immediate termination authority in § 423.509, we propose to establish in § 423.2520(c) that CMS may terminate the LI NET contract immediately if:

- CMS determinates that a delay in termination, resulting from non-compliance with the procedures provided in this Part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the LI NET sponsor, per § 423.509(b)(2)(i)(A);

- The LI NET sponsor has experienced financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to beneficiary health, or otherwise fails to make services available to the extent that such a risk to health exists per § 423.509(b)(2)(i)(B); or

- The LI NET sponsor has had one or more of the issues enumerated in paragraphs (a)(4)(i) and (xii) of § 423.509.

Proposed § 423.2520(d) would provide that if CMS intends to terminate the contract under proposed § 423.2520(c), CMS provides written notice to the LI NET sponsor informing it of its termination appeal rights in accordance with subpart N of this Part.

We expect to identify the LI NET contract as X0001, and advance the plan benefit package number by one each year so that we can update the payment rates in our systems for the new payment year. If the LI NET contract with a particular LI NET sponsor is terminated, we would not discontinue use of the contract number X0001. Instead, we would terminate the relationship with that specific LI NET sponsor to provide LI NET coverage, and continue to allow enrollment under contract X0001.

6. Bidding and Payments to the LI NET Sponsor

Section 1860D-14(e) of the Act does not specify how CMS is to determine the amounts that it pays to the LI NET sponsor under the contract or how payments are to be made. We propose to establish the methodology and formulas that we would use to determine the amounts we pay to the LI NET sponsor under the contract. We use our payment policies under the demonstration, including the bidding requirements, as the basis for the proposed LI NET payment policies in this rule. We do so because LI NET payment activities bear many similarities to those of typical Part D plans, because the infrastructure to pay in this manner is

already established, and because we are proposing that the LI NET sponsor must be a Part D sponsor who would be familiar with these payment activities already, in this proposed rule.

We propose in § 423.2524(a) that CMS payments for the LI NET program would be made from the Medicare Prescription Drug Account, as payments are made to other Part D sponsors.

In § 423.2524(b) we propose requirements related to the LI NET bid. Because most of the provisions in Subpart F would not be applicable to LI NET, we propose to waive Subpart F except for those provisions we propose to apply to LI NET.

Section 423.2524(b)(1) proposes that the submission of LI NET bids and related information will follow the requirements and limitations in Part 423, Subpart F, §§ 423.265(b), (c), (d)(1), (d)(2)(i), (d)(2)(ii), (d)(2)(iv), (d)(2)(v), (d)(4), (d)(6), and (e). This proposal would require the LI NET sponsor to submit a bid and supplemental information in a format specified by CMS, with the same deadline as other Part D bids of no later than the first Monday of June each year. It also gives CMS the ability to request additional information from the LI NET sponsor to support bid amounts, and the ability to require revisions to the submitted LI NET bid before it is accepted. As with other Part D bids, a qualified actuary, whether internal or external to the plan sponsor, would certify the LI NET sponsor's actuarial valuation (which may be prepared by others under the qualified actuary's direction or review). The qualified actuary would need to be a member of the American Academy of Actuaries.

We propose in § 423.2524(b)(2) that the following provisions would apply in the review, negotiation, and approval of the LI NET bid: § 423.272(a), (b)(1), and (b)(4). This would allow CMS to review the LI NET bid, conduct negotiations regarding the terms and conditions of the proposed bid, and approve it only if the bidding LI NET sponsor and the LI NET plan comply with all applicable CMS Part D requirements. As in typical Part D bid reviews, CMS would be able to decline the LI NET bid if it proposes significant increases in cost sharing (§ 423.272(b)(4)). This approach follows the bid process under the demonstration, in which the

LI NET sponsor submits a bid that estimates their costs and includes assumptions for enrollment and utilization based on prior experience. Starting with PY2021, the LI NET sponsor began using an LI NET Bid Pricing Tool (BPT) and accompanying instructions that were adapted from the traditional Part D BPT and instructions. Once the LI NET bid is accepted, we update this information in our systems for the new payment year for the LI NET demonstration. Each year, we advance by one the number designating the current plan benefit package. For example, the contract-PBP was X0001-011 for plan year 2021 and X0001-012 for plan year 2022.

Proposed § 423.2524(b)(3) specifies the basic rule and major components of the LI NET bid, which are the LI NET sponsor's estimate of its revenue needs for Payment Rates A and B, which are discussed in greater detail in proposing § 423.2524(d).

In § 423.2524(c) we propose that CMS would provide advance monthly LI NET payments, on a per-member, per-month (PMPM) basis, equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid submitted annually under paragraph (b) of this proposed section. Paying on a PMPM basis would align with other Part D payments and with our operations under the LI NET demonstration in which we provide a capitated PMPM amount established by the bid for each beneficiary enrolled in the demonstration. Unlike typical Part D monthly payments, the monthly LI NET payment under the demonstration is a PMPM amount that represents the sum of Payment Rates A and B, as determined by the LI NET bid. The bid represents the LI NET sponsor's total expected cost, minus any beneficiary co-pays, and with a reasonable margin that represents the LI NET sponsor's profit. Also, unlike other Part D payments, payments under the LI NET demonstration would not be risk adjusted. Because payments under the LI NET demonstration are cost reconciled (with the exception of risk corridors) and there is no concern about the LI NET sponsor cherry-picking beneficiaries, we use a simpler payment methodology that does not include risk adjustment.

We propose in § 423.2524(c)(1) that Payment Rate A would be a monthly payment for projected administrative costs, constrained by an annual percentage cap set as part of the bid

review and negotiation under § 423.272(a). Payment Rate A would include two elements, as it does under the demonstration. The first would be the LI NET sponsor's estimated administrative costs, which would represent the administrative costs to run the LI NET program inclusive of an amount for the margin, which represents the LI NET sponsor's profit. The second element in Payment Rate A would be the LI NET sponsor's estimated costs to pay pharmacy claims for prescriptions filled by immediate need individuals, for which the LI NET sponsor may not be able to submit a prescription drug event (PDE) record to CMS due to the individual's unconfirmed LIS status. We expect that these are generally the "immediate need" beneficiaries discussed in section II.D.2.a. of this proposed rule (under the heading "Eligibility and Enrollment") who are not confirmed to be LIS-eligible. We propose in § 423.2524(c)(1)(i) that for the 2024 plan year, the LI NET sponsor includes in its bid the assumption that Payment Rate A cannot exceed a 2 percent increase from the prior year's Payment A, which is a figure CMS will provide to the LI NET sponsor. For the 2025 plan going forward, we propose in § 423.2524(c)(1)(ii) the LI NET sponsor will specify their assumption for any increase needed to the prior year's Payment Rate A, submitting justification to CMS in its bid if the cap exceeds 2 percent. Any proposed increase in Payment Rate A from year-to-year would not be able to exceed the percentage cap. Similar to how CMS determines reasonableness in evaluating a plan's anticipated profit in the bid, we would use the same reasonableness standard in setting and negotiating the cap on Payment Rate A in the bid.

In § 423.2524(c)(2), we propose that Payment Rate B would reflect the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit. Payment Rate B would be the estimated actual drug costs minus direct and indirect remuneration (DIR). In the demonstration, we apply risk corridors to Payment Rate B so that excess gains and losses are shared between CMS and the LI NET sponsor. These risk corridors are symmetrical in sharing upside and downside risk, but are narrower than the risk corridors provided for under section 1860D-15(e) of the Act and applicable to other Part D plans. Because the risk corridors in the

demonstration are so narrow, the LI NET sponsor has not assumed as much risk for LI NET as traditional Part D plans assume. CMS has not shared risk on Payment Rate A, in keeping with typical Part D plans for which CMS does not share risk on margin or administrative costs. In 2012, CMS revised the risk corridors under the LI NET demonstration to limit payment adjustments on Payment Rate B. For the portion of a plan's cost for drugs that is between the target amount and the threshold upper limit (101 percent of the target amount), the LI NET sponsor pays 100 percent of this amount. For the portion of the plan's cost for drugs that exceeds the threshold upper limit, the government pays 99.9 percent and the plan pays 0.1 percent. Similarly, if a plan's cost for drugs is between the target amount and the threshold lower limit (99 percent of the target amount), the LI NET sponsor keeps 100 percent of the difference between the drug cost and the target amount. If a plan's cost for drugs is lower than the threshold lower limit, the government keeps 99.9 percent and the plan keeps 0.1 percent of the difference between the plan's drug cost and the threshold lower limit.

Both under the demonstration and for other Part D plans, after a payment year is over and the deadline for submitting payment data for that payment year has passed, we reconcile the payments for the year. This allows us to narrow the gap between what predicted and actual costs were in a given year, as well as share risk with plan sponsor in gains and losses. To provide for payment reconciliation and risk sharing in the LI NET program, we propose in § 423.2524(d) to establish the payment policies for reconciliation and risk corridors, including adopting targeted provisions of existing risk sharing requirements. Proposed § 423.2524(d)(1) provides that CMS would conduct LI NET payment reconciliation each year for Payment Rates A and B after the annual PDE data submission deadline has passed and make the resulting payment adjustment consistent with § 423.343(a).

In § 423.2524(d)(2), we propose to establish the same risk corridors for Payment Rate B that apply under the demonstration: no risk sharing within 1 percent of the target amount and symmetrical 0.1 percent risk sharing beyond the 1 percent corridor. To carry out risk sharing as

part of reconciliation, we propose to have § 423.336(c) apply to LI NET, which requires a plan sponsor to provide necessary cost data information to CMS and authorizes CMS to make either lump-sum payments or adjustments based on the risk corridor calculations.

Proposed § 423.2524(e) would establish that the LI NET contract is subject to the existing provision at § 423.346 pertaining to payment reopenings. Per § 423.346, CMS may reopen and revise an initial or reconsidered final payment determination for up to 5 payment years. Under the demonstration, each LI NET reconciliation has been in alignment with § 423.346 and included the prior 5 years of PDEs. The most recently completed payment year gets reconciled for the first time along with reopening the prior 4 years. For example, in 2019, PBP 008 for payment year 2018 was reconciled for the first time while PBPs 004-007 (for payment years 2014 through 2017) were reopened. Sequestration is not used or accounted for in reconciliation, consistent with how we apply sequestration for other Part D plans. Under the demonstration, we maintain consistency between LI NET's PDE and DIR reporting deadlines and the reporting deadlines that apply to Part D plans (for example, the yearly deadline for data used for payment year reconciliation is June 30th). Enrollment, risk adjustment, and PDE certifications (attestations) are collected under the LI NET demonstration just like other contracts, and we propose to adopt the requirements in § 423.505(k)(1) through (5), except for certifying to reinsurance data because LI NET does not receive a reinsurance subsidy. This proposal would require the LI NET sponsor to certify to the accuracy, completeness, and truthfulness of all data related to payment.

As noted earlier in this section of this proposed rule, as a general matter, all payment rights and responsibilities under Part D that otherwise apply and are not explicitly waived in proposed § 423.2536 would apply to the LI NET program, as appropriate. Proposed § 423.2524(f) would provide that the LI NET sponsor could appeal the payment calculation under § 423.350. Proposed § 423.2524(g) would establish that the LI NET contractor is subject to the "report and return" overpayment requirements under § 423.360.

7. Part D Program Waivers

Because the LI NET sponsor is a Part D sponsor and the LI NET contract is a PDP contract, many existing provisions in Part 423 apply to LI NET. The exceptions are those provisions waived by the statute, those provisions that are inapplicable to LI NET, and the requirements we propose to waive through this rulemaking.

The LI NET statute at section 1860D-14(e)(5)(A) of the Act provides that paragraphs (1) and (3)(B) of section 1860D-4(a) of the Act, subparagraphs (A) and (B) of section 1860D-4(b)(3) of the Act, and paragraphs (1)(C) and (2) of section 1860D-4(c) of the Act do not apply to the LI NET program; thus, requirements relating to dissemination of general information and the provision of formulary information, formulary requirements, and medication therapy management (MTM) program requirements do not apply to LI NET. For this reason, we propose to waive formulary requirements in §§ 423.120(b), 423.128(e)(5), and 423.128(e)(6) and MTM program requirements in § 423.153.

Section 1860D-14(e)(5)(B) of the Act contains broad waiver authority to "waive such other requirements of title XI and this title as may be necessary to carry out the purposes of the program established under this subsection". We also propose to waive for LI NET some of the cost control and quality improvement requirements in Part 423 Subpart D, except for the provisions we explicitly propose to adopt in § 423.2508(d)(1) through (d)(5) that relate to appropriate dispensing, patient safety, electronic dispensing, QIO activities, compliance, and accreditation. This proposal would waive requirements that would not make sense in the context of temporary coverage with access to an open formulary. The requirements we propose to waive pertain to drug utilization management programs, medication therapy management programs, and consumer satisfaction surveys.

We solicit comment on whether we should waive any additional regulatory provisions related to paragraphs (1) and (3)(B) of section 1860D-4(a) of the Act and subparagraphs (A) and (B) of section 1860D-4(b)(3) of the Act.

As discussed in section II.D.4. of this proposed rule, we are proposing that the LI NET sponsor submit most of the certifications listed in § 423.505(k), with the exception that we are waiving the certification of accuracy of data for price comparison in paragraph (k)(6), given that the LI NET plan is not one for which beneficiaries shop.

Part D beneficiaries receiving a low-income subsidy are not eligible for the coverage gap discount program, and under the demonstration LI NET was not subject to coverage gap discount requirements under subpart W of Part 423. Thus, we propose in § 423.2536(i) to waive subpart W in full for LI NET.

We propose in § 423.2536(j) to waive the MLR requirements in subpart X of Part 423.

Section 1857 as incorporated into 1860D-14(e) of the Act does not speak to MLR requirements for LI NET. Under the LI NET demonstration, CMS does not require the LI NET sponsor to meet the minimum medical loss ratio (MLR) requirement or to report the MLR for the LI NET contract as it does for other Part D contracts. This is due to the unique payment structure for the contract. Under Part D, a sponsor submits a single bid including estimated administrative costs, returns on investment, and drug costs, which are risk-adjusted. After a payment year concludes, Part D sponsors are required under subpart X of Part 423 to report the MLR for each contract, and if the MLR for a contract is below 85 percent, the sponsor is required to remit payment to CMS. Enrollment sanctions are applied to contracts that fail to meet the minimum MLR requirement for three3 consecutive years, and contracts that fail to meet the requirement for 5 consecutive years are subject to termination. The minimum MLR requirement is intended to create incentives for Part D sponsors to reduce administrative costs such as marketing costs, profits, and other such uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. Because of the limits we are proposing to place on how much administrative costs in LI NET under Payment Rate A can increase year over year and because of the differing payment structure, we do not believe MLR reporting should be applicable to LI NET.

The Affordable Care Act amended section 1893(h) of the Act to expand the use of Recovery Audit Contractors (RACs) to include the MA and Part D programs. Section 1893(h)(9) of the Act specifies that, under contracts with the Secretary, Part D RACs are required to ensure that each PDP has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan, to examine claims for reinsurance payments to determine whether PDPs submitting such claims incurred costs in excess of the costs allowed, and to review estimates submitted by PDPs with respect to the enrollment of high-cost beneficiaries and compare such estimates with the numbers of such beneficiaries actually enrolled by such plans. Because the LI NET sponsor must enroll every eligible LI NET beneficiary, and because LI NET does not receive reinsurance, a Part D RAC's review or examination of LI NET claims would likely be extremely limited in scope. As other audit, oversight, and compliance requirements would continue to apply to the LI NET program, the other program integrity safeguards we have proposed for the LI NET program would be adequate, and we therefore propose to waive application of the RAC requirements in subpart Z of Part 423.

In surveying the items under Part 423 for the Voluntary Medicare Prescription Drug Benefit, we attempted to categorize existing requirements as applicable, inapplicable, or a candidate for waiver. We solicit comment on whether there are additional provisions in part 423 that we have not mentioned in this proposed rule and that we should address for LI NET.

8. Technical Corrections

In the course of this rulemaking, we noticed the need for a technical correction in § 423.505(b)(22), which requires Part D sponsors to address and resolve complaints received by CMS against the Part D sponsor. The regulation text currently refers to MA organization when it should refer to Part D sponsor, and thus we propose to make the correction.

We also propose to make a technical correction in the header of subpart Z of Part 423. The header in regulation text currently is "Recovery Audit Contractor Part C Appeals Process"

when it should be referring to Part D. Thus, we propose to make the technical correction so the header correctly reads, "Recovery Audit Contractor Part D Appeals Process."

E. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)

The Part D low income subsidy (LIS) helps people with Medicare who meet certain statutory income and resource criteria pay for prescription drugs and lowers the costs of prescription drug coverage. Individuals who qualify for the full LIS receive assistance to pay their full premiums and deductibles (in certain Part D plans) and have reduced cost sharing. Individuals who qualify for the partial LIS pay reduced premiums (on a sliding scale based on their income) and also have reduced deductibles and cost sharing.

Currently, in order to qualify for the full subsidy, an individual must live in 1 of the 50 States or the District of Columbia and meet the income and resource standards established in at section 1860D-14(a)(3)(D) of the Act and codified at § 423.773. To be eligible for the full subsidy, individuals must have countable income below 135 percent of the Federal poverty level (FPL) for the individual's family size. In addition, an individual must have resources that do not exceed three times the resource limit under section 1613 for applicants for Supplemental Security Income (SSI) under title XVI. The resource limit increases annually by the percentage increase in the Consumer Price Index (CPI, all items, U.S. city average) as of September for the year before and is rounded to the nearest multiple of $10. The resource limits in 2006 (at the start of the Part D benefit) were $6,000 for a beneficiary who was single or $9,000 if the beneficiary was married, and in 2022 the amounts are $8,400, if single, or $12,600, if married.

Individuals who are not eligible for the full LIS subsidy may be eligible for the partial LIS subsidy if they live in 1 of the 50 States or the District of Columbia and have incomes below 150 percent of the FPL for their family size and have resources that do not exceed the amounts specified in section 1860D-14(a)(3)(E)(I) of the Act. Similar to the resource limits for the full subsidy group, these amounts are increased annually by the percentage increase in the CPI as of

September for the year before and rounded to the nearest multiple of $10. The resource limits for the partial subsidy in 2006 were $10,000 for a beneficiary who was single or $20,000 if the beneficiary was married, and the limits in 2022 are $14,010, if single, or $27,950, if married.

Section 11404 of the Inflation Reduction Act (IRA) (Pub. L. 117-169), enacted on August 16, 2022, amended section 1860D-14 of the Act to expand eligibility for the full LIS subsidy group to individuals with incomes below 150 percent of the FPL and who meet either the resource standard in paragraph (3)(D) or paragraph (3)(E) of section 1860D-14(a) of the Act, beginning on or after January 1, 2024. This change will provide the full LIS subsidy for those who currently qualify for the partial subsidy.

To implement the changes to the LIS income requirements, we propose to amend § 423.773(b)(1) to add that to be eligible for the full subsidy for plan years beginning on or after January 1, 2024, an individual must have an income below 150 percent of the FPL. To coordinate with this change, we are also proposing to amend § 423.773(d) to specify that the requirement that an individual have an income below 150 percent of the FPL to be eligible for the partial subsidy applies only to plan years beginning before January 1, 2024. This latter change will effectively sunset the partial subsidy income requirements after 2023.

To implement the changes to the resource limits, we propose to amend § 423.773 to state that the current resource limits applicable for the full subsidy at paragraph (b)(2)(ii) apply to years 2007 through 2023. We also propose to add a new § 423.773(b)(2)(iii) to state that for years beginning on or after January 1, 2024, the resource limits at paragraph (d)(2) of § 423.773 – the resource standards currently applicable for the partial subsidy – would apply to full subsidy eligible individuals.

Lastly, we propose to amend § 423.780(d) to specify that the sliding scale premium amounts currently applicable for individuals with the partial subsidy apply with respect to plan years beginning before January 1, 2024. These individuals who have incomes between 135 and 150 percent of the FPL and who meet the resource requirements will now qualify for the full

subsidy beginning in 2024, and will be entitled to a premium subsidy of 100 percent of the premium subsidy amount, as outlined in § 423.780(a).

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

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

1. Introduction

On January 20, 2021, President Biden issued Executive Order (E.O.) 13985: "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," (hereinafter referred to as E.O. 13985).[6] 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. In response, CMS announced its 2022 CMS Strategic Plan, and "Advance Equity" is the first pillar of that Strategic Plan.[7] This pillar emphasizes the importance of advancing health equity by addressing the health disparities that impact our health 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."[8] This is the definition of health equity that we use for all health equity provisions in this proposed rule.

CMS continues to work diligently to identify regulatory actions that can help support CMS's goal to advance health equity or that already address health equity topics but should be expanded in order to meet the increasingly diverse needs of enrollees served by MA organizations. In order to support the Administration's goal of advancing equity for all, it is imperative that we ensure our regulations address topics that enable disadvantaged populations to

[6]https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/
[7]https://www.cms.gov/cms-strategic-plan
[8]https://www.cms.gov/pillar/health-equity

fully access the care that the regulations already allow them to receive. Consequently, we are proposing several regulatory updates in the MA program related to health equity. These proposals include requirements intended to ensure equitable access to MA services, ensure MA provider directories reflect providers' cultural and linguistic capabilities and notate MOUD-waivered providers, ensure MA enrollees with low digital health literacy are identified and offered digital health education to assist them in accessing any medically necessary covered telehealth benefits, and ensure MA organizations incorporate one or more activities into their overall quality improvement program that reduce disparities in health and health care among their enrollees. CMS believes that the proposed changes included in this proposed rule would address health disparities in the MA program and could be essential to more broadly supporting other equity-focused efforts across CMS policies and programs.

2. Ensuring Equitable Access to Medicare Advantage (MA) Services (§ 422.112)

As discussed extensively in section III.A.1. of this proposed rule, E.O. 13985 describes the Administration's policy goals to advance equity across the Federal Government. Currently, § 422.112(a)(8) requires MA organizations that offer coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

As discussed in the interim final rule with comment period titled, "Medicare Program; Establishment of the Medicare+Choice Program," which appeared in the **Federal Register** on June 26, 1998 (63 FR 34968, 34989) (the June 1998 IFC), the goal of this regulatory requirement was to ensure that enrollees with limited English proficiency, limited education, or other socioeconomic disadvantages receive the health care to which they are entitled. This requirement was part of several provisions implementing and setting standards for ensuring access to covered services. CMS later finalized the provision in the final rule titled Medicare Program; Medicare+Choice Program, which appeared in the **Federal Register** on June 29, 2000 (65 FR 40170) (the June 2000 final rule) with a somewhat detailed discussion of the objectives

served by this provision (65 FR 40217 through 40218). The principle objective underlying the current requirement to provide services in a culturally competent manner is to address unique racial and ethnically-related health care concerns. However, the regulation explicitly applies to all enrollees and does not include an exception for any enrollees; therefore, this consideration must be part of an MA organization's work in ensuring that all covered benefits are available and accessible to all enrollees. The regulation applies to "all enrollees" even though specific populations are mentioned as examples of enrollees to whom services must be provided in a culturally competent manner.

In the June 2000 final rule (65 FR 40217), CMS discussed that appropriate care delivery should accommodate the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their caregivers to improve services, strengthen programs, increase community participation and eliminate disparities in health status among diverse population groups; CMS also emphasized the importance for health care providers and administrative staff to possess a set of attitudes, skills, behaviors, and policies that enables the organization to effectively provide services to diverse population groups. While § 422.112(a)(8) already applies to all enrollees, CMS believes that amendments to the current regulatory text would better reflect the broad scope of underserved populations that MA organizations must ensure have access to services provided in a culturally competent manner. As the populations that CMS serves become increasingly diverse, it is imperative to keep regulations updated to ensure broad protections are available that minimize the potential for discriminatory barriers, including any electronic tools that use discriminatory algorithms, to surface. Thus, CMS is proposing the following changes and additions to the regulatory language at § 422.112(a)(8) with an intention to clarify the scope of the existing requirements, consistent with the direction and goals of E.O. 13985. CMS notes that the requirements at § 422.112(a)(8) were originally codified using our authority in section 1852(d) of the Act (concerning access to services) as well as our authority in section 1856(b)(1) of the Act to establish standards under Part C; the intent of this proposal is to update the

regulatory language at § 422.112(a)(8) for clarification purposes rather than to make actual changes in requirements. We continue to rely on sections 1852(d) and 1856(b)(1) of the Act as the basis for § 422.112, including these changes, consistent with the June 1998 IFC and finalization in a February 1999 final rule (64 FR 7981) of these existing requirements.

The current paragraph heading at § 422.112(a)(8), which precedes the existing equitable access provisions, is titled "Cultural considerations." CMS acknowledges that the term "cultural considerations" could create the misconception that the protections of the provisions apply only to some populations and not others. CMS is proposing to revise this heading to "*Ensuring Equitable Access to Medicare Advantage (MA) Services*." The term "equitable access" is a broader and more suitable description for the paragraph, as it does not suggest an emphasis on protecting access to care for one population over another. We believe these changes will more clearly reflect the inclusive nature of the protections MA organizations must guarantee for all enrollees under these provisions.

Additionally, the current regulatory language describes some underserved groups as examples of populations that may require accommodations that are specific to their needs—those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds. Amending the text to identify additional types of underserved groups will provide clarity with regard to the populations MA organizations must accommodate in order to meet requirements for access to services. At § 422.112(a)(8), CMS proposes to replace the phrase "those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds" after the word "including" and to add in its place additional paragraphs listing more examples of underserved populations to whom an MA organization must ensure that services are provided in a culturally competent manner and promote equitable access to services in order to satisfy the existing requirement. The proposed new list would be as follows: (i) people with limited English proficiency or reading skills; (ii) people of ethnic, cultural, racial, or religious minorities; (iii) people with disabilities; (iv) people who identify as lesbian, gay, bisexual, or other diverse

sexual orientations; (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (vi) people who live in rural areas and other areas with high levels of deprivation; and (vii) people otherwise adversely affected by persistent poverty or inequality. CMS notes that MA organizations must provide all enrollees, without exception, accommodations to equitably access services according to applicable statutory, regulatory, and other guidance. These provisions should not be construed to mean that accommodations are required only for enrollees who belong to the groups listed herein.

CMS believes these clarifications are necessary and are consistent with the Administration's goal of ensuring equity across Federal programs, consistent with E.O. 13985. CMS welcomes public comment in response to this proposal.

3. Medicare Advantage (MA) Provider Directories (§ 422.111)

Section 1852(c)(1) of the Act requires an MA organization to disclose, among other things, the number, mix, and distribution of plan providers in a clear, accurate, and standardized form to each enrollee in an MA plan offered by the MA organization at the time of enrollment and at least annually thereafter. We implemented this requirement in a regulation at § 422.111(a) and (b)(3)(i), requiring that an MA organization must disclose the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services, in the manner specified by CMS, to each enrollee electing an MA plan it offers; in a clear, accurate, and standardized form; and at the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period. In addition, under § 417.427, the MA disclosure requirements at § 422.111 also apply to section 1876 cost plans.

CMS has historically interpreted the disclosure requirement at § 422.111(b)(3)(i)—"the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services"—as referring to the provider directory. CMS developed the MA

and Section 1876 Cost Plan Provider Directory Model,[9] a model material created as an example of how to convey the required information to enrollees. In accordance with § 422.2267(c), when drafting their provider directories based on CMS's model, organizations must accurately convey the required information and follow the order of content specified by CMS.

The current provider directory model contains an array of specific required information based on § 422.111(b)(3)(i); we refer to this information collectively as required provider directory data elements. For example, organizations must list only the office or practice location(s) where the provider regularly practices, must clearly identify the capacity in which the provider is serving (that is, specialty type), and must clearly identify whether or not a provider is accepting new patients or provide a notice directing beneficiaries to contact a provider to determine if he or she is accepting new patients. Other examples of required provider directory data elements include up-to-date provider practice names and notations next to providers' listings indicating any restrictions on access. Several of these data elements are tied to how § 422.111(b)(3)(i) requires the organization to disclose information about providers from whom enrollees may reasonably be expected to obtain services; issues of access, including whether the provider is accepting new patients, are integral to whether an enrollee may reasonably be expected to obtain covered services from that provider. In addition, some of these provider directory data elements (for example, restrictions on access notations, accepting new patients indicator) contain important information that organizations should be taking into account to verify that their networks are truly adequate. This enables the organization to ensure that all covered services are available and accessible under the plan, as required by section 1852 of the Act and § 422.112(a).

In addition to the required provider directory data elements, CMS guidance addresses best practices for provider directories, including encouraging organizations to identify non-

[9] The current MA and Section 1876 Cost Plan Provider Directory Model is located at: https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.

English languages spoken by each provider and provider/location accessibility for people with physical disabilities. CMS proposes to codify these two best practices (the latter in terms of deaf or hard of hearing individuals) as a regulatory requirement at § 422.111(b)(3)(i). Specifically, we propose to mirror the Medicaid provider directory requirements at § 438.10(h)(1)(vii) by adding the phrase "each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office" to paragraph (b)(3)(i). This would change these two best practices to required data elements that all organizations must include in their provider directories. Currently, the Medicaid managed care regulation at § 438.10(h)(1)(vii) requires that provider directories for Medicaid managed care plans include information on the provider's cultural and linguistic capabilities, including languages (including American Sign Language (ASL)) offered by the provider or a skilled medical interpreter at the provider's office as well as other information identifying the provider's location, contact information, specialty, and other information important for beneficiaries in selecting a healthcare provider. The proposal here makes use of the precedent established by the Medicaid program and helps move the agency closer to its goal of aligning the various CMS program requirements.

We note that the phrase "cultural and linguistic capabilities" as proposed here for § 422.111(b)(3)(i) refers to the capabilities of a provider (or skilled medical interpreter at the provider's office) to deliver culturally and linguistically appropriate services (CLAS), which are defined by the HHS Office of Minority Health as "services that are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs."[10] As indicated by several research studies, language concordance between providers and limited English proficient individuals is associated with better health outcomes, and so better matching patients with providers who speak the same language is

[10]https://www.minorityhealth.hhs.gov/Assets/PDF/TCH%20Resource%20Library_CLAS%20CLC%20CH.pdf

expected to improve quality of care and reduce disparities.[11] CMS believes this important proposed regulatory change would enhance the quality and usability of provider directories, particularly for non-English speaking enrollees searching for providers who speak their preferred language, for limited English proficient individuals, and for those enrollees seeking providers who use ASL themselves or have an ASL interpreter available in their office.

This proposal does not implement, take the place of, or supersede an organization's or provider's obligations to take reasonable steps to ensure meaningful access to such programs or activities by limited English proficient individuals and appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in such programs or activities, including the provision of oral language assistance services and/or auxiliary aids and services when required by applicable law (section 1557 of the Patient Protection and Affordable Care Act (PPACA) and 45 CFR part 92). We are proposing this new requirement for MA provider directories as a standard for implementing and ensuring compliance with section 1852(c)(1)(C) of the Act and as a necessary and appropriate standard to ensure that MA enrollees have the information they need in order to access covered services from an MA plan.

This proposal is also consistent with the health equity objectives of CMS's first strategic pillar "Advance Equity" under the 2022 CMS Strategic Plan.[12] It supports current CMS efforts to advance health equity by giving enrollees a fair and just opportunity to access health care services regardless of preferred language. Please refer to sections III.A.1. and III.A.2. of this proposed rule for more extensive discussion of health equity issues in the MA program.

To further enhance our requirements for MA provider directories in the area of behavioral health, we also propose to add a new required provider directory data element for

[11]https://pubmed.ncbi.nlm.nih.gov/20878497/;
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2599011;
https://link.springer.com/article/10.1007/s11606-019-04847-5
[12]https://www.cms.gov/cms-strategic-plan

certain providers who offer medications for opioid use disorder (MOUD). Access to MOUD can be life-saving, but too often, patients do not know how to access this type of care. MA enrollees may have little insight as to which providers can provide MOUD. This problem is especially urgent, as overdose deaths from opioids have skyrocketed during the COVID-19 pandemic.[13] Therefore, we propose to require organizations to identify certain providers in their provider directories who have obtained a waiver under section 303(g)(2) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)(2)(B)(i)-(ii)) from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) to treat patients with MOUD (for example, methadone, buprenorphine, naltrexone, naloxone, or Suboxone) and who are listed on SAMHSA's Buprenorphine Practitioner Locator (BPL).[14]

Specifically, we propose to include this new regulatory requirement at § 422.111(b)(3)(i) by adding the phrase "notations for MOUD-Waivered Providers as defined in § 422.116(b)(1)(xxx) who are listed on the Substance Abuse and Mental Health Services Administration's Buprenorphine Practitioner Locator" to paragraph (i). We are using the term "MOUD-Waivered Providers" as section III.B.2. of this proposed rule is proposing to define this term at proposed § 422.116(b)(1)(xxx) as "providers who are waived by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Agency to administer, dispense, or prescribe narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment for opioid use disorder in accordance with section 303(g)(2) of the Controlled Substances Act." Thus, to avoid duplication and ensure consistency in application of the term, at proposed § 422.111(b)(3)(i), we cross-reference the definition at proposed § 422.116(b)(1)(xxx). This proposed change to the content requirements for provider directories would allow MA enrollees to use their provider directories to search for

[13] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[14] https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator

the providers that have special training to provide MOUD and are allowed to administer, dispense, or prescribe the medications in an office setting.

In order for the organization to flag the provider in its provider directory, the provider must: (1) possess a waiver currently approved by SAMHSA and the DEA; (2) have a valid and active "X-number" from the DEA in order to administer, dispense, or prescribe MOUD; and (3) be listed on SAMHSA's BPL (have allowed their practice location to be disclosed publicly).[15] For more information on how providers can become MOUD-waivered providers, see the SAMHSA website.[16] This proposal would require organizations to identify such providers in their provider directories by including notations next to the providers' listings indicating that the providers are able to treat patients with MOUD. No reference to the actual waiver in the provider directory is necessary to provide the necessary notices to the enrollee; however, the organization would need to determine which providers in their network currently have the waiver, have the valid and active "X-number," and are listed in SAMHSA's BPL in order to know which providers to flag in the provider directory as able to treat patients with MOUD. The provider directory would need to include language to indicate the meaning of the MOUD-waivered providers notation, which is that these providers have completed the training so that they may administer, dispense, or prescribe MOUD in an office setting and have agreed to be publicly identified, but that such notations are not inclusive of all providers who may do so.

We believe that this new proposed MA provider directory data element is important and necessary for ensuring access to behavioral health services for MA enrollees. It supports both national and CMS efforts related to behavioral health priorities and strategies, as described in section III.B.1. of this proposed rule. This proposal will help MA enrollees struggling with OUD find providers who can treat them by prescribing MOUD, moving them further along the path towards long-term recovery.

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[15] https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator
[16] https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner

If finalized, CMS intends to monitor organization compliance with the proposed new requirements described here through periodic online provider directory reviews, as CMS deems necessary, and other activities that are consistent with CMS's existing compliance monitoring regarding provider directory requirements.

These proposals to amend § 422.111(b)(3)(i) both codify as new requirements certain existing guidance on best practices and introduce a new provider directory data element. Organizations that do not currently collect data on their contracted providers' cultural and linguistic capabilities or their status as a MOUD-waivered provider may do so by using the same means and methods by which they already collect other information from contracted providers for inclusion in provider directories. Also, organizations would use SAMHSA's BPL to identify approved providers who have allowed their practice location to be disclosed. We expect this proposed provision to impose an additional minimal amount of information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) on organizations in terms of the updating of their existing processes related to provider directories, such as a template, related software, and the added data points for providers. However, we believe this burden does not need to be submitted to the Office of Management and Budget (OMB) based on the currently approved control number 0938-0753 (CMS-R-267), which states: "The additional burden of translating this network into a directory which is posted on the plan website as well as the update and maintenance of this directory is part of the usual and customary normal business activities and as such is exempt from PRA by 5 CFR 1320.3(b)(2)." Consequently, there is no need for review by OMB under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.). In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

In summary, CMS is proposing to add two new requirements to § 422.111(b)(3)(i) that organizations must include providers' cultural and linguistic capabilities and identify certain providers waived to treat patients with MOUD in their provider directories. We solicit comment

on these proposed improvements to the content of MA provider directories. We also refer readers to section III.B.2. of this proposed rule for our proposal to add prescribers of MOUD as a new specialty type to be subject to MA network adequacy evaluation.

4. Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth (§ 422.112)

Telehealth has become increasingly popular and essential to providing access to health care, especially during the COVID-19 Public Health Emergency (PHE). For the purposes of this section of this proposed rule, we are using the term "telehealth benefits" very broadly to encompass covered services that are furnished to the enrollee (that is, the patient) in a different location than where the provider is located; there are multiple categories of covered benefits where this circumstance is present, with additional criteria or requirements applying to different categories of covered benefits when the enrollee and provider are not in the same place at the time the service is furnished. Under the MA program, there are various requirements and options for coverage of telehealth benefits. When original Medicare covers telehealth benefits, such as services described in section 1834(m) of the Act and § 411.78, MA organizations must cover those telehealth benefits as basic benefits, as defined in § 422.100(c). If an MA organization wishes to offer telehealth benefits that go beyond the scope of the original Medicare telehealth benefits that must be covered by every MA plan, MA organizations have the option to offer "Additional Telehealth Benefits" (ATBs) and/or supplemental telehealth benefits. Section 1852(m) of the Act and § 422.135 outline the requirements for ATBs, which are generally services for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act, and the services are furnished when the patient and the physician or practitioner are not in the same location. If an MA organization wishes to offer telehealth benefits that are not covered by original Medicare and are not within the scope of § 422.135, then the MA organization may choose to offer them as supplemental benefits. The requirements for MA supplemental benefits are set forth at section 1852(a)(3) of the Act and §§ 422.100(c)

and 422.102. An MA organization's bid must accurately reflect the covered telehealth service, whether it is covered as an ATB or a supplemental benefit. In addition, during the COVID-19 PHE, MA organizations have been required to take into account the various waivers, amendments to regulations, and other guidance published by CMS, with regard to telehealth benefits. In using the term "telehealth benefits" here, we mean to include all of these various categories of covered benefits. In the regulation text we are proposing here, we use the phrase "covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135" as a means to encompass all of the potential covered benefits included in our broad use of the term "telehealth benefits." As defined in § 422.135, electronic exchange means electronic information and telecommunications technology, which we believe is broad enough to include telecommunications and technologies permitted for covered Part B services under section 1834(m) of the Act and implementing regulations as well as MA ATBs and other supplemental benefits.

In recent years, CMS has seen a significant boost in the offering of telehealth benefits in the MA program. Almost 99 percent of MA plans offered some form of telehealth benefits in contract year 2022, either in the form of ATBs or supplemental telehealth benefits. This is a 16 percent increase since contract year 2018 and a 9 percent increase since contract year 2020, which was the first year MA organizations were permitted to offer ATBs. ATB offerings alone have increased by approximately 39 percent since their inception 2 years ago. The total number of MA enrollees who have access to MA telehealth benefits of any kind has risen from approximately 89 percent in contract year 2018 to nearly 100 percent in contract year 2022.

While the supply and demand of telehealth has clearly grown in recent years, there is evidence that barriers to accessing telehealth leave room to improve health equity in telehealth. The regulatory change we are proposing here is an attempt to improve health equity in telehealth and is consistent with both E.O. 13985 and CMS's first strategic pillar "Advance Equity" under

the 2022 CMS Strategic Plan.[17,18] For purposes of this provision, we are using CMS's definition of health equity, which is included in section III.A.1. of this proposed rule.[19] In developing this proposal, we are also guided by HHS's definition of "health equity in telehealth" as meaning the "opportunity for everyone to receive the health care they need and deserve, regardless of social or economic status. Providing health equity in telehealth means making changes in digital literacy, technology, and analytics, which will help telehealth providers reach the underserved communities that need it the most."[20]

Health equity in telehealth is difficult to attain due to barriers to telehealth access, which may include: lack of video sharing technology (for example, a smartphone, tablet, or computer), spotty or no internet access, lack of housing or private space to participate in virtual visits, few local providers who offer telehealth practices, language barriers (including oral, written, and signed language), the inability to incorporate third party auxiliary aids and services such as live captioners, telehealth software, apps, and websites that are accessible and usable by people with disabilities, and lack of adaptive equipment for people with disabilities along with incompatibility with external assistive technologies used by people with disabilities.[21] These barriers are especially burdensome on populations that may already experience health disparities, such as those who are adversely affected by persistent poverty and inequality, those who live in rural areas, people from some racial and ethnic groups, immigrants, people who identify as LGBTQI+, people with disabilities, older people, limited English proficient individuals, people with limited digital literacy, and people who are underinsured or uninsured. Such underserved communities often lack equitable access to health care, leading to consequences such as: higher

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[17]https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/
[18]https://www.cms.gov/cms-strategic-plan
[19]https://www.cms.gov/pillar/health-equity
[20]https://telehealth.hhs.gov/providers/health-equity-in-telehealth/
[21]Valdez RS, Rogers CC, Claypool H, Trieshmann L, Frye O, Wellbeloved-Stone C, Kushalnagar P. Ensuring full participation of people with disabilities in an era of telehealth. J Am Med Inform Assoc. 2021 Feb 15;28(2):389-392. doi: 10.1093/jamia/ocaa297. PMID: 33325524; PMCID: PMC7717308.
Annaswamy TM, Verduzco-Gutierrez M, Frieden L. Telemedicine barriers and challenges for persons with disabilities: COVID-19 and beyond. Disabil Health J. 2020;13(4):100973. doi:10.1016/j.dhjo.2020.100973

mortality and disease rates, more severe disease and illness, higher medical costs, lack of access to treatment, and lack of access to health insurance.[22]

The existence of communities with low digital health literacy who in turn cannot access telehealth represents a significant obstacle in achieving health equity in telehealth. The World Health Organization defines digital health literacy as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem. Examples of digital health literacy include accessing your electronic health record, communicating electronically with your health care team, ability to discern reliable online health information, and using health and wellness apps."[23] Low digital health literacy can impact an individual's access to or quality of telehealth visits.[24] Evidence shows that those with low digital health literacy tend to be older, lower income, less educated, and Black or Hispanic.[25]

Many older adults with low digital health literacy experience gaps in access to the health care they need, and this is concerning for the MA program, whose enrollee population includes individuals age 65 and older (as well as individuals under age 65 with disabilities). For example, the American Association of Retired Persons (AARP) annual technology survey found that more than half of older adults (age 50 and older) in 2021 indicated they need more digital education, while more than one in three said they lacked confidence when using technology.[26] Of the 32 million Americans who cannot use a computer, approximately one-third are seniors.[27] Further, less than one-third of Medicare beneficiaries over 65 have at-home digital access, and those over age 75 and with less than high school-level education are less likely to use telehealth.[28] For

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[22]https://telehealth.hhs.gov/providers/health-equity-in-telehealth/
[23]https://nnlm.gov/guides/intro-health-literacy
[24]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8464820/
[25]https://nces.ed.gov/pubs2018/2018161.pdf
[26]Kakulla, Brittne. 2021 Tech Trends and the 50-Plus: Top 10 Biggest Trends. Washington, DC: AARP Research, April 2021. https://doi.org/10.26419/res.00420.001
[27] https://www.telehealthequitycoalition.org/improving-digital-literacy-to-improve-telehealth-equity.html
[28]Shah MK, Gibbs AC, Ali MK, Narayan KMV, Islam N

people with disabilities, 15 percent reported not using the internet as opposed to 5 percent in the general population in a Pew Foundation Survey, while 62 percent of people with disabilities as opposed to 81 percent of the general population own their own desktop or laptop computer. [29] Other studies have confirmed a significant gap in digital literacy among people with disabilities.[30] Another survey found that Black, Latino, and Filipino seniors and those 75 years and older are significantly less likely to own devices like computers and smartphones compared to non-Hispanic whites, Chinese, and younger seniors (ages 65–69); this was also true in terms of these groups' respective use of the internet and e-mail, as well as their ability and willingness to use technology for telehealth purposes.[31]

As outlined here, research indicates that older adults, people with disabilities, people from some racial and ethnic groups, rural communities, underserved populations, and those adversely affected by persistent poverty and inequality are all disadvantaged by limited access to modern information and communications technology (sometimes referred to as a digital divide).[32] Individuals with a higher degree of digital health literacy receive more healthcare information, are better equipped to evaluate the quality of information regarding their healthcare, and report higher telehealth usage.[33] Further, individuals with chronic diseases also benefit from digital health literacy; when such individuals possess digital health literacy, they tend to monitor and manage their diseases more competently, are more satisfied with the telemedicine services, and respond faster to changes that might adversely affect their situation, thereby improving their

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Overcoming the Digital Divide in the Post–COVID-19 "Reset": Enhancing Group Virtual Visits with Community Health Workers
J Med Internet Res 2021;23(7):e27682
doi: 10.2196/27682

[29]Andrew Perrin and Sara Atske, *Americans with disabilities less likely than those without to own some digital devices, Pew Research, September 10, 2021*, online at https://www.pewresearch.org/fact-tank/2021/09/10/americans-with-disabilities-less-likely-than-those-without-to-own-some-digital-devices/

[30]Eun Ji Kim, MS, MD,[4] Yiyang Yuan, MS, MPH, Jane Liebschutz, MPH, MD, Howard Cabral, MPH, PhD,[4] and Lewis Kazis, ScD, Understanding the Digital Gap Among US Adults With Disability: Cross-Sectional Analysis of the Health Information National Trends Survey 2013, *JMIR Rehabil Assist Technol*. 2018 Jan-Jun; 5(1): e3. Online at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4799429/.

[31]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4799429/

[32]https://academic.oup.com/jamia/article/27/12/1949/5899728

[33]https://jamanetwork.com/journals/jama/article-abstract/2426088

overall health.[34] This is significant because individuals with two or more chronic diseases are more likely to be individuals 65 and over.[35]

CMS does not currently have requirements for MA organizations in the area of digital health literacy. Given the need to increase digital health literacy in many communities with MA enrollees and the goal to achieve health equity in telehealth, we believe it is necessary to implement regulations addressing digital health literacy in the MA program. CMS expects that these digital health literacy proposals, if finalized, would help underserved communities in need of assistance to improve their digital health literacy and help advance the goal of achieving health equity in telehealth.[36]

We propose to add requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist them with accessing any medically necessary covered telehealth benefits. Specifically, we propose to amend current continuity of care requirements for MA organizations offering coordinated care plans to "ensure continuity of care and integration of services through arrangements with contracted providers" at § 422.112(b), by adding a new paragraph (9). The new proposed paragraph would require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange; we use the term "electronic exchange" as it is broadly defined in § 422.135. This proposed new continuity of care requirement would apply to all MA organizations offering coordinated care plans (that is, HMOs, PPOs, HMO-POSs, and SNPs) and would be relevant for all types of covered telehealth benefits, including basic telehealth benefits, ATBs, and supplemental telehealth benefits offered by MA coordinated care plans. We solicit comment on whether to amend § 422.100 instead of

[34]https://www.sciencedirect.com/science/article/pii/S0738399114001876
[35]https://www.cdc.gov/pcd/issues/2020/20_0130.htm
[36]https://telehealth.hhs.gov/providers/health-equity-in-telehealth/

§ 422.112(b) in order to apply this new requirement to all MA plans and not just coordinated care plans. This proposed additional standard is intended to ensure that MA enrollees are able to access covered benefits and that MA organizations meet their obligations under section 1852(d) of the Act to make covered benefits available and accessible to enrollees in the plan. Section 1856(b) of the Act authorizes the adoption of standards that are consistent with and to carry out the Part C statute. As telehealth benefits become more prevalent in the MA program, taking steps to provide enrollees with digital health education will ensure that these telehealth benefits are truly accessible and available to enrollees.

This proposal would be a first step for MA organizations to assess the landscape of health equity in telehealth in their plans and help enrollees navigate telehealth. Under this proposal, CMS would provide a degree of discretion for MA organizations in the procedures developed and used to identify enrollees with low digital health literacy and the digital health education services the MA organization provides for those enrollees. In order to comply with the proposed new regulation, MA organizations would necessarily have to introduce a digital health literacy screening program or other similar procedure to identify current enrollees with low digital health literacy, however, MA organizations would have flexibility to design their own screening program or procedure. Some experts recommend such an assessment should examine patient-level barriers such as telehealth readiness, broadband access, and inaccessible or unusable information and communication technologies by individuals with disabilities that limit patient use of telehealth.[37] Others recommend considering certain digital foundation skills based on a specific framework.[38] CMS encourages MA organizations to research current trends and successes in the field when developing their own methods to identify enrollees with low digital health literacy. CMS anticipates that some MA organizations could ask enrollees, for example, if they have internet access and reliable connectivity, if they have a device that meets appropriate

[37]https://link.springer.com/content/pdf/10.1007/s00520-021-06629-4.pdf
[38]https://www.digitalinclusion.org/definitions/

telehealth system requirements, if they use e-mail, if they can download a mobile app, or if they can change applicable settings on a device (for example, browser or camera settings), as a means to identify which enrollees have low digital heath literacy.[39]

Once the MA organization determines which enrollees experience low digital health literacy, the MA organization would then have to implement a digital health education program to offer to these enrollees. CMS is not proposing to identify explicit parameters for this digital health education requirement, rather, we have chosen to keep it flexible and allow for innovation in this area by MA organizations. Depending on the specific enrollment in an MA plan, the procedures to identify enrollees and the mechanisms and content of the digital health education could vary. However, some examples of digital health education designs include: distributing educational materials about how to access certain telehealth technologies in multiple languages, including sign language, and in alternative formats; holding digital health literacy workshops; integrating digital health coaching; offering enrollees in-person digital health navigators; and partnering with local libraries and/or community centers that offer digital health education services and supports.

As a best practice, CMS encourages MA organizations to ensure that there are no system requirements (for example, online portal enrollment) that could act as barriers to accessing covered telehealth benefits, or the proposed digital health education for enrollees with low digital health literacy, so as to promote ease of access in the simplest way possible. In addition, if an MA organization offers enrollees assistance with any necessary telehealth technology—for instance, if they provide limited use smartphones/tablets or cellular data plans as supplemental benefits in order to aid in the use of telehealth services—then the MA organization must comply with applicable laws about those benefits and make enrollees aware of these available benefits per section 1852(c)(1)(F) of the Act and § 422.111(b)(6). This disclosure is especially important for enrollees identified as having low digital health literacy. Smartphones and tablets (or other

[39]https://www.telehealthequitycoalition.org/improving-digital-literacy-to-improve-telehealth-equity.html

similar equipment) must only be used for primarily health related purposes (and cellular data plans can only be provided if use of these plans is locked and limited to health-related activities), such as when the device is locked except for remote monitoring or to enable engagement with health care providers, in order for these items and services to be permissible supplemental benefits under § 422.100(c)(2)(ii). However, furnishing or covering a cellular data plan without limitations might be permissible (under section 1852(a)(3)(D) of the Act and § 422.102(f)) as a non-primarily health related special supplemental benefit for the chronically ill (SSBCI) when the benefit is limited to a chronically ill enrollee and has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. For more information on SSBCI, please see the June 2020 final rule and 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 which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) (hereinafter referred to as the January 2021 final rule). CMS encourages MA organizations whose plans have a high number of enrollees with low digital health literacy to consider offering the aforementioned supplemental benefits and pairing an appropriate digital health education program with the provision of such devices to enrollees, where permitted by applicable law.

To further emphasize the importance of health equity and health equity in telehealth specifically, CMS reminds MA organizations that § 422.112(a)(8) as it currently reads requires MA organizations offering coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including limited English proficient individuals or those with limited reading skills, and those with diverse cultural and ethnic backgrounds. CMS is proposing, in section III.A.2. of this proposed rule, to amend § 422.112(a)(8) to better reflect the broad scope of potentially underserved populations and to emphasize how MA plans must ensure equitable access to services. As adopted and with our proposed revisions, § 422.112(a)(8)

requires MA organizations to ensure that services are provided in an equitable manner to all enrollees. MA organizations must take into account these additional obligations, as applicable, when developing and maintaining the digital health education programs they would be required to implement under this proposal. Furthermore, the HHS Office for Civil Rights and the U.S. Department of Justice (DOJ) Civil Rights Division recently published new guidance providing clarity on how Federal nondiscrimination laws require accessibility for people with disabilities and limited English proficient individuals in health care provided via telehealth.[40] These Federal civil rights laws—including the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, title VI of the Civil Rights Act of 1964, and section 1557 of the PPACA—require that telehealth be accessible to people with disabilities and limited English proficient individuals. CMS strongly encourages MA organizations and their contracted providers to review this new guidance issued by HHS and DOJ to ensure compliance with Federal civil rights laws pertaining to telehealth.

In order to monitor the impact of our new proposed requirement for digital health literacy screening and digital health education programs—on MA organizations, providers, enrollees, and the MA program as a whole—we are also proposing to require MA organizations to make information about these programs available to CMS upon request, per proposed § 422.112(b)(9)(i). We propose that this requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of § 422.112(b)(9). The purpose of requiring MA organizations to make such information available to CMS upon request would be to identify best practices for improving digital health literacy amongst MA enrollees and to determine whether CMS should make

[40]https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in-telehealth.pdf

improvements to the regulation and/or guidance regarding this requirement. We note that the regulation text at proposed § 422.112(b)(9)(i) includes the language "upon request," which we intend here to communicate that CMS does not intend to establish uniform data collection from all MA organizations at this time, but instead reserves the right to ask for this information from individual MA organizations. However, we note that our proposed § 422.112(b)(9)(i) would not limit CMS's audit access when program audits review the performance of MA organizations. We solicit comment on this aspect of our proposal and whether we should require regular reporting of data of this type from all MA organizations alongside other Part C reporting requirements.

This proposal to amend § 422.112(b) would impact MA organizations in terms of the burden required to both identify enrollees with low digital health literacy and to develop digital health education programs for these enrollees. However, our estimated analysis of these impacts is qualitative in nature as we are proposing to provide MA organizations flexibility in determining how they wish to implement these proposed CMS requirements. CMS does not currently collect data regarding digital health literacy among MA enrollees and therefore, we have no way of knowing or estimating the extent of low digital health literacy specifically among MA organizations' enrollees, how MA organizations would approach digital health literacy screening and digital health education, how much spending they would engage in related to these efforts, how much savings they would encounter (due to improved enrollee health outcomes because of improved digital health literacy), for example, how much time they would spend on these efforts, or how the MA program would grow as we see the effects of the proposed regulation. We estimate the direct qualitative burden consists of MA organization staff hours spent, resources purchased, and any digital health education for enrollees performed. MA organizations may also differ in how their spending for the proposed requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation. Thus, the proposed provision would impose an unknown amount of information collection

requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) because burden cannot be quantified. We solicit comment from MA organizations on how much burden they expect this proposed provision might add. Regarding the impact of the proposed requirement for the MA organization to make information about its digital health literacy screening and digital health education programs available to CMS upon request, we do not anticipate requesting this information from more than nine MA organizations in a given year. However, we believe it is important to reserve the right to ask for this information if necessary and have structured the proposed regulation text accordingly. Since we estimate fewer than ten respondents, the information collection requirement is exempt (5 CFR 1320.3(c)) from the requirements of the PRA of 1995 (44 U.S.C. 3501 et seq.). Consequently, there is no need for review by OMB under the authority of the PRA.

In terms of economic impact on the Medicare Trust Fund, we do expect that improved digital health literacy would increase telehealth visits, which in turn would increase prevention of MA enrollee illness, both of which affect Medicare Trust Fund spending. Yet we have no way of knowing or estimating how much of an increase in telehealth visits there would be, for what specific services they would increase, or the effects of prevented future illnesses among MA enrollees. Thus, this provision is expected to have an unknown economic impact on the Medicare Trust Fund.

In summary, CMS is proposing to add a new requirement at § 422.112(b)(9) that MA organizations must have procedures to identify enrollees with low digital health literacy and offer them digital health education to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135. In addition, the proposal includes a requirement that MA organizations make information about these programs available to CMS upon request. We solicit comment on this proposal.

5. Quality Improvement Program (§ 422.152)

In accordance with section 1852(e) of the Act, all MA organizations must have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to enrollees. Per § 422.152(a), MA organizations must develop a QI plan that sufficiently outlines the QI program elements; have a chronic care improvement program (CCIP) that meets the requirements at § 422.152(c) and addresses populations identified by CMS based on a review of current quality performance; and, encourage its providers to participate in CMS and HHS quality improvement initiatives.

Section 422.152(c) provides that CCIPs must include methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a CCIP; mechanisms for monitoring MA enrollees that are participating in the CCIP and evaluating participant outcomes, such as changes in health status; performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research, and systematic and ongoing follow-up on the effect of the CCIP. Organizations must report the status and results of each program to CMS as requested. The intent of the CCIPs is to promote effective chronic disease management and improve care and health outcomes for enrollees with chronic conditions. Furthermore, CCIPs should support the CMS Quality Strategy; include interventions that surpass MA organizations' inherent care coordination role and overall management of enrollees; engage enrollees as partners in their care; promote utilization of preventive services; facilitate development of targeted goals, specific interventions, and quantifiable, measurable outcomes; guard against potential health disparities; and produce best practices[41].

In accordance with 1852(e) of the Act, MA organizations are required to report quality performance data to CMS. MA organizations generally report such data through the Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), Consumer Assessment of Healthcare Providers and Systems (CAHPS), and other related data collection

[41]https://www.cms.gov/Medicare/Health-Plans/Medicare-Advantage-Quality-Improvement-Program/5CCIP

tools. As codified at § 422.152(b)(3) and (5), MA coordinated care plans are required to report on quality performance data which CMS can use to help beneficiaries compare plans; MA local and regional PPO plans must similarly report under § 422.152(e)(2)(i). The areas of measurement include outcomes, patient experience, access, and process measures. In addition, CMS uses this information to develop and publicly post a 5-star rating system for MA plans based on its authority to disseminate comparative information, including about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act.

Lastly, to meet the needs of their enrolled special needs populations, MA special needs plans (SNPs) have additional QI program requirements, including the implementation of an approved model of care (MOC), which serves as the framework for meeting the individual needs of SNP enrollees, and the infrastructure to promote care management and care coordination (see § 422.152(g)). As part of the initial MA SNP application and renewal requirements and through MOC submissions, SNPs provide to CMS a detailed profile of the medical, social, cognitive, and environmental aspects, the living conditions, and the co-morbidities associated with the SNP population, including information about health conditions impacting SNP enrollees along with other characteristics that affect health, such as population demographics (for example, average age, sex, gender, ethnicity), and potential health disparities associated with specific groups (for example, language barriers, deficits in health literacy, poor socioeconomic status, cultural beliefs/barriers, caregiver considerations, or other). SNPs must also capture limitations and barriers that pose potential challenges for accessing care and/or maintaining and improving SNP enrollee health status.

Additionally, through health risk assessments (HRAs), SNPs identify the medical, functional, cognitive, psychosocial, and mental health needs of their enrollees, who are all special needs individuals, and address those needs in an individualized care plan for each enrollee. In the final rule titled “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** May 9, 2022 (87 FR 27704), CMS finalized a new requirement for SNPs at § 422.101(f)(1)(i), requiring the HRA tool to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on the domains of housing stability, food security, and access to transportation beginning in 2024. We expect that this data collection would also provide information to MA organizations about potential health disparities among their enrollees.

Persistent inequities in health care outcomes exist in the United States, including among populations enrolled in MA organizations[42]. Belonging to a racial or ethnic minority group, living with a disability, being a member of the LGBTQI+ community, having limited English proficiency, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes. [43 44 45 46 47 48 49] Such disparities in health outcomes are the result of a number of factors and exist regardless of health insurance coverage type. Although not the sole determinant, poor health care access and provision of lower quality health care contribute to health disparities. Research has shown that the expansion of health insurance coverage, for example through Medicaid expansion under the ACA, and the resulting increased access to

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[42]Disparities in Health Care in Medicare Advantage by Race, Ethnicity and Sex, April 2022
[43]Lindenauer, P.K., Lagu, T., Rothberg, M.B., Avrunin, J., Pekow, P.S., Wang, Y., Krumholz, H., & Hines, H. (2013). Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal.
[44]Trivedi, A.N., Nsa, W., Hausmann, L.R.M., Lee, J., Ma, A., Bratzler, D., Mor, M., Baus, K., Larbi, F., & Fine, M. (2014). Quality and Equity of Care in U.S. Hospitals. *New England Journal of Medicine.* 371(24):2298-2308.
[45]Polyakova, M., Udalova, V., Kocks, G., Genadek, K., Finlay, K., & Finkelstein, A.N. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. Health affairs (Project Hope), 40 (2), 307-316. https://doi.org/10.1377/hlthaff.2020.02142.
[46]Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. (2018). Rural Health Research Gateway. https://www.ruralhealthresearch.org/recaps/5.
[47]2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. (2020). HHS Office of Minority Health. https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.
[48]Sexual Orientation Disparities in Risk Factors for Adverse COVID-19-Related Outcomes, by Race/Ethnicity. (2021, February 5). CDC. www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.
[49]Poteat, T.C., Reisner, S.L., Miller, M., & Wirtz, A.L. (2020). COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv: The preprint server for health sciences, 2020.07.21.20159327. https://doi.org/10.1101/2020.07.21.20159327.

health care, is linked to reductions in disparities in health insurance coverage as well as reductions in disparities in health outcomes. [50]

In the final rule titled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023", which appeared in the **Federal Register** May 6, 2022 (87 FR 27208), CMS finalized a proposal to update the quality improvement strategy (QIS) standards for qualified health plan (QHP) issuers, requiring them to address health and health care disparities as a specific topic area within their QIS beginning in 2023. Examples of QIS activities that fall under the health and health care disparities topic area for QHPs can include language services, community outreach, cultural competency trainings, social needs-sensitive self-management recommendations, and increased demographic and disparities-related data collection; see the QIS Technical Guidance and User Guide for the 2023 Plan Year for more information. CMS is committed to advancing health equity for MA enrollees. Based on CMS' definition of health equity and in alignment with similar CMS programs, we believe that MA organizations' QI programs are an optimal vehicle to develop and implement strategies and policies designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved.

MA organizations have long focused on addressing health disparities through QI program requirements. By assessing cultural, language, health literacy, financial, psychosocial & family support, community networks, and transportation needs, etc., and addressing those needs through a variety of QI program activities across their enrollee populations, MA organizations gain insight into their enrollee populations. Some of the specific QI activities include addressing barriers to health care, for example assisting enrollees with transportation to follow-up primary care visits post-hospitalization, linking enrollees to community resources, and improving care coordination and case management, especially for vulnerable and/or underserved enrollees. In

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[50]Guth, M., Garfield, R., & Rudowitz, R. (2020). The Effects of Medicaid Expansion Under the ACA: Studies from January 2014 to January 2020. Kaiser Family Foundation. https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/.

addition to implementing QI activities for the broader enrollee populations, we are aware that some MA organizations have focused their QI activities on underserved groups. For example, to better serve these groups, several MA organizations have made efforts to improve their communication by providing cultural trainings for their staff, tailoring enrollee materials to ensure they are linguistically and culturally appropriate, and hiring plan staff and establishing contracts with providers who are bilingual. Some MA organizations have implemented specific interventions that target blood pressure control, or improved rates for various cancer screenings in targeted groups. These types of activities can improve the health of and healthcare for MA enrollees.

To improve the quality of care and health outcomes for MA enrollees and support the first pillar in the 2022 CMS strategic plan for advancing health equity, CMS proposes to amend the MA QI program regulations at § 422.152(a). Specifically, we propose to amend § 422.152 by adding a new paragraph (a)(5), to require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees. As previously described, we believe that many MA organizations are already addressing disparities and gaps in care for underserved populations through a variety of quality initiatives. Rather than limit these activities to specific QI program requirements such as the CCIPs, we are proposing that MA organizations would be required to incorporate one or more activities that reduce disparities in health and health care across the broad spectrum of QI program requirements. CMS expects that MA organizations may implement activities such as improving communication, developing and using linguistically and culturally appropriate materials (to distribute to enrollees or use in communicating with enrollees), hiring bilingual staff, community outreach, or similar activities. MA organizations should tailor these activities to meet the needs of their enrollees, and therefore CMS is generally not proposing to be prescriptive in the types of activities MA organizations must implement to meet this proposed new requirement. However, MA organizations must ensure that these activities are broadly

accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparity in health or health care. Furthermore, we believe adopting this proposed requirement for MA organizations as part of their required QI programs will align with health equity efforts across CMS policies and programs. CMS believes that several organizations have already incorporated these activities into their QI programs, thereby meeting the proposed requirement.

B. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116)

1. Introduction

On March 1, 2022, President Biden announced a national strategy regarding behavioral health to strengthen system capacity and connect more individuals to care by ensuring that the nation's health and social services infrastructure addresses mental health holistically and equitably.[51] Further, the 2022 CMS Strategic Framework describes CMS' broad goals to expand coverage and enhance access to equitable health care services for those covered under CMS programs.[52] CMS is also prioritizing, as part of the agency's many cross-cutting initiatives, to improve access to behavioral health services and outcomes for people with behavioral health care needs.

According to the Health Resources and Services Administration (HRSA), more than one-third of Americans live in designated Mental Health Professional Shortage Areas,[53] meaning these communities do not have enough providers to meet the needs of their population. Furthermore, according to the results from the 2020 National Survey on Drug Use and Health, published by SAMHSA, while overall 65 percent of people with serious mental illnesses (SMI) receive treatment,[54] people of color with SMI receive care at significantly lower rates. More

[51] https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/
[52] https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf
[53] https://data.hrsa.gov/topics/health-workforce/shortage-areas
[54]https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf

specifically, while approximately 69 percent of white people with SMI received mental health care, for Black, Hispanic, and Asian people with SMI the rates were 55 percent, 56 percent, and 44 percent respectively.[55] The 2020 National Survey results also indicate that common reasons for not receiving treatment for SMI include: inability to afford the cost of treatment, not knowing where to go to receive services, and health insurance not covering services.[56] CMS recently included a request for information (RFI) in the proposed rule titled "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) (hereinafter referred to as the January 2022 proposed rule), to solicit public comment regarding the challenges that exist with accessing behavioral health providers within MA plans. We sought stakeholders' input concerning a range of topics, including the challenges related to building behavioral health networks for MA plans, accessing behavioral health providers for MA enrollees, and requesting suggestions on how to address issues with building adequate behavioral health networks within MA plans. We received a number of comments from stakeholders, some of which are discussed later in this preamble in connection with specific proposals.

CMS continues to evaluate and seek ways to enhance our behavioral health policies to address the healthcare needs of those we serve. In order to support these goals, we are proposing regulatory changes that focus on ensuring access to behavioral health services for MA enrollees.

We welcome comment on our proposals.

2. Behavioral Health Specialties in Medicare Advantage (MA) Networks (§§ 422.112 and 422.116)

Section 1852(d)(1) of the Act permits 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

[55]https://www.samhsa.gov/data/sites/default/files/reports/rpt35324/2021NSDUHMHChartbook102221B.pdf
[56]https://www.apa.org/monitor/2020/07/datapoint-care

with promptness and in a manner which assures continuity in the provision of benefits. To implement and adopt related standards for this, CMS codified, with some modifications, network adequacy criteria and access standards that were previously outlined in sub-regulatory guidance 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. Although § 422.116(b)(3) authorizes removal of a specialty or facility type from the network evaluation criteria for a specific year without rulemaking, CMS did not adopt in § 422.116 a mechanism to add new provider types without rulemaking. We are proposing to add to the list of provider specialties here to address access to behavioral health services more broadly than the current regulation.

Currently, MA organizations are required to demonstrate that they meet network adequacy for two behavioral health specialty types, psychiatry and inpatient psychiatric facility services, under § 422.116(b). Further, the regulation at § 422.112 includes a number of requirements to ensure that MA enrollees have adequate access to covered services. Of note, § 422.112(a)(1) requires MA organizations to maintain and monitor a network of appropriate providers that provides access to typically used services including, primary care providers, specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics and other providers.

In response to the RFI in the January 2022 proposed rule, we received comments emphasizing the importance of network adequacy and ensuring adequate access to behavioral health providers in MA plans. Stakeholders suggested that CMS expand the network adequacy time and distance standards for MA plans beyond those that we currently review through our network adequacy evaluations. Commenters suggested that we expand the standards to add other

outpatient behavioral health physicians and health professionals, including those that treat substance use disorders (SUDs), that can meet MA enrollees needs in accessing behavioral healthcare.

Even though over one million Medicare beneficiaries had a diagnosis of Opioid Use Disorder (OUD) and more than fifty thousand experienced an overdose in 2021, fewer than 1 in 5 of these Medicare beneficiaries with a diagnosis of OUD receive treatment for their OUD.[57] Current standards of care for OUD include treatment through three Food and Drug Administration (FDA) approved medications (buprenorphine, naltrexone and methadone), along with other services to provide the best approach to treating SUD. Enrollees can access Medications for Opioid Use Disorder (MOUD) in various settings including in Opioid Treatment Programs (OTPs) and through qualified practitioners (physicians, nurse practitioners, physician assistants, etc.) who have obtained a waiver through SAMHSA to dispense these medications in office settings.

CMS is committed to ensuring that MA enrollees have access to provider networks sufficient to provide covered services, including access to behavioral health service providers. Medicare fee-for-service claims data for 2020 shows that for certain outpatient behavioral health services, the top provider specialty types to provide services to beneficiaries included psychiatrists, clinical social workers, nurse practitioners, and clinical psychologists. OTPs had the largest number of claims for SUD in this same time period. Therefore, we propose to strengthen our network adequacy requirements for MA plans as it relates to behavioral health in three ways.

First, we propose to add three new provider specialty types to the list at § 422.116(b)(1), requiring these new specialty types to be subject to network adequacy evaluation. The three new specialty types we propose to add are: (1) clinical psychology, (2) clinical social work, and (3)

[57]https://oig.hhs.gov/oei/reports/OEI-02-22-00390.pdf

one category called Prescribers of Medication for Opioid Use Disorder that includes two specialty types: providers with a waiver under section 303(g)(2) of the Controlled Substances Act (CSA) and OTPs. Most of these new specialty types are defined the same way as they are used for the original Medicare program in section 1861(hh) of the Act (defining "clinical social worker"), § 410.71(d) (defining "clinical psychologist"), and section 1861(jjj)(2) of the Act (defining "Opioid Treatment Program"). Section 303(g)(2)of the CSA (21 U.S.C. 823(g)(2)(G)(ii)) establishes which providers have a waiver and we do not believe a definition in the MA regulations at 42 CFR part 422 is necessary.

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 provider specialty types under § 422.116(b)(1), we are proposing base time and distance standards and minimum number of in-person providers in each county type for each new specialty type as follows:

Maximum Time and Distance Standards:

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
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
Clinical Social Work	20	10	30	20	50	35	75	60	125	110
Prescribers of Medication for Opioid Use Disorder (including MOUD Waivered Providers and/or OTPs)	20	10	30	20	50	35	75	60	110	100

Minimum Ratios:

Minimum Ratio	Large Metro	Metro	Micro	Rural	CEAC
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
Prescribers of Medication for Opioid Use Disorder (including MOUD Waivered Providers and/or OTPs)	0.03	0.03	0.03	0.03	0.03

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" proposed rule 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). CMS established the current base time and distance standards for the provider and facility types listed in § 422.116 by mapping the various specialty types' practice locations from the National Provider and Plan Enumeration System (NPPES) National Provider Identifier (NPI) file compared with Medicare beneficiary locations from CMS enrollment data. We further explained that we then tested different options for combinations of beneficiary coverage percentages and maximum travel distances to determine what was feasible and practical for the majority of counties given the trade-off between beneficiary coverage and travel distance. The travel time standards were calculated according to the average driving speeds in each of the ZIP code types (urban, suburban, rural) that beneficiaries would traverse between their homes and the provider locations (85 FR 9097). Other than the use of the different and more recent data sources that are identified in this preamble, we followed the same analysis and steps to develop the time and distance standards that we propose to apply to the new behavioral health specialty types.

Further, we explained in the February 2020 proposed rule that CMS determines the minimum number requirement for all provider specialty types by multiplying the "minimum ratio" by the "number of beneficiaries required to cover," dividing the resulting product by 1,000, and rounding up to the next whole number. This is reflected in § 422.116(e)(2)(i) and (e)(3); the current regulation text addresses how the number of beneficiaries required to cover is calculated and will apply to the proposed new provider specialty types. The minimum ratio is the number of providers required per 1,000 beneficiaries. We developed the minimum ratios that

currently appear in § 422.116 using various data sources, including, Medicare fee for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, US Census population data, National Ambulatory Medical Care Survey data, and AMA data on physician productivity. In developing the proposal here to add new specialty types subject to network adequacy evaluation, we conducted additional research to inform appropriate minimum ratio requirements. We reviewed utilization data among FFS Medicare beneficiaries for the proposed specialty types for 2019 through 2021. We reviewed literature on the prevalence of behavioral health disorders among Medicare beneficiaries and existing models for projecting the needed behavioral health workforce such as the Health Resources and Services Administration's (HRSA) Health Workforce Simulation Model[58], to inform estimates of the potential demand for behavioral health services. We also reviewed data on the potential supply of behavioral health providers, that is, Medicare-enrolled providers in the Provider Enrollment, Chain, and Ownership System (PECOS)[59], the list of practitioners waivered to provide buprenorphine for the treatment of OUD published by the Substance Abuse and Mental Health Services Administration (SAMHSA)[60], and the list of OTP providers enrolled in Medicare published by CMS[61]. We also sought clinical consultation regarding the types of behavioral health providers that treat Medicare beneficiaries, the service locations in which beneficiaries typically use behavioral health care, and typical patterns of care for accessing medication treatment for opioid use disorder, that is, the use of office-based and OTP-based care. Other than the use of different and more recent data sources as identified in this preamble, we followed the same analysis and steps to develop the proposed minimum provider ratios for these new specialty types.

[58] https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand/behavioral-health
[59] https://pecos.cms.hhs.gov/pecos/login.do#headingLv1
[60] https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator
[61] https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers

Second, in order to reinforce regulatory requirements for MA plans on their responsibility to provide access to critical behavioral health care services, we propose to amend the list of health care providers in the existing access to services standards at § 422.112(a)(1)(i) to include that the network must also include providers that specialize in behavioral health services.

Finally, to encourage increased access to telehealth providers in contracted MA networks, § 422.116(d)(5) provides that for certain specialties, MA plans may receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards 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. 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. As noted previously, the top provider specialty types to provide certain outpatient behavioral services to beneficiaries in that year included psychiatrists, clinical social workers, nurse practitioners, and clinical psychologists. Additionally, previous input from stakeholders discussed the importance of access to telehealth services specific to behavioral health in expanding access to care. Based on these considerations, we also propose to add all the new behavioral health specialty types 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.

3. Behavioral Health Services in Medicare Advantage (MA) (§§ 422.112 and 422.113)

In addition to ensuring that there are specific types of providers in behavioral health specialties accessible within certain parameters in an MA organization's network of providers, it is important to ensure that access to these services is available for enrollees as part of overall delivery and coordination of services. CMS recognizes that knowing where to go to receive

behavioral health care services is key to ensuring accessibility to those services. While CMS requires MA organizations to maintain publicly available resources, such as the provider directory, in order to help enrollees access care, we acknowledge that such resources may not always be sufficient to connect enrollees with the services to which they are entitled.

CMS also acknowledges that situations may arise when a behavioral health services provider and an enrollee are not a good fit, and the enrollee needs assistance finding a different provider. Further, when a provider leaves the network, enrollees could experience an interruption in services. Timely provision of care is important with respect to behavioral health outcomes, and with the following proposals, we seek to ensure that enrollees who need behavioral health services are able to access them in a timely manner.

Section 1852(d)(1)(A) of the Act requires MA organizations to make benefits under the plan available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits. To ensure MA enrollees have access to their services that is consistent with the requirements of the statute, CMS proposes to use our authority under section 1856(b)(1) of the Act to adopt standards to implement section 1852(d)(1)(A) of the Act to ensure that access to behavioral health services is prioritized appropriately in the Part C program. CMS proposes to advance this goal by adding behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services at § 422.112(b)(3). First, we propose to revise § 422.112(b)(3) to include behavioral health services by adding the phrase ", and behavioral health services" after the words "community-based services" at the end of § 422.112(b)(3). CMS believes that this proposed change to include behavioral health care services among the services for which MA organizations must have a care coordination program in place will help close the equity gap for enrollees in coordinated care plans. This proposed change would ensure that behavioral health care services are included as part of the enrollee's care coordination.

Next, CMS proposes to codify the agency's interpretation of section 1852(d)(3)(B) of the Act which is used to determine a condition that qualifies as an "emergency medical condition" for purposes of carrying out the requirements of section 1852(d)(1)(E) of the Act. Section 1852(d)(1)(E) of the Act requires MA organizations to reimburse a provider for emergency services without regard to prior authorization or the emergency care provider's contractual relationship with the MA organization.

Currently, under § 422.113(b)(1)(i), an "emergency medical condition" is defined as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in serious jeopardy to the health of the individual or their unborn child, serious impairment to bodily function, or serious dysfunction of any bodily organ or part; this regulatory definition generally mirrors the statutory definition in section 1852(d)(3)(B) of the Act. However, the definition does not explicitly address that its criteria extends to conditions both physical and mental. CMS interprets the scope of the definition to pertain to both physical and behavioral health conditions when those conditions meet the prudent layperson standard discussed in § 422.113(b)(1)(i), consistent with the statute.

For example, one could reasonably be expected to cause serious injury (or death) to oneself if one's behavioral health condition results in a suicide plan, attempt, other suicidal behavior, or other forms of serious self-harm; CMS believes such cases are sufficient to satisfy the prudent layperson standard, therefore immediate emergency medical intervention must be provided without regard to prior authorization or the emergency care provider's contractual relationship with the organization, consistent with the requirements of section 1852(d)(1)(E) of the Act.

It is important to ensure that MA organizations and affected stakeholders interpret the definition of "emergency medical condition" found in § 422.113(b)(1)(i) in the same manner as

CMS. Therefore, in an effort to mitigate the possibility that an applicable emergency medical condition, such a qualifying mental health condition, could be inadvertently excluded from the requirements and enrollee protections in § 422.113 due to misinterpretation by an MA organization or entities acting on its behalf, CMS proposes to add language to our regulations that will definitively clarify that an emergency medical condition can be physical or mental in nature. This interpretation and position on what § 422.113 means and requires will guide our enforcement of the regulation. MA organizations, providers and enrollees must comply with this interpretation of the regulation and doing so will assure that MA enrollees receive medically necessary services in a medical emergency.

At § 422.113(b)(1)(i), CMS proposes to amend the regulation by inserting ", mental or physical," after the word "condition" and before the word "manifesting." This proposed revision would ensure that emergency medical conditions are easily interpreted as such, thereby prohibiting the use of prior authorization when required and guaranteeing that coverage is provided by the MA organization, consistent with the statute. This will ensure that enrollees have access to emergency behavioral health services in parity with access to other medical emergency services.

We solicit comment on this proposal, and thank commenters in advance for their input on our proposed regulatory revisions.

4. Medicare Advantage (MA) Access to Services: Appointment Wait Time Standards (§ 422.112)

CMS solicited public comment through the RFI that appeared in the January 2022 proposed rule regarding the challenges that exist with accessing behavioral health providers for MA enrollees and how to resolve issues with building adequate behavioral health networks within MA plans. The responses to this RFI included requests that CMS consider strengthening network adequacy standards and improving access to care and services for enrollees by establishing requirements for appointment wait times for behavioral health services. We also

heard that beneficiaries experience barriers to treatment for behavioral health conditions, including opioid use disorder.

Section 1852(d) of the Act requires MA plans that use provider networks, make covered benefits available and accessible to enrollees in the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits, and that medically necessary care must be available and accessible 24 hours a day and 7 days a week. The MA regulation at § 422.112 includes requirements and standards to ensure that MA organizations that offer coordinated care plans, which generally use networks of providers, meet the statutory requirements. Under these rules, MA organizations must ensure that all covered services are made available and accessible to enrollees by the plan's designated provider network. Furthermore, MA organizations are required under § 422.112(a)(6)(i) to maintain written standards that require timely access to care for enrollees which meet or exceed those established by CMS. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the MA organization must take corrective action as necessary. CMS has provided guidelines for MA organizations in the Medicare Managed Care Manual (MMCM), Chapter 4, "Benefits and Beneficiary Protections," section 110.1.1,[62] regarding provider network standards. That guidance includes directions that MA organizations make their timeliness standards known to network providers (which is necessary in order to ensure that providers in the network comply with MA plan's written standards) and that the MA organization should consider an enrollee's need for the services and common waiting times in the community. In particular, the Manual provides examples of appointment wait times for certain primary care services, based on the type of services and level of need: (1) urgently needed services or emergency—immediately; (2) services that are not emergency or urgently needed, but requires medical attention—within 1 week; and (3) routine and preventive care—within 30 days.

[62]https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

The 2022 CMS Behavioral Health Strategy[63] describes CMS' goals to increase and enhance access to equitable behavioral health care services for people with behavioral health care needs. To support these goals, CMS is committed to strengthening our requirements for MA organizations to ensure beneficiaries can access needed behavioral health care services similar to how they access needed physical health services. Therefore, we propose to codify appointment wait times as standards for primary care services that are the same as the appointment wait times described in the Manual and to extend those standards to behavioral health services. These new minimum appointment wait time standards would be added to the existing requirement that MA organizations establish written policies for the timeliness of access to care and member services so that MA organizations must have appointment wait times that meet or exceed the standards we propose here.

Behavioral health services include both mental health services and substance use disorder services. We remind MA organizations that substance use disorder services include medications for opioid use disorder (MOUD), which is particularly important as opioid-related overdose deaths have spiked during the pandemic,[64] and we have heard from commenters that beneficiaries have experienced barriers to behavioral health treatment. Proposing to codify these wait time standards as discussed by commenters through our RFI, should reduce access barriers to behavioral health treatment for those who need it; and help ensure access to a robust array of practitioners furnishing behavioral health services, including Opioid Treatment Providers who prescribe medications for opioid use disorder.

In addition, the proposal to codify wait time standards for primary care is consistent with the goal to increase access to primary care articulated in HHS' Initiative to Strengthen Primary Care.[65] The National Academies for Science, Engineering, and Medicine (NASEM) Report

[63]https://www.cms.gov/cms-behavioral-health-strategy
[64]https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[65]https://www.hhs.gov/about/news/2022/06/27/fact-sheet-hhs-initiative-to-strengthen-primary-health-care-seeking-public-comment.html

outlined the importance of ensuring that high-quality primary care is available to every individual and family in every community, particularly those that are underserved. After all, access to primary care practitioners, as opposed to any other practitioner type, is associated with decreased mortality.[66]

We are also seeking comment on alternative specific appointment wait times standards to apply to MA organizations. For example, we are considering, as suggested by a commenter on our RFI, establishing appointment wait time standards that align with those established for qualified health plans, (QHPs) as outlined by CMS in the "2023 Final Letter to Issuers in the Federally-facilitated Exchanges.[67]" The appointment wait time standards for QHPs include: Behavioral health appointments must be available within 10 business days, Primary care (routine) must be available within 15 business days; and Specialty care (non-urgent) must be available within 30 business days. Under our proposal, the wait time requirements, , would be applicable to primary care and behavioral health specialty types. We solicit comment whether a more flexible approach would be appropriate, such as requiring MA organizations have these specific appointment wait time standards in their written internal policies but that CMS require MA plans to meet the specific appointment wait time limits for routine or non-emergency services only for a significant portion (for example, 95 percent) of appointments.

This proposed additional requirement to specify maximum wait times for MA enrollees is intended to ensure that MA enrollees are able to access covered services and that MA organizations meet their obligations under section 1852(d) of the Act to make covered benefits available and accessible to enrollees in the plan. Section 1856(b) of the Act authorizes the adoption of standards that are consistent with and to carry out the Part C statute.

We are also considering requiring new and expanding service area applicants to attest to their ability to provide timely access to care consistent with the CMS appointment wait time

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[66]https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724393

[67] https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2023-Letter-to-Issuers.pdf

standards we would add to § 422.112(a)(6)(i). We would implement a new application requirement by adding a new attestation to our "Part C - Medicare Advantage and 1876 Cost Plan Expansion Application" that specifically addresses requirements at § 422.112(a)(6)(i). Such an attestation would not be reflected in a specific regulation, however, because we believe that the requirement at § 422.501(c)(2), that an applicant thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, permits CMS to use an attestation to support the ability of an MA organization to comply with performance requirements. Adequate access to services for MA enrollees is a key consideration.

We solicit comment on our proposal, including whether one or more of the previously described sets of wait time standards would more effectively address our goals of ensuring that MA organizations are meeting timely access standards for primary care and behavioral health services for enrollees, supporting parity between behavioral health and physical health services, and strengthening our requirements for MA organizations to ensure beneficiary protections in access to care. In addition, we solicit comment on whether a specific appointment wait time limit for emergency or urgently needed services is duplicative of the mandatory coverage and access requirements in § 422.113.

C. Medicare Advantage (MA) Network Adequacy: Access to Services (§ 422.112)

Section 1852(d)(1)(A) of the Act establishes that an MA organization offering an MA plan may select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits. This is generally implemented at § 422.112(a), which provides that an MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services are available and accessible under the plan. The regulation also includes specific additional requirements for MA organizations offering coordinated care plans related to

the availability and accessibility of coverage. In addition, the statute and regulation apply these requirements to all benefits covered by the plan, including both basic and supplemental benefits.

More specifically, section 1852(d)(1)(D) of the Act requires an MA organization to provide access to appropriate providers, including credentialed specialists, for medically necessary treatment and services, as a condition of the MA organization limiting coverage to a specified network of providers. CMS implemented this statutory requirement at § 422.112(a)(1)(i), which provides that the MA organization offering a coordinated care plan must maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. In addition, § 422.112(a)(3) requires that the MA organization provide or arrange for necessary specialty care and arrange for specialty care outside of the plan's provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

Historically, CMS has interpreted these statutory and regulatory requirements to mean that in the event an in-network provider or service is unavailable or inadequate to meet an enrollee's medical needs, the MA organization must arrange for any medically necessary covered benefit outside of the plan provider network at in-network cost sharing for the enrollee. For example, if an enrollee needs OTP services but there is no in-network OTP available, then the MA organization must arrange for the enrollee to go to an out-of-network OTP at in-network cost sharing. In our view, furnishing access out of network with higher cost sharing when the MA plan's network is inadequate or otherwise does not address the medically necessary benefit required by an enrollee is not consistent with section 1852(d)(1) of the Act. Enrollees should not bear a financial burden because of the inadequacy of the MA plan's network. This interpretation is reflected in CMS guidance in section 110.1.1 of Chapter 4 of the MMCM,[68] and CMS has routinely emphasized this interpretation to MA organizations about their obligations whenever

[68]https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

the need arises, for example, when an MA organization is undergoing a network change due to a provider termination. Therefore, MA organizations are familiar with the policy and should be applying it in the routine course of operations within their MA plans. It is important that MA organizations ensure adequate access to medically necessary covered benefits for enrollees when the plan network is not sufficient by both arranging or covering the out-of-network benefits and only charging in-network cost sharing for those out-of-network benefits. To reflect this important and well-established enrollee protection in the MA program, we are proposing to amend § 422.112(a)(1) and (a)(3) to more clearly state the scope of the MA organization's obligation to ensure adequate access to medically necessary covered benefits.

Currently, the regulation text at § 422.112(a)(3) does not fully account for the scope of an MA organization's obligations when medically necessary benefits are only accessible out of network in two key ways. First, the regulation text refers to specialty care only, not all medically necessary covered benefits. This oversight does not align with the statutory requirement at section 1852(d)(1)(D) of the Act, which states broadly that the organization must provide access to "appropriate providers, including credentialed specialists," and does not limit the requirement to specialists only. Second, the aspect of maintaining in-network cost sharing when the MA organization arranges for the benefit outside of the network is not clearly stated in § 422.112(a)(3). Therefore, CMS proposes to amend § 422.112 to align more closely with current subregulatory policy and our implementation of section 1852(d) of the Act.

CMS proposes to codify this policy by revising § 422.112(a)(3) and adding new regulatory text to § 422.112(a)(1) to reflect the longstanding policy. Specifically, we propose to move the sentence requiring the MA organization to arrange for out-of-network care currently in paragraph (a)(3) to a new proposed paragraph (a)(1)(iii) and revise and supplement it with additional text to better state the full scope of the current policy. Proposed paragraph (a)(1)(iii) would require MA organizations offering coordinated care plans to arrange for 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.

CMS currently monitors MA organization compliance with this existing policy through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations alert CMS to any issues with access to care, and CMS may require MA organizations to address these matters if they arise. If finalized, CMS intends to continue these oversight operations to ensure MA organizations' compliance with the proposed regulation.

This proposal to amend § 422.112 codifies the agency's existing interpretation of applicable law and longstanding guidance. CMS has not been made aware of any issues of MA organization non-compliance with this policy and, as such, believes that MA organizations have been complying with this longstanding guidance. Therefore, the proposed amendment to § 422.112 would not impose new information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements), and we have not provided burden estimates in the Collection of Information section of this proposed rule. In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

We solicit comment on this proposal, including on the accuracy of our assumptions regarding information collection requirements and regulatory impact.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

As provided in section 1852(d) of the Act and discussed in section 110.1.2.1 of Chapter 4 of the MMCM, MA organizations have considerable discretion to select the providers with whom to contract in order to build high-performing, cost effective provider networks.[69] This flexibility is also apparent in how CMS is prohibited by section 1854(a)(6)(B)(iii) of the Act from requiring MA organizations to contract with a particular provider. Under our current regulations, MA organizations are able to make changes to these networks at any time during the

[69] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

contract year, as long as they continue to furnish all Medicare-covered services in a non-discriminatory manner, meet established access and availability standards and timely notice requirements, and ensure continuity of care for enrollees. Thus, an MA organization may terminate providers from its network during the plan year, which could impact enrollees who are patients of those providers. CMS requires notification to MA enrollees when a provider network participation contract terminates. Most notably, CMS's disclosure regulations at § 422.111(e) require MA organizations to make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. Additionally, § 422.111(e) requires that when a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified. CMS established these enrollee notification requirements at § 422.111(e) over 22 years ago in the "Medicare Program; Medicare+Choice Program" final rule with comment period, which appeared in the **Federal Register** on June 29, 2000 (65 FR 40170) (hereinafter referred to as the June 2000 final rule). The MA program and its policies have evolved considerably since the inception of § 422.111(e). Therefore, CMS is proposing to revise this particular disclosure requirement by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also proposing to revise § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

First, we propose to clarify the regulatory text at § 422.111(e) regarding whether the provider contract termination was for cause or without cause. The regulation currently requires that the MA organization must make a good faith effort to notify enrollees at least 30 calendar days before the termination effective date, irrespective of whether the termination was for cause

or without cause. This last clause does not consider § 422.202(d)(4), which outlines the timeframe requirement for suspension or termination of an MA organization's contract with a provider. An MA organization and a contracted provider are required by § 422.202(d)(4) to provide at least 60 days written notice to each other before terminating the contract without cause. Consequently, because MA organizations are provided at least a 60-day notice of any no-cause provider contract termination, MA organizations should be able to timely meet a CMS established enrollee notification requirement that provides the MA organization a period of time that is less than 60 days to notify enrollees of the no-cause provider contract termination. Provider contract terminations that are for-cause, however, do not have an equivalent notification requirement as exists at § 422.202(d)(4) for MA organizations and contracted providers, which means that for-cause provider contract terminations could potentially occur with little notice or without any notice at all. In this case, it may not always be possible for the MA organization to notify enrollees in a reasonable amount of time before the provider contract termination effective date. Thus, we will preserve the phrase "good faith effort" for enrollee notifications for for-cause provider contract terminations regarding the proposed timeframes. Under our proposal, the "good faith effort" standard would apply to the timing component for for-cause provider contract terminations. However, we propose to remove "good faith effort" for no-cause provider contract terminations. We believe that when an MA organization's contracted provider network changes, these enrollee notifications are essential for updating enrollees who are patients of the terminating providers. If an enrollee's provider is dropped from their network during the contract year, the enrollee must be notified so that they can decide how to proceed with the care they are receiving from that provider. By limiting the "good faith effort" standard to the timing of for-cause provider contract terminations, we make it clear that issuing the notification to enrollees is a requirement that all MA organizations must follow without exception, but in the case of for-cause provider contract terminations, MA organizations must make a good faith effort to notify enrollees of the termination within the proposed timeframes.

Next, we propose to add new provisions to § 422.111(e) to address provider contract terminations that involve behavioral health providers. For purposes of this proposal, CMS considers various specialty types (both providers and facilities) as fitting the category of behavioral health providers so long as the treatment they furnish to enrollees is about behavioral health; these include but are not limited to psychiatrists, clinical social workers, clinical psychologists, inpatient psychiatric facilities, outpatient behavioral health clinics, OTPs, and MOUD-waivered providers approved by SAMHSA/FDA. As noted in section III.B.1. of this proposed rule, behavioral health is a top priority of both CMS and the broader administration. Specifically, CMS's goal is to improve access to behavioral health services and improve outcomes for people with behavioral health care needs. The CMS Behavioral Health Strategy seeks to remove barriers to care and services.[70] To support these policy goals, using a behavioral health perspective, we have reexamined the MA enrollee notification requirements when a provider contract termination occurs at § 422.111(e).

According to a recent study, because of the ongoing nature of patient/provider relationships, when a provider leaves a plan's network, there is a potential disruption to the patient's treatment plan; this disruption could be especially problematic in the case of behavioral health treatment because this treatment may be longer in duration than that of physical health, and providers and patients are likely to need more time to develop mutual trust.[71] Trusting relationships and continuity in the relationship between the patient and provider have shown to be central for behavioral health recovery, therefore, breaks in these relationships tend to cause patient stress, anxiety, and generally less opportunity to contribute to their treatment plan.[72] Thus, ensuring continuity of care in these situations becomes even more critical. As a consequence, sufficient enrollee notification is needed when a behavioral health provider leaves an MA network. We believe that affected enrollees need ample time to make decisions that may

[70]https://www.cms.gov/cms-behavioral-health-strategy
[71]https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785383
[72] https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2719-9

determine the trajectory of their behavioral health treatment. They may wish to continue seeing the terminated provider with whom they have already established a secure, comfortable relationship (potentially with higher out-of-network cost sharing), they may switch to a new provider in the network (forcing them to start a new relationship), or they may choose to stop treatment altogether (which could be detrimental to their health or perhaps fatal in the case of patients with suicidal ideation). Regardless of what action the enrollee takes, however, the enrollee needs to know that their behavioral health provider is leaving their plan's network prior to the contract termination date.

A similar case is made for terminating primary care providers both due to the fact that behavioral health services are often offered by primary care providers and the foundational role primary care providers play in an individual's overall health. According to the American Academy of Family Physicians, up to 75 percent of primary care visits include aspects of behavioral health.[73] Primary care is foundational because it integrates services to meet the patient's health needs throughout a lifetime, including key elements such as health promotion, disease prevention, treatment, rehabilitation, and palliative care.[74] Furthermore, CMS believes that the importance of a patient's relationship with their primary care provider is likely higher in managed care situations, such as MA, where referrals to specialists are often dependent on the primary care provider. Therefore, similar to behavioral health, continuity of care is essential, and sufficient enrollee notification is needed when a primary care provider leaves an MA network. For these reasons, we are proposing more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. We expect positive impacts associated with improving communication about provider terminations from MA networks, including providing more time to MA enrollees with behavioral health conditions to make informed decisions about the future of their behavioral health treatment after their provider

[73] https://www.aafp.org/pubs/fpm/issues/2021/0500/p3.html#fpm20210500p3-b1
[74] https://www.who.int/health-topics/primary-health-care#tab=tab_1

leaves their network. Enrollee benefits would result from increased enrollee protections when unexpected primary care and behavioral health network changes occur, and we would also expect to see benefits for providers and facilities who keep their patients informed if they are leaving their MA plan's network.

To address the aforementioned concerns surrounding unexpected changes in MA primary care and behavioral health provider networks, we are proposing to add specific enrollee notification requirements for these types of provider contract terminations. Our proposal has three key aspects. We first propose to add behavioral health providers to the current requirement at § 422.111(e) that all enrollees who are patients of a terminating primary care provider must be notified (not just those enrollees who are patients seen on a regular basis by the terminating provider, which is the case for all other specialty types), and expand the scope of this requirement to refer to all enrollees who have ever been patients of these terminating primary care or behavioral health providers (not just current patients). This addition would be reflected at proposed new paragraph (e)(1)(iii). Next, at proposed new paragraph (e)(1)(ii), we propose to require MA organizations to provide notice to enrollees at least 45 calendar days before the termination effective date for contract terminations that involve a primary care or behavioral health provider, which is longer than the 30-day standard for all other specialty types. Finally, we propose to require both written and telephonic notice for contract terminations that involve a primary care or behavioral health provider at new proposed paragraph (e)(1)(i), while only written notice is required for all other specialty types. We are proposing that both types of notice need to be provided at least 45 calendar days before the termination effective date. For the telephonic notice, we propose that the first telephone call be made to the enrollee at least 45 calendar days in advance. Under our proposal here, the MA organization would be required to continue attempting to reach the enrollee by telephone to provide notice of the termination of the provider from the network. We are not proposing a specific number of attempts required by the MA organization when they reach out to the enrollee by telephone and the call goes unanswered,

but we are soliciting comment from MA organizations on how many telephonic attempts they believe are reasonable in this circumstance (for example, 1-5, 6-10, 11-15). To help inform our proposal, we are requesting qualitative feedback based on any MA organization's actual experience providing enrollees telephonic notice of primary care and behavioral health provider contract terminations.

These new proposed requirements for MA organizations providing enrollees notice of primary care and behavioral health provider contract terminations are intended to raise the standards for the stability of enrollees' primary care and behavioral health treatment. If finalized, these requirements would require MA organizations to notify all current enrollees who have ever been patients of the primary care or behavioral health provider or providers leaving their plan's network (regardless of whether these enrollees are patients currently seen on a regular basis, as that standard is established in proposed new paragraph (e)(2)(iii)), give enrollees more notice (and therefore more time) to decide how to proceed with their course of treatment, and provide enrollees with two different means by which they receive the notice from their MA organization. These strengthened enrollee notification requirements for primary care and behavioral health provider contract terminations would generally increase enrollee protections when MA network changes occur. As discussed earlier, continuity of care is essential for both primary care and behavioral health, and consequently, adequate communication to enrollees is vital when network changes occur, so that patients of any terminating primary care or behavioral health providers can decide how to proceed with their course of treatment. By receiving adequate notice of the terminations, enrollees will be able to make an informed decision on how to proceed with their care and have more time to potentially locate and establish a relationship with a new provider. Thus, enrollees are protected from any undue harm that may result from an unexpected provider contract termination involving their primary care or behavioral health provider (for example, sudden lack of medication, psychotic episodes, suicide). The proposed

enrollee notification requirements are a positive step in the context of our policy for MA provider contact terminations.

Under our proposal, MA organizations will continue to be required to provide written notice at least 30 days before the termination effective date of a termination of a contracted provider that is not a primary care or behavioral health provider to all enrollees who are patients seen on a regular basis by the terminating provider. We also propose to codify at § 422.111(e)(2)(iii) a definition of the phrase "enrollees who are patients seen on a regular basis by the provider whose contract is terminating." CMS currently has sub-regulatory guidance in section 110.1.2.3 of Chapter 4 of the MMCM that defines this term as enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated, also called "affected enrollees."[75] As this guidance has been in place since 2016, and based on various MA organization inquiries we have received asking how CMS defines "regular basis," we believe the majority of MA organizations have come to adopt this CMS standard and use it routinely as they determine which enrollees to notify when provider contract terminations occur, in order to comply with § 422.111(e). Therefore, we propose to codify this definition at proposed § 422.111(e)(2)(iii).

The requirements for contract terminations that involve specialty types other than primary care or behavioral health (written notice only, at least 30 calendar days before the termination effective date, and to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating) would be set forth at new proposed § 422.111(e)(2). This provides a clear distinction for MA organizations between CMS's enrollee notification requirements for contract terminations that involve a primary care or behavioral health provider (at new proposed paragraph (e)(1)) and all other provider contract terminations. We reiterate that the beginning proposed revised regulatory text at § 422.111(e) also distinguishes between no-cause and for-cause provider contract terminations, with the former scenario prompting a

[75] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

requirement for MA organizations to provide the enrollee notifications and the latter requiring MA organizations to make a good faith effort to notify enrollees within the required timeframes. Regardless, whenever an MA organization notifies enrollees about a provider contract termination (whether it is with or without cause), CMS proposes that MA organizations must follow these new requirements outlined at proposed paragraphs (e)(1) and (2).

Finally, regarding the content of the provider termination notice, CMS's regulation at § 422.2267(e)(12) currently provides that the Provider Termination Notice is a required model communications material through which MA organizations must provide the information required under § 422.111(e). CMS has provided additional guidance regarding the content of the provider termination notice in section 110.1.2.3 of Chapter 4 of the MMCM.[76] Similar to the definition of "affected enrollees," these best practices have been in our guidance since 2016, thus we believe the majority of MA organizations likely already follow them as they develop the content of their provider termination notices. Therefore, we propose to codify the best practices for provider termination notices at § 422.2267(e)(12). Specifically, we propose to make these requirements for the content of MA organizations' provider termination notices and also require MA organizations to include additional pieces of information in the notice.

First, at proposed § 422.2267(e)(12)(ii)(A), we are proposing that the provider termination notice must inform the enrollee that the provider will no longer be in the network and the date the provider will leave the network. We have modeled this proposed regulatory text after the established precedent for the equivalent notice requirement for the Non-renewal Notice model communications material as provided at § 422.2267(e)(10)(ii)(A) (we refer readers to section III.P. of this proposed rule for our proposal to amend paragraph (e)(10) to make the Non-renewal Notice a standardized communications material). Next, we propose to codify a requirement to include the information currently described in the best practices guidance in Chapter 4 of the MMCM at proposed § 422.2267(e)(12)(ii)(B), (C), and (E), specifically: names

[76] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

and phone numbers of in-network providers that the enrollee may access for continued care (this information may be supplemented with information for accessing a current provider directory, including both online and direct mail options) (at proposed paragraph (e)(12)(ii)(B)); how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider (at proposed paragraph (e)(12)(ii)(C)); and the MA organization's call center telephone number, TTY number, and hours and days of operation (at proposed paragraph (e)(12)(ii)(E)). For proposed paragraph (e)(12)(ii)(B) and (C), we are proposing to use the same description for the relevant content that is currently found in CMS's guidance in Chapter 4 of the MMCM. However, for proposed paragraph (e)(12)(ii)(E), instead of using the existing Chapter 4 language ("customer service number(s) where answers to questions about the network changes will be available"), we have chosen to model the proposed regulatory text after the established precedent of a requirement for the Non-renewal Notice at § 422.2267(e)(10)(ii)(H). We believe that the proposed new language of "call center telephone number, TTY number, and hours and days of operation" is more inclusive as it encompasses not just the customer service number but also the TTY number and operation times.

In addition, at proposed § 422.2267(e)(12)(ii)(D), we are proposing that the provider termination notice must provide information about the Annual Coordinated Election Period (AEP) and the MA Open Enrollment Period (MA-OEP) and must explain that an enrollee who is impacted by the provider termination may contact 1-800-MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period (SEP), as specified in § 422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP. We solicit comment on our proposal to consider an enrollee who is impacted by a provider contract termination to be someone who is experiencing an exceptional condition, as specified in § 422.62(b)(26), and therefore eligible for this SEP. We also solicit comment on alternative approaches; specifically, the adoption of a new

SEP for this type of provider contract termination, with explicit standards for when termination of a provider from the network should serve as a basis for SEP eligibility.

The last proposal we are making regarding the provider termination notice requirements at § 422.2267(e)(12) concerns CMS's requirements for the telephonic notice that we are proposing MA organizations must provide to enrollees at least 45 days in advance of a primary care or behavioral health provider contract termination. Specifically, at proposed § 422.2267(e)(12)(iii), we propose that the telephonic notice of provider termination specified in proposed § 422.111(e)(1)(i) must relay the same information as the written provider termination notice as described in paragraph (e)(12)(ii) of § 422.2267. We believe that requiring the MA organization to communicate the same information on the primary care or behavioral health provider contract termination through two different channels—a written letter and a telephone call—will ensure that affected enrollees receive the information they need to decide how to proceed with their current course of treatment. The telephonic communication will reiterate the change occurring in the plan's network and the options the enrollee has moving forward in the absence of their current provider.

The provider termination notice is a model communications material which, per § 422.2267(c), is created by CMS as an example of how to convey enrollee information. When drafting this required communications material, MA organizations must: (1) accurately convey the vital information in the required material to the enrollee, although the MA organization is not required to use the CMS model material verbatim; and (2) follow CMS's order of content, when specified (see § 422.2267(c)(1) and (2)). While the regulation currently identifies the provider termination notice as a model communications material, CMS has not yet developed the model document for MA organizations to use. Rather, MA organizations have been expected to follow the current guidance in section 110.1.2.3 of Chapter 4 of the MMCM.[77] Given that we are now proposing new regulatory requirements for the content of these provider termination notices

[77] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

(including codifying existing best practices provided in CMS's guidance), CMS intends to create a model document for the provider termination notice that contains the requirements at proposed § 422.2267(e)(12), if finalized. We believe that this model document would be welcomed by MA organizations as it will provide a useful template that MA organizations may follow when developing their own provider termination notices. Our proposal for § 422.2267(e)(12) specifies the required information, and the model document that CMS intends to develop would reflect this information as well. In addition, when developing provider termination notices, all MA organizations must follow the general communications materials and activities requirements outlined at § 422.2262 and the standards for required materials and content at § 422.2267(a).

Regarding compliance monitoring for the regulatory amendments proposed here, CMS currently monitors MA organization compliance with the existing policies at §§ 422.111(e) and 422.2267(e)(12) through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations alert CMS to any issues with enrollees that did not receive adequate notice of a provider contract termination, and CMS may require MA organizations to address these matters if they arise. If finalized, CMS intends to continue these oversight operations to ensure MA organizations' compliance with the proposed regulation. In accordance with § 422.2261(c)(2), CMS may require submission or submission and approval of communications materials prior to use if additional oversight is warranted as determined by CMS based on feedback such as complaints or data gathered through reviews. This is to ensure the information being received by enrollees is accurate. Furthermore, § 422.2261(d)(1) and (3) establish that CMS reviews materials to ensure compliance with all applicable requirements under §§ 422.2260 through 422.2267 and that CMS may determine, upon review of such materials (either prospective or retrospective), that the materials must be modified, or may no longer be used. Therefore, CMS reserves the right to review any MA organization's provider termination notice if we receive complaints or other information signifying that the notice warrants additional oversight to ensure compliance with CMS regulations for provider

termination notices at §§ 422.111(e) and 422.2267(e)(12). If CMS does exercise its authority under § 422.2261(c) to review an MA organization's provider termination notice, per § 422.2261(d)(1) and (3), CMS will review the notice to ensure compliance with the applicable regulations and, as a result, may require the MA organization to modify the notice or no longer use it.

In summary, CMS is proposing to revise: (1) § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur; and (2) § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination. We solicit comment on these proposals.

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

1. Introduction

A majority of MA plans are coordinated care plans, which is defined at § 422.4(a) as a plan that includes a network of providers that are under contract or arrangement with an MA organization to deliver the benefit package approved by CMS. CMS regulations at § 422.202(b) require that each MA organization consult with network providers on the organization's medical policy, quality improvement programs, medical management procedures, and ensure that certain standards are met. For example, coordinated care plans must ensure that practice guidelines and utilization management guidelines are based on reasonable medical evidence or a consensus of health care professionals in the particular field; consider the needs of the enrolled population; are developed in consultation with contracting physicians; and are reviewed and updated periodically. Further, these guidelines must be communicated to providers and, as appropriate, to enrollees.

Coordinated care plans are designed to manage cost, service utilization, and quality by ensuring that only medically necessary care is provided. This is done in part through the use of utilization management tools, including prior authorization, expressly referenced at section 1852(c)(1)(G) and (c)(2)(B) of the Act. These tools are designed to help MA plans determine the medical necessity of services and minimize the furnishing of unnecessary services, thereby helping to contain costs and protect beneficiaries from receiving unnecessary care. Additionally, section 1852(g)(1)(A) of the Act states that MA plans shall have a procedure for making determinations regarding whether an enrollee is entitled to receive a health care service and that such determinations must be made on a timely basis; that provision applies to both prior authorization determinations and to post-service decisions about coverage and payment.

In addition, CMS regulations at § 422.101(a) and (b) require that MA plans provide coverage of all basic benefits (that is, services covered under Medicare Parts A and B, except hospice care and the cost of kidney acquisitions for transplant) and that MA plans must comply with Traditional Medicare national coverage determinations (NCDs) and local coverage determinations (LCDs) applicable in the MA plan's service area.[78] In recent years, CMS has received feedback from various stakeholders, including patient groups, consumer advocates, providers and provider trade associations that utilization management in MA, especially prior authorization, can sometimes create a barrier to patients accessing medically necessary care. Stakeholder feedback has included concerns about the quality of MA plans' prior authorization decisions (for example, coverage denials being made by plan clinicians who do not have expertise in the field of medicine applicable to the requested service) and process challenges (for example, repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care).

[78]The terms "Traditional Medicare" and "Original Medicare" are used interchangeably throughout this section and both mean the Medicare Fee-For-Service program.

In addition, in April 2022, the Office of the Inspector General (OIG) released a report[79] titled, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," which summarized the results of a study by the OIG of MA plan denials of requests for prior authorization of services. The OIG found that some prior authorization requests were denied by MA plans, even though the requested services met Medicare coverage guidelines. In other cases, the OIG found that prior authorization requests were inappropriately denied due to errors that were likely preventable through process or system changes by MA organizations. Citing a concern that such inappropriate denials may prevent or delay beneficiaries from receiving medically necessary care, the OIG recommended that CMS: (1) issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews; (2) update its audit protocols to address the issues related to MA organizations' use of clinical criteria and/or examining particular service types; and (3) direct MA organizations to take steps to identify and address vulnerabilities that can lead to manual review errors and system errors.[80]

CMS understands that utilization management tools are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. In light of the feedback we have received from stakeholders and the findings in the OIG report, however, we have concluded that certain guardrails are needed to ensure that utilization management tools are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans. We propose to clarify requirements for the coverage criteria that MA plans use when making medical necessity determinations. We are also proposing additional beneficiary protection requirements in order to improve care continuity and integration of health care services and to increase plan compliance responsibilities with regards to utilization management policies. Our proposals here would

[79]https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[80]https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf, pg. 3

interpret and implement the requirements in section 1852 regarding the provision and coverage of services by MA plans and are therefore proposed under our authority in section 1856 of the Act to adopt standards to carry out the Part C statute and MA program.

As originally stated in the June 2000 final rule (65 FR 40207), MA organizations must cover all Part A and B benefits, excluding hospice services and the cost of kidney acquisitions for transplant, on the same conditions that items and services are furnished in Traditional Medicare. This means that MA organizations may not limit coverage through the adoption of policies and procedures – whether those policies and procedures are called utilization management and prior authorization or the standards and criteria that the MA organization uses to assess and evaluate medical necessity – when those policies and procedures result in denials of coverage or payment where the Traditional Medicare program would cover and pay for the item or service furnished to the beneficiary. In addition, this means that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to set the scope of basic benefits as defined in § 422.100(c).

MA organizations have flexibility to furnish and cover services without meeting all substantive conditions of coverage in Traditional Medicare, but that flexibility is limited to and in the form of supplemental benefits. As stated in the June 2000 final rule, MA organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the MA program. If Traditional Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Traditional Medicare benefits (that is, basic benefits) component of an MA plan. MA organizations may cover the same service when the conditions are not met, but these benefits would then be defined as supplemental benefits within the scope of §§ 422.100(c)(2) and 422.102 and must be included in the supplemental benefits portion of

the MA plan's bid. For example, when services are furnished by a type of provider other than the type of provider who may furnish the service in Traditional Medicare, those services are supplemental benefits. In this rule, we are proposing policies that would provide less flexibility for MA organizations to deny or limit coverage of basic benefits than provided in the 2000 final rule. However, as provided by section 1852(a)(3) of the Act and reflected in §§ 422.100(c)(2) and 422.102, MA plans may cover benefits beyond what is covered (and when it is covered) under Traditional Medicare by offering supplemental benefits. Our proposal is primarily directed at ensuring that minimum coverage requirements are met and that MA plans do not deny or limit coverage of basic benefits; we are not proposing to limit the scope of permissible supplemental benefits, but our proposal would apply certain requirements for the use of utilization management (UM) for all covered benefits as discussed in section III.E. of this proposed rule.

In this proposed rule, we clarify acceptable cost-effective utilization management approaches for MA organizations to use in the context of the new proposed requirements. These clarifications aim to ensure access to medically necessary care while maintaining MA organizations' ability to apply utilization management that ensures clinically appropriate care. Additionally, our proposals address substantive rules regarding clinical coverage criteria for basic benefits and how they interact with utilization management policies, including revisions to existing regulations and adopting new regulations to ensure that MA enrollees receive the basic benefits coverage to which they are entitled and to ensure appropriate treatment of a benefit as a basic benefit or supplemental benefit for purposes of the bid under § 422.254. We solicit comment on whether our proposed regulatory provisions sufficiently address the requirements and limits that we describe in the preamble.

2. Coverage Criteria for Basic Benefits

In interpreting requirements involving coverage criteria, whether used for prior authorization or post-service payment, CMS has a longstanding policy, discussed in sub-

regulatory guidance (section 10.16 of Chapter 4 of the MMCM), that MA plans must make medical necessity determinations based on internal policies, which include coverage criteria that are no more restrictive than Traditional Medicare's national and local coverage policies and approved by a plan's medical director. In light of the previously discussed feedback and the OIG recommendation that we issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews, we propose to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare. Section 1862 of the Act requires original Medicare benefits to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Thus, in order to meet the statutory requirements at section 1852(a)(1) of the Act, which requires MA plans to cover A and B services, MA plan coverage criteria must do the same. We also are proposing to amend § 422.101(b) and (c) to clarify the obligations and responsibilities for MA plans in covering basic benefits.

Section 1852(a)(1) of the Act and CMS regulations at § 422.101(a) and (b) require all MA organizations to provide coverage of, by furnishing, arranging for, or making payment for, all items and services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. Section 422.101 requires MA organizations to comply with all NCDs; LCDs written by Medicare Administrative Contractors (MACs) with jurisdiction for Medicare claims in the MA organization or plan's service area; and coverage instructions and guidance in Medicare manuals, instructions and other guidance documents unless those materials are superseded by regulations in part 422.

We propose to amend § 422.101(b)(2) by removing the reference to "original Medicare manuals and instructions" and clarify that MA organizations must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, when making coverage decisions. Our proposal is designed to prohibit MA organizations from limiting or denying coverage when the item or service would be covered

under Traditional Medicare and continue the existing policies that permit MA organizations to cover items and services more broadly than original Medicare by using supplemental benefits. In proposing this change to § 422.101(b)(2), we are reiterating that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to define the scope of basic benefits. By removing the reference to "original Medicare manuals and instructions," we are not diminishing the content and value that these manuals and instructions provide in interpreting and defining the scope of Part A and Part B benefits. MA organizations should follow and comply with CMS's interpretation of Medicare laws and coverage requirements as reflected in the manuals, guidance and instructions issued by CMS, which is the agency with the applicable expertise and authority for Medicare. The proposed revision to § 422.101(b)(2) clarifies that statutes and regulations that set the scope of coverage in the Traditional Medicare program are applicable to MA organizations in setting the scope of basic benefits that must be covered by MA plans. We also propose to refer in § 422.101(b)(2) to specific Medicare regulations that include coverage criteria for Part A inpatient admissions, Skilled Nursing Facility (SNF) care, Home Health Services and Inpatient Rehabilitation Facilities (IRF) as examples of general coverage and benefit conditions in Traditional Medicare that apply to basic benefits in the MA program. The list of Medicare regulations referred to is not exhaustive and provides examples of substantive coverage and benefit conditions that apply to MA. In addition, we are also proposing to revise the current provision that states that Traditional Medicare coverage rules apply unless superseded by regulations in this part. We propose to revise that aspect of § 422.101(b)(2) to refer to laws applicable to MA plans in order to avoid implying that a Part 422 regulation could supersede an applicable statute.

The existing rule at § 422.101(c), which states that MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of post-hospital SNF care in the

absence of the prior qualifying hospital stay is an example of a special rule in MA that deviates from coverage criteria articulated in Traditional Medicare. The regulation is based on section 1812(f) of the Act, which authorizes CMS to permit coverage of SNF care without the 3 day qualifying hospital stay in limited circumstances. (68 FR 50847-50848) This rule provides MA organizations the flexibility to cover SNF stays for MA enrollees that would not be otherwise coverable in Traditional Medicare, if the beneficiary had not met the prior qualifying hospital stay of 3 days prior to admission in the SNF. This special rule continues to apply in the MA program; however, we propose to redesignate this rule to paragraph (c)(2) of § 422.101 as part of our proposal to add a heading to § 422.101(c) and to expand the scope of the paragraph. We propose to add the heading "Medical Necessity Determinations and Special Coverage Provisions" to § 422.101(c). As such, we propose to reassign the special rule for coverage of posthospital SNF in the absence of the prior qualifying hospital stay as § 422.101(c)(2).
The proposed new heading for § 422.101(c), "Medical Necessity Determinations and Special Provisions," signals that paragraph (c) will address medical necessity criteria and special rules that apply to MA basic benefits that do not necessarily conform to coverage rules in Traditional Medicare.

We propose to codify at § 422.101(c)(1)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c). This means that when an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. It is our interpretation that certain utilization management processes, such as clinical treatment guidelines that require another item or service be furnished prior to receiving the requested item or service, would violate the proposed requirements at § 422.101(b) and (c), and thus, would be prohibited under this proposal unless it

is specified within the applicable NCD or LCD or Medicare statute or regulation. We note that we are not proposing to revise § 422.136, which authorizes MA plans to use step therapy policies for Part B drugs under certain circumstances; in the next paragraph, we discuss the basis for authorizing step therapy for Part B drugs in § 422.136 in more detail. Clinical criteria that restrict access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD, would be considered additional internal coverage criteria that are prohibited under this proposal. When MA plans are allowed to create internal coverage criteria as specified at proposed § 422.101(b)(6), the current evidence in widely used treatment guidelines or clinical literature relied upon to make the coverage determination may recommend clinical treatment guidelines that require another item or service first. As long as the supporting widely used treatment guidelines or clinical literature recommend another item or service first, this would be acceptable under our proposed policy. We discuss the proposal to add § 422.101(b)(6) later in this section of the proposed rule.

In a HPMS memo released August 7, 2018, CMS announced that under certain conditions beginning in contract year 2019, MA plans may use utilization management tools such as step therapy for Part B drugs. In a May 2019 final rule (84 FR 23832), we codified MA organizations' ability to use step therapy for Part B drugs under certain conditions that protect beneficiaries and acknowledged that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs.

We clarified that, with respect to clinical concerns and interference with provider care, step therapy or other utilization management policies may not be used as unreasonable means to deny coverage of medically necessary services or to eliminate access to medically necessary Part B covered drugs. (84 FR 23856) The requirements in the 2019 rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care. Organizations have been and remain subject

to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements. Thus, this proposal remains consistent with the 2019 rule in that plans must still comply with NCDs and LCDs when developing step therapy programs for Part B drugs.

Finally, in the May 2019 final rule, we did not authorize step therapy practices for Part A or Part B (non-drug) items or services and our proposal here will limit the ability of MA organizations to use such UM policies in connection with non-drug covered items or services that are basic benefits. There are a number of differences with step therapy for Part B drugs and step therapy for non-drug items and services. From a clinical standpoint, there tends to be more than one drug that has demonstrated success in treating a certain disease or condition, and also there are generic alternatives, which is somewhat different than other Part A and B services. Often, there are not head-to-head comparisons between drugs in a certain class of medications, because a non-inferiority study[81] was conducted in order to bring the drug to market. This means that it is not always obvious what the clinically superior drug is for certain diseases or conditions, while there may be a significant difference in pricing. Furthermore, there are several studies[82] demonstrating how increased cost sharing for medications can, in and of itself, reduce patient adherence to those medications.

In addition, the manner in which Part B drugs are purchased and furnished is somewhat different from coverage of non-drug healthcare items and services. Generally, MA organizations pay the provider for both the service of administering a Part B drug and the cost of the drug, but do not directly pay drug manufacturers or suppliers for the cost of the drug. MA organizations may negotiate pricing discounts or rebates with the manufacturer, who is not the entity that

[81] https://www.fda.gov/media/78504/download.
[82] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/

directly furnishes the Part B drug to enrollees and who is not ordinarily paid directly by the MA organization for what is furnished to enrollees. As we explained in the May 2019 final rule (84 FR 23858, 23863, and 23869), we believe that § 422.136 can put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing for the beneficiary. Furthermore, as mentioned previously, studies have demonstrated that increased cost sharing for medications can reduce patient adherence to those medications. Therefore, we are not proposing to revise our current regulations regarding Part B step therapy at this time.

Similar to MACs in Traditional Medicare, we expect MA organizations to make medical necessity decisions by using NCDs, LCDs, and other applicable coverage criteria in Medicare statutes and regulations to determine if an item or service is reasonable, necessary and coverable under Medicare Part A or Part B. In some circumstances, NCDs or LCDs expressly include flexibility that allows coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD. For example, an NCD or LCD may state that the item or service can be covered when reasonable and necessary for the individual patient. When deciding whether an item or service is reasonable and necessary for an individual patient, we expect MA organizations to make medically necessary decisions in a manner that most favorably provides access to services for beneficiaries and aligns with CMS's definition of reasonable and necessary in the Medicare Program Integrity Manual, Chapter 13, section 13.5.4. This expectation applies to coverage determinations made before the item or service is provided (pre-certification/prior authorization), during treatment (case management), or after the item or service has been provided (claim for payment). As recommended by the OIG, this proposal clarifies the limited clinical coverage criteria can be applied to basic benefits and reinforces our longstanding policy that MA organizations may only apply coverage criteria that are no more restrictive than Traditional Medicare coverage criteria found in NCDs, LCDs, and Medicare laws. We reiterate that this proposal also applies to substantive coverage criteria and benefit

conditions found in Traditional Medicare regulations, such as those governing inpatient admissions and transfers to post-acute care settings, which are not governed by NCD or LCD. Therefore, MAOs may only deny a request for Medicare-covered post-acute care services in a particular setting, if the MAO determines that the Traditional Medicare coverage criteria for the services cannot be satisfied in that particular setting. As we will discuss in section III.E.3 in this proposal, this does not restrict an MA organization's ability to use certain utilization management processes, like prior authorization or post claim review, to ensure items and services meet Medicare coverage rules; it simply limits the coverage criteria that an MA organization can apply to deny an item or service during those reviews. We solicit comment about the specificity of the coverage conditions in Traditional Medicare regulations and whether we should consider, and under what circumstances, allowing MA organizations to have internal coverage criteria in addition to requirements in current regulations.

We recognize that there are some Part A or Part B benefits that do not have applicable Medicare NCDs, LCDs, or specific traditional Medicare coverage criteria in regulation for MA plans to follow when making medical necessity determinations. Therefore, we propose at § 422.101(b)(6) that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. In creating these internal policies, we propose that MA organizations must follow similar rules that CMS and MACs must follow when creating NCDs or LCDs. Specifically, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations.

Section 1862(l) of the Act requires the Secretary to issue publicly a discussion and explanation of the factors considered in making NCDs, after following a process that affords the public an opportunity to comment prior to implementation. We propose at § 422.101(b)(6) that

MA organizations must follow a somewhat similar process when creating internal plan coverage criteria by providing a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. We are not proposing that MA organizations must provide a pre-determination explanation and opportunity for the public to comment on the MA organization's coverage criteria; however, providing a publicly accessible summary of the evidence, a list of the sources of evidence, and an explanation of the rationale for the internal coverage criteria will protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature. This requirement provides further transparency into MA organizations' medical necessity decision making and is consistent with CMS's expectation that MA organizations develop and use coverage criteria in a way that aligns with Traditional Medicare.

We are also proposing at § 422.101(b)(6) a requirement that an MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions (such as referring to the Infectious Diseases Society of America for the Treatment of *Clostridium Difficile*[83]) or to determine appropriate level of care (such as the American Society of Addiction Medicine Criteria for placement[84], continued stay, and transfer or discharge of patients with addiction and co-occurring conditions). Clinical literature that CMS considers to be of high enough quality for the justification of internal coverage criteria include large, randomized controlled trials or cohort studies or all-or-none studies with clear results,

[83]Reference: https://www.idsociety.org/practice-guideline/clostridium-difficile/
[84]https://www.asam.org/asam-criteria

published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question published in a peer-reviewed journal with clear and consistent results. Evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization, or that does not comply with the standards, as previously described, would not represent proper justification for instituting internal coverage guidelines that would restrict access to care. This evidentiary standard is overall consistent with published frameworks[85] that rank the reliability of different types of studies in the clinical literature. CMS solicits comment on the definition of widely used treatment guidelines and clinical literature that would justify internal coverage criteria used in the absence of NCDs, LCDs, or Traditional Medicare statutes or regulations along with the other requirements proposed in new § 422.101(b)(6)

Medical Necessity Determinations

CMS has longstanding guidance interpreting the obligations of MA organizations when making medical necessity determinations. Per CMS regulations at § 422.112(a)(6)(ii), MA plans must have policies and procedures that allow for individual medical necessity determinations. As a result, an MA organization's coverage rules, practice guidelines, payment policies, and utilization management policies should be applied to make individual medical necessity determinations based on the individual circumstances for the enrollee and item or benefit to be covered. Chapter 4 of the MMCM, section 10.16, provides that MA organizations make coverage determinations that are based on: (1) the medical necessity of plan-covered services based on coverage policies (this includes coverage criteria no more restrictive than traditional Medicare described previously and proposed at § 422.101(b)(6)); (2) where appropriate, involvement of the plan's medical director per § 422.562(a)(4); and (3) the enrollee's medical

[85] (for example, Oxford Centre for Evidence-Based Medicine levels of evidence https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009 and Strength of Recommendation Taxonomy https://www.jabfm.org/content/17/1/59#F1)

history (for example, diagnoses, conditions, functional status)), physician recommendations, and clinical notes. We are proposing to codify these existing standards for medical necessity decision making at § 422.101(c)(1)(i) and propose some new requirements to connect medical necessity determinations to our new requirements at § 422.101(b). Therefore, as previously mentioned, we are proposing to codify at § 422.101(c)(1)(i)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as defined at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not found in those sources. Second, we propose at § 422.101(c)(1)(i)(B) to require MA organizations to consider whether the item or service is reasonable and necessary under 1862(a)(1) of the Act. We note that this has been a longstanding policy in MA based on how section 1852 of the Act requires MA plans to cover items and services for which benefits are available under original Medicare, however we believe it is important to acknowledge this in the context of MA organization decisions involving medical necessity. Third, we propose to codify existing policy at § 422.101(c)(1)(i)(C) that MA organizations consider the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes. Finally, consistent with current requirements at § 422.562(a)(4), we propose at § 422.101(c)(1)(i)(D) that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate. We solicit comments on when it would be appropriate for the MA organization's medical director to be involved, in light of how § 422.562(a)(4) requires the medical director to be responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity.

Authority for MA organizations to use utilization management policies with regard to 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 provisions. We believe these proposals will further implement the requirements set forth in

section 1852 of the Act and §§ 422.100 and 422.101, which require MA organizations to furnish all reasonable and necessary Part A and B benefits. These proposed requirements for how MA organizations make coverage decisions will ensure that MA organizations provide equal access to Part A and Part B benefits as provided in the Traditional Medicare program; overall our proposals mean that MA organizations will not be able to deny coverage for basic benefits using coverage criteria that is not consistent with coverage criteria in Medicare statutes, regulations, NCDs and LCDs or that is not consistent with the limitations proposed in § 422.101(b)(6).

We affirm that coordinated care plans may continue to include mechanisms to control utilization, such as prior authorization, referrals from a gatekeeper for an enrollee to receive services within the plan, and, subject to the rules on physician incentive plans at §§ 422.208 and 422.210, financial arrangements that offer incentives to providers to furnish high quality and cost-effective care in addition to the coverage criteria that comply with § 422.101(b). We affirm that MA organizations may furnish a given service using a defined network of providers, some of whom may not see patients in Traditional Medicare. Further, we affirm that MA organizations may encourage patients to see more cost-effective provider types than would be the typical pattern in Traditional Medicare (as long as those providers are working within the scope of practice for which they are licensed to provide care and comply with the provider antidiscrimination rules set forth under § 422.205). For instance, MA organizations may offer more favorable cost sharing for certain provider types within their network.

We also stated in the June 2000 final rule that when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, that an MA plan could choose how the covered services will be provided. We are proposing a narrower policy that permits MA organizations to continue to choose who provides Part A and Part B benefits through the creation of their contracted networks, but limits MA organizations' ability to limit when and how covered benefits are furnished when Traditional Medicare will cover different provider types or settings. As a result of the proposal at § 422.101(c)(1)(i), when

care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the criteria outlined in § 422.101(c)(1)(i). (We are proposing to reserve paragraph (c)(1)(ii) to provide flexibility in modifying the limits on MA medical necessity policies in the future.) For example, if an MA patient is being discharged from an acute care hospital and the attending physician orders post-acute care at a SNF because the patient requires skilled nursing care on a daily basis in an institutional setting, the MA organization cannot deny coverage for the SNF care and redirect the patient to home health care services unless the patient does not meet the coverage criteria required for SNF care in §§ 409.30-409.36 and proposed § 422.101(b) and (c).

In order to demonstrate how these policies will apply to actual cases, we discuss these proposed requirements in the context of two case examples that were cited in the OIG report. In the first case, an MA patient was a smoker and had a history of lung nodules and the provider ordered a Computed Tomography (CT) scan of the chest. NCD 220.1[86] identifies Medicare coverage and limitations for CT scans. In this specific case, the MA organization cited internal clinical criteria that limited CT scans based on the size of nodules and the receipt of chest X-rays. In our proposed policy, the internal criteria applied by the MA organization would be prohibited because there is no provision in the NCD that requires other diagnostic tests, such as a chest X-ray, to be tried before CT scanning is used. In order to appropriately deny this request for a CT scan under our proposed policy, the MA organization would need to identify why the CT scan, as the initial diagnostic test, was not reasonable and necessary based on the medical necessity determination requirements at the proposed 422.101(1)(A) through (D).

In another case, an MA patient had a history of dementia, hypertension and was legally blind due to glaucoma. The patient was admitted to the acute-care hospital for worsening

[86]https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=176

dementia and acute agitation. The acute-care hospital requested that the patient be discharged to a SNF, but the MA organization denied the request based on the MA organization's internal clinical criteria that determined that the patient did not have a need for skilled care. The specific conditions for meeting level of care requirements at a SNF, the criteria for skilled services, and the need for skilled services can be found at 42 CFR §§ 409.30-409.36. The internal clinical criteria used by the MA organization in this case were not identified by the OIG. However, if the internal criteria were not consistent with the criteria listed in §§ 409.30-409.36, it would be prohibited under our proposal. The OIG noted that because the patient required physician supervision and access to physical and occupational therapy, the MA organization should have covered the SNF care requested.

In this proposed rule, we are unable to quantify the impact of these changes on MA organizations because many MA organizations may already be interpreting our current rules in a way that aligns with our proposal. MA organizations may have interpreted our longstanding policy that they cannot apply coverage criteria that are more restrictive than Traditional Medicare national and local coverage policies to mean exactly what we are proposing here: that they may only deny Medicare items or services based on criteria consistent with Traditional Medicare coverage rules. Other MA organizations may have interpreted our current rules to mean that they can use internal policies, like utilization management guidelines, to deny approval for a particular item or service while directing the MA enrollee to different, but clinically appropriate, Medicare-covered item or service. The OIG stated in their report that "CMS guidance is not sufficiently detailed to determine whether MA organizations may deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules." As a result, in this proposal we are making it clear that MA organizations may not deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules or comply with proposed § 422.101(b)(6) addressing standards for when MA internal coverage rules are permissible. However, we are unable to quantify or predict

how many MA organizations are currently operating in a manner that conforms with our proposal. We solicit comment from stakeholders on the full scope of this burden.

3. Appropriate Use of Prior Authorization

Except for emergency, urgently needed, and stabilization services (§ 422.113(a)), and out-of-network services covered by MA PPO plans, all services covered by MA coordinated care plans (including MSA network plans, which are coordinated care plans under 422.4(a)(iii)(D)), may be subject to prior authorization. In addition, MA PFFS and MA MSA plans are not permitted to use prior authorization policies or "prior notification" policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS or MSA plan in advance that services will be furnished. See § 422.4(a)(2)(i)(B) and (a)(3)(iv). Appropriate prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care. We propose to codify this at new § 422.138(a). Specifically, we are proposing a new § 422.138(a) to provide that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only when the prior authorization processes are consistent with new § 422.138. We propose to use the term "processes" to include prior authorization policies and procedures that address any and all aspects of how prior authorization is used by an MA organization in a coordinated care plan. We are also proposing a new § 422.138(b)(1) through (3) to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate. This is consistent with longstanding guidance in Chapter 4, section 30.2, of the MMCM (and also stated in the CY 2021 Final Rule [86 FR 5864]) that supplemental benefits must be medically necessary.

We are aware that Special Supplemental Benefits for the Chronically Ill (SSBCI) may be non-primarily health related. Regular supplemental benefits must be medically necessary, but SSBCI need to have a reasonable expectation of improving or maintaining the health or overall function of the enrollee as required at § 422.102(f)(1)(ii)) and discussed in CY2020 Final Rule (85 FR 33796).

To illustrate how these proposed prior authorization policies would work, we discuss an example regarding coverage of acupuncture. Traditional Medicare currently has an NCD for Acupuncture for Chronic Lower Back Pain (cLBP).[87] This NCD authorizes acupuncture for Medicare patients with chronic Lower Back Pain (cLBP) for up to 12 visits in 90 days under the following circumstance: lasting 12 weeks or longer; nonspecific, in that it has no identifiable systemic cause (that is, not associated with metastatic, inflammatory, infectious disease, etc.); not associated with surgery; and not associated with pregnancy. Here, an MA plan may require prior authorization, before authorizing treatment as a covered basic benefit, to verify the patient's pain is not the result of metastatic, inflammatory, infectious disease, as specified in the NCD. In this example, the plan is using the prior authorization to confirm a diagnosis specified in appropriate Medicare Part B coverage policy (in this case an NCD). Hence, prior authorization is used in this case to verify appropriate use of clinical standards and thus ensuring appropriate care, which is acceptable. Another example would be a beneficiary scheduled to undergo a non-emergency surgery. Here, an MA plan may use prior authorization before approving the surgery to review the beneficiary's medical history to verify that the surgery is medically necessary based on § 422.101(c)(1). In this example, the plan is using prior authorization to ensure that the surgery is clinically appropriate. (It is worth noting that if the surgery is an emergency or urgent surgery, or for stabilization purposes, then prior authorization would not be allowed).

CMS guidance (section 10.16 of Chapter 4 of the MMCM) currently states that if the plan approved the furnishing of a service through an advance determination of coverage, it may not

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[87]https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373

deny coverage later on the basis of a lack of medical necessity. This means that when an enrollee or provider requests a pre-service determination and the plan approves this pre-service determination of coverage, the plan cannot later deny coverage or payment of this approval based on medical necessity. The only exception here would be medical necessity determinations for which the plan has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616. This has been longstanding sub-regulatory guidance (section 10.16 of Chapter 4) that we are proposing to codify at § 422.138(c) to ensure the reliability of an MA organization's pre-service medical necessity determination. Therefore, we do not believe there is any additional impact. We solicit stakeholder input on the reasonableness of this assumption. We also solicit comment whether combining all of our proposals on prior authorization (here and in section III.E.4 of this proposed rule) in proposed new § 422.138 would make applying and understanding these requirements clearer for the public and MA organizations.

Finally, we also remind MA plans that section 1852(b) of the Act states that an MA plan may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status–related factor described in section 2702(a)(1) of the Public Health Service Act. Additionally, per CMS regulations at § 422.100(f)(2), plan benefit designs may not discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. We consider prior authorization policies to be part of the plan benefit design, and therefore cannot be used to discriminate or direct enrollees away from certain types of services.

A complete estimation of impact on this provision cannot be given because we require detailed knowledge of proprietary plan information on the frequency and specific services for

which prior authorization is done in each plan. We solicit comment from stakeholders on the impact and any additional information that would assist CMS in making an estimation.

4. Continuity of Care

In addition to the requirements of section 1852(d) of the Act, § 422.112(b) requires MA organizations that offer coordinated care plans to ensure continuity of care and integration of services through arrangements with contracted providers. Requirements in § 422.112(b)(1) through (b)(7) detail specific arrangements with contracted providers by which MA coordinated care plans are to ensure effective continuity and integration of health care services for their enrollees. This includes requiring MA coordinated care plans to have policies and procedures that provide enrollees with an ongoing source of primary care, programs for coordination of plan services with community and social services, and procedures to ensure that the MA coordinated care plan and its provider network have the information required for effective and continuous patient care and quality review.

a. Stakeholder Feedback

Stakeholders have communicated to CMS that MA coordinated care plans' prior authorization processes sometimes require enrollees to interrupt ongoing treatment. We also have received complaints that MA plans require repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care or are receiving ongoing treatments for a chronic condition. When MA plans require repetitive prior approvals, enrollees may face delays in receiving medically necessary care or experience gaps in care delivery that threaten an enrollee's health.

b. Proposed Regulatory Changes

We believe the inclusion of additional continuity of care requirements at § 422.112 will help ensure coordinated care plans comply with and implement the statutory requirement (in section 1852 of the Act) that MA plans provide access to all medically necessary Medicare covered benefits. We propose to add a new paragraph (b)(8)(i) and (ii) at § 422.112 to set two

new requirements for the use of prior authorization by MA coordinated care plans for covered Part A and B services (that is, basic benefits as defined in § 422.100(c)). Section 422.112(b) requires MA organizations offering coordinated care plans to ensure continuity of care and integration of services through arrangements with contracted providers that include the types of policies, procedures and systems that are specified in current paragraphs (b)(1) through (b)(7). First, we propose, at § 422.112(8)(i) that MA coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization for basic benefits. These prior authorization policies must reflect that all approved prior authorizations must be valid for the duration of the entire approved prescribed or ordered course of treatment or service. To illustrate this, if an MA coordinated care plan has approved a prescribed or ordered course of treatment or service for which the duration is 90 days, then the MA coordinated care plan's prior authorization approval must apply to the full 90 days, and the MA coordinated care plan may not subject this treatment or service to additional prior authorization requirements prior to the completion of the approved 90-day treatment or service. To further illustrate, if the MA coordinated care plan approves a prescribed or ordered course of treatment for a series of five sessions with a physical therapist, the MA coordinated care plan may not subject this active course of treatment or service to additional prior authorization requirements. We solicit comment on whether the prior authorization should be required to be valid for the duration of the prescribed order or ordered course of treatment provided that the criteria in proposed § 422.101(b) and (c) are met. Second, at § 422.112(b)(8)(ii)(A), we define "course of treatment" as a prescribed order or ordered course of treatment for a specific individual with a specific condition, as outlined and decided upon ahead of time, with the patient and provider. (A course of treatment may, but is not required to be part of a treatment plan). We also propose to define an "active course of treatment" at § 422.112(b)(8)(ii)(B) as a course of treatment in which a patient is actively seeing a provider and following the prescribed or ordered course of treatment as outlined by the provider for a particular medical condition.

Additionally, we propose at § 422.112(b)(8)(i)(B) that MA organizations offering coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. This includes enrollees who are new to an MA coordinated care plan having either been enrolled in a different MA plan with the same or different parent organization, or an enrollee in Traditional Medicare and joining an MA coordinated care plan, and beneficiaries new to Medicare and enrolling in an MA coordinated care plan. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

This means that for a minimum of 90 days, when an enrollee switches to a new MA coordinated care plan, any active course of treatment must not be subject to any prior authorization requirements. During the initial 90 days of an enrollee's enrollment with an MA coordinated care plan, the MA coordinated care plan cannot subject any active course of treatment (as defined at the proposed § 422.112(b)(8)(ii)(B)) to additional prior authorization requirements, even if the service is furnished by an out-of-network provider. We expect any active course of treatment to be documented in the enrollee's medical records so that the enrollee, provider, and MA plan can track an active course of treatment and avoid disputes over the scope of this proposed new requirement. We also intend that an active course of treatment can include scheduled procedures regardless whether there are specific visits or activities leading up to the procedure. To further illustrate, if an enrollee has a procedure or surgery planned for January 31st at the time of enrollment in a new MA coordinated care plan effective January 1, the new MA coordinated care plan must cover this procedure without subjecting the procedure to prior authorization. The planned surgery is a part of an active course of treatment and thus cannot be subjected to prior authorization by the MA coordinated care plan in which the

beneficiary has newly enrolled. In proposing to limit the way MA coordinated care plans use prior authorization for enrollees undergoing an active course of treatment, CMS seeks to ensure the availability and accessibility of basic benefits, which is consistent with section 1852 of the Act. CMS is proposing to use a 90 day transition policy here because it mirrors Part D transition requirements and using the same period will ensure consistency across the MA and Part D programs. In addition, use of one consistent transition period will likely make it easier for new enrollees to understand their transition coverage. We solicit public comment on alternative timeframes for transition periods of ongoing treatment, including the clinical and economic justification for alternative proposals.

CMS has authority to adopt standards to carry out the applicable MA provisions in Title XVIII of the Act and to add new contract terms that we find necessary, appropriate, and not inconsistent with the statute in sections 1856(b) and 1857(e) of the Act. In addition, section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. To the extent that these new minimum standards for MA organizations and how they cover benefits would not implement section 1852 of the Act, establish standards to carry out the MA program under section 1856(b) of the Act (which CMS does not concede as these are important protections to ensure that MA enrollees receive Medicare covered services), or be contract terms that we are authorized to adopt under section 1857(e)(1) of the Act, we believe that our negotiation authority in section 1854 of the Act permits creation of minimum coverage requirements. While the rules proposed here do not limit our negotiation authority (which is addressed in § 422.256), they provide minimum standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids, in addition to establishing important protections to ensure that enrollees have access to medically necessary items and services that are covered under Part A and Part B. We note that CMS has similar negotiation authority for the Part D program at section 1860D-11(d)(2) of the Act. CMS implemented a similar policy regarding coverage during a transition

period using that authority and a similar explanation in the 2005 final rule (70 FR 4193). Our proposal is similar to Part D transitional requirements currently codified at § 423.120(b), which require Part D sponsors to provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on their Part D plan's formulary (including Part D drugs that are on a sponsor's formulary, but require prior authorization or step therapy under a plan's utilization management rules). Similar to Part D, as explained previously, we would establish a transition period for services provided as an active course of treatment to enrollees who switch from traditional Medicare to an MA plan and for when an enrollee switches from an MA a plan to another MA plan as described previously. Our experience with oversight and monitoring of the Part D program indicates that the transition policy has proved effective in ensuring continuity of care for Part D beneficiaries. Based on this experience, we believe it is appropriate to incorporate a similar beneficiary protection and coverage requirement in the MA program.

Coordinated care plans are already required to ensure continuity of care and integration of services through arrangements with contracted providers at 422.112(b). Therefore, some MA organizations may already be exercising discretion to waive prior authorization for enrollees undergoing an active course of treatment. However, CMS has received anecdotal feedback from stakeholders that care transitions can be difficult due to MA plan processes that require new coverage decisions when a patient transitions from one MA plan to another. However, we are not aware of the extent to which current MA plans are already ensuring continuity of care in this way nor do we have a strong basis upon which to quantify how often this type of transition occurs. Therefore, we are not quantifying the impact in this proposed rule and we solicit stakeholder input on both of these assumptions: that some MA plans are providing continuity of care as defined in the proposed § 422.112(b)(8) today and the lack of available data by which to quantify it.

5. Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee (§ 422.137)

We are proposing procedural improvements to ensure that utilization management policies are reviewed on a timely basis and have the benefit of provider input. Any authority for MA organizations to use utilization management policies with regard to 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 for to carry out the MA provisions. In light of the feedback we have received and our concern that enrollees may be facing unreasonable barriers to needed care, we propose to require MA organizations to establish a Utilization Management (UM) committee to operate similar to a Pharmacy and Therapeutics, or P&T, committee. We propose to add requirements pertaining to this UM committee in a new regulation at § 422.137.

a. Review and Approval of UM Policies

At § 422.137(a), we propose that an MA organization that uses utilization management (UM) policies, such as prior authorization, must establish a UM committee that is led by an MA plan's medical director (described in § 422.562(a)(4)). Section 422.562(a)(4) requires every MA organization to employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity and establishes that the medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We are also proposing, at § 422.137(b), that an MA plan may not use any UM policies 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. This proposal would ensure that plan policies and procedures meet the standards set forth in this proposed rule beginning with the contract year after the finalization of this proposed rule. We anticipate that there will be sufficient time between our issuance of a final rule and January 1, 2024, for each MA organization to engage in the necessary administrative activity to establish

the UM committee and have its existing UM policies reviewed and, if they meet the standards in this proposed regulation, approved for use.

We propose the committee responsibilities at § 422.137(d). The responsibilities would include that the UM committee, at least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. We propose at § 422.137(d)(1)(i) through (iii) that such review must consider--

- The services to which the utilization management applies;
- Coverage decisions and guidelines for original Medicare, including NCDs, LCDs, and laws; and
- Relevant current clinical guidelines.

We propose at § 422.137(d)(2)(i) though (iv) the committee approve only utilization management policies and procedures that:

- Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);
- Comply with requirements and standards at § 422.138(a)-(c);
- Comply with requirements and standards at § 422.202(b)(1); and
- Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

Currently, § 422.202(b) requires MA organizations to establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures; that formal mechanism for consultation must ensure that certain standards are met. Specifically, § 422.202(b)(1)(i) through (iv) require that MA plan practice guidelines and UM guidelines must: (i) be based on reasonable medical evidence or a consensus of health care professionals in the particular field; (ii) consider the needs of the enrolled population; (iii) be developed in consultation with contracting physicians; and (iv) be reviewed and updated periodically. We are proposing to modify § 422.202(b)(1)(i) to align it

with our standard for creating internal coverage criteria. We therefore propose to replace the requirement that practice and UM guidelines be based on reasonable medical evidence or a consensus of health care professionals in the particular filed with a requirement that UM guidelines be based on current widely used treatment guidelines or clinical literature. This is consistent with the proposed coverage criteria requirements at § 422.101(b)(6), which are discussed in detail in section III.E.2. of this proposed rule.

We solicit comment on whether we should also require the UM committee to ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure, as required by § 422.202(b)(2), that MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees; and whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies. We also propose at § 422.137(d)(3) that the committee must revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines. Mandating annual review of utilization management policies using these standards will help ensure that medically necessary services are accessible to all enrollees. Because prior authorization and referral or gatekeeper policies are included in UM policies and procedures, these proposed requirements would apply as well to those polices used by MA organizations. CMS expects MA organizations to update their UM policies after the UM committee approves or revises them. We solicit comment as well on the extent to which the proposed regulation text sufficiently and clearly establishes the standards and requirements discussed here.

We are considering whether the duties of this UM Committee should be expanded to include all internal coverage policies of an MA plan (or at least of all coordinated care plans).

Whether a policy is explicitly called "utilization management" or a "coverage criteria," the policy can limit enrollee access to plan-covered services. As this proposed rule as a whole makes clear, ensuring that enrollees have access to and are furnished covered benefits is a priority. We solicit comment on whether to require the UM Committee to review all internal coverage criteria used by the MA plan.

b. Utilization Management Committee Membership

At § 422.137(c)(1) through (4), we propose that the UM committee must include a majority of members who are practicing physicians; include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan; include at least one practicing physician who is an expert regarding care of elderly or disabled individuals; and include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies. These composition requirements are in addition to the proposal that the medical director, required for each MA plan under § 422.562(a)(4), lead the UM committee.

We solicit comment on recommendations for other types of providers, practitioners, or other health care professionals that should also be included on the UM committee and whether additional standards for composition of the UM committee are necessary with regard to expertise, freedom of conflicts of interest, or representation by an enrollee representative. We have received feedback from the provider community that UM policies for specific services or items are often not reviewed by providers with the expertise appropriate for the service. Therefore, we also solicit comment on whether we should include a requirement, that when the proposed UM committee reviews UM policies applicable to an item or service, that the review must be conducted with the participation of at least one UM committee member who has expertise in the use or medical need for that specific item or service.

c. Documentation of Determination Process

We propose at § 422.137(d)(4) that the UM committee must clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. Finally, we propose at § 422.137(d)(5) that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. The documentation should provide CMS with an understanding of the UM committee's rationale for their decision, and may include, but is not limited to, information such as meeting minutes outlining issues discussed and any relevant supporting documentation.

d. Interchangeable Use of the P&T and Utilization Management Committees

We believe it is appropriate that this proposal for the establishment of an MA plan UM committee largely mirror, with certain exceptions, the requirements in § 422.136 that MA organizations have a pharmacy and therapeutic committee that reviews and approves step therapy programs for Part B drugs and the requirements regarding membership, scope, and responsibilities of that P&T committee. We believe that similar requirements, which were modeled after the longstanding Part D P&T committee requirements at § 423.120(b), are generally adequate for the purposes of the UM committee. Overall, this proposal is designed to require review and approval of utilization management policies, including utilization management policies that use or impose coverage criteria, to ensure that these policies and procedures are medically appropriate, consistent with Medicare coverage rules, and do not negatively impact access to medically necessary services.

To meet the existing requirements at § 422.136(b), MA-PDs are permitted to utilize an existing P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter. Thus, we anticipate that some of the requirements proposed for the UM

committee may overlap or duplicate existing P&T committee requirements in connection with coverage of and utilization management policies for Part B drugs. Therefore, we solicit comment on whether an MA plan should be permitted to utilize the proposed UM committee at § 422.137 to also meet the existing P&T committee requirements of § 422.136(b), provided that elements and requirements of all applicable regulations governing the committees and their functions (that is, §§ 422.136, proposed 422.137, and 423.120) are met. To the extent that LCD policies and localized or regional professional standards of practice are used by the proposed UM committee in performing its duties, it may not be advisable to permit use of one UM committee to serve multiple functions for diverse service areas. We also solicit comment on whether to explicitly permit an MA organization, or the parent organization of one or more MA organizations, to use one UM committee to serve multiple MA plans, including whether that should be limited to MA plans that are offered under the same contract.

6. Additional Areas for Consideration and Comment

a. Termination of Services in Post-Acute Care

We have received complaints about potential quality of care issues regarding early termination of services in post-acute care settings by MA organizations. The complaints allege that MA organizations are increasingly terminating beneficiaries' coverage of post-acute care before the beneficiaries are healthy enough to return home. It is further alleged that, in some situations, even after a beneficiary has successfully appealed to the Quality Improvement Organization (QIO) and received a favorable decision to reauthorize coverage of services delivered by providers of services described in §§ 422.624 and 422.626, the MA organization sends another notice of termination of services a day or two after the coverage was reinstated. As described in section III.E.2. of this proposed rule, we are proposing to revoke the current policy, outlined in the June 2000 final rule, that when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, an MA plan could choose how the covered services will be provided. Under the proposal at § 422.101(c)(1)(i),

when care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the criteria outlined in § 422.101(c)(1)(i) While CMS believes this may address some of the issues regarding early termination of services, we are soliciting feedback from stakeholders that have information related to this situation, and investigating internally, in order to get a more thorough understanding on the issue.

The rules at 42 § 422.624 define what constitutes a termination of services from home health agencies, SNFs, and comprehensive outpatient rehabilitation facilities and how enrollees must be notified of upcoming terminations of services. We solicit comment on potential changes we could make to existing rules, including § 422.624, or in adopting new rules to better manage incentives between MA organizations and post-acute care providers to deliver the best possible care for Medicare beneficiaries. Some topics for comment include:

- How MA organizations preauthorize treatment in discrete increments and the extent to which our proposals (at proposed §§ 422.101(b) and (c) and 422.112(b)(8)) may address or limit these practices;
- Whether enrollees should have additional time to file appeals or be able to file late appeals to the QIO regarding terminations of services;
- Whether enrollees should receive information from the MA plan regarding the basis for termination of services (for example, the clinical rationale for termination of services) as part of the termination notice and without the enrollee having to request an appeal to the QIO (see § 422.626(e)(1) and (2));
- When coverage is reinstated based on a QIO decision, whether the enrollee should have more than the 2 day period from the date of a new termination of services notice before

coverage can be terminated again by the MA organization, taking into account any medical necessity determinations made by the QIO.

We thank commenters in advance for carefully considering and providing information on this important issue.

b. Gold Carding

In the 2020 proposed rule titled "Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications," which appeared in the Federal Register on December 18, 2020 (85 FR 82586), (hereinafter the December 2020 proposed rule), CMS requested comments on "gold-carding," MA plan programs that relax or reduce prior authorization requirements for contracted providers that have demonstrated a consistent pattern of compliance with plan policies and procedures. At 85 FR 82619, CMS noted that some MA plans relieve certain contracted providers from prior authorizations requirements based on consistent adherence to plan requirements, appropriate utilization of items or services, and other evidence-driven criteria that the MA plan deems relevant. In the December 2020 proposed rule, CMS also discussed its own experience and success with a similar approach in the Medicare FFS Review Choice Demonstration for Home Health Services.[88] It is appropriate to reiterate in this rule that we believe the use of gold-carding programs could help alleviate the burden associated with prior authorization and that such programs could facilitate more efficient and timely delivery of health care services to enrollees. We encourage MA plans to adopt gold-carding programs that would allow providers to be exempt from prior authorization and provide more

[88]https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Choice-Demonstration/Review-Choice-Demonstration-for-Home-Health-Services.html

streamlined medical necessity review processes for providers who have demonstrated compliance with plan requirements.

c. Address Vulnerabilities that can lead to Manual Review Errors and System Errors

Finally, the April 2022 OIG report indicated that some denials were the result of MA plan errors. This included both human and system related errors. For example, the OIG found situations where a request was denied because the MA plan reviewer misidentified important information in a request. They also found situations where a request was denied because provider coverage details were incorrectly configurated in the MA plan's system. As a result of these findings, the OIG recommends that CMS should direct MA organizations to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors. We concurred with this recommendation, and are directing MA plans to review PA procedures, protocols, and systems to identify and address vulnerabilities that can lead to errors. Currently, § 422.503(b)(4) requires all MA organizations to have administrative and management arrangements that include an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse; MA organizations are required to include in this compliance program the establishment and implementation of an effective system for routine monitoring and identification of compliance risks. Failure to furnish medically necessary covered services in a timely manner implicates compliance with §§ 422.100, 422.101 and 422.112 at a minimum, and we believe that the OIG's April 2022 report has sufficiently identified this area as a compliance risk that MA organizations must address in accordance with § 422.503(b)(4)(vi)(F) and (G).

We solicit comment on whether and how existing requirements at § 422.503(b)(4)(vi) may be adjusted to better account for these medical review and system errors. In addition, we solicit comment whether proposed § 422.137 should include a provision for the UM committee

to develop, implement and oversee activities by MA organizations related to utilization policies and procedures.

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS is soliciting comment on a potential revision to the regulation governing MA Reward and Incentive (R&I) programs. CMS first authorized MA organizations to offer R&I programs in a regulation (§ 422.134) finalized in 2014 (79 FR 29956, published May 23, 2014) and subsequently updated that regulation in a January 2021 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" (85 FR 5864, January 21, 2021).

CMS's intent in adopting § 422.134 to authorize MA R&I programs to be offered by MA organizations is to incentivize healthy behaviors among enrollees.. Under § 422.134, MA plans have the option to uniformly offer enrollees rewards in exchange for participating in health related activities which either promote improved health, prevent injury and illness, or promote efficient use of health care resources. Our experience has shown that these programs have been successful to date.

In adopting the regulation governing MA R&I programs, we relied on our authority under sections 1856(b)(1) and 1857(e)(1) of the Act. In addition, several of the provisions of the regulation, such as compliance with relevant fraud and abuse laws including the Federal anti-kickback statute and compliance with MA program anti-discrimination provisions, are consistent with laws governing the Medicare program and the MA program as whole.

Sections 1851(h)(4) and 1854(d)(1) of the Act prohibit an MA organization from giving enrollees cash or monetary rebates as an inducement for enrollment or otherwise. Based on this statutory prohibition of cash or cash equivalents, CMS prohibits a reward item consisting of cash or cash equivalents at 42 CFR 422.134(d)(2)(i). 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 February 18, 2020 **Federal Register** (85 FR 9002), we explained that we were proposing at that time to adopt the Office of Inspector General (OIG)'s definition of cash equivalents (81 FR 88393), which defined ''cash equivalents'' as items convertible to cash (such as a check) or items that can be used like cash (such as a general purpose debit card) but not including a gift card that can be redeemed only at certain store chains or for a certain purpose, like a gasoline card. CMS finalized § 422.134(d)(3)(ii) in a January 2021 final rule with a provision that it is permissible for an MA organization's R&I program to offer a gift card "that can be redeemed only at specific retailers or retail chains or for a specific category of items or services."

However, we have been prompted by several considerations suggesting that CMS may need to further revise and clarify the definition of "cash equivalent" in the framework of MA R&I programs. First, in a recent rule (85 FR 77684, December 2, 2020), OIG explained that cash equivalents include "gift cards offered by large retailers or online vendors that sell a wide variety of items (for example, big-box stores)…". Additionally, the January 2021 CMS final rule also finalized authority for a separate R&I program in connection with a Part D real time benefit tool requirement at § 423.128(d)(4) and (5). In the preamble of that regulation, CMS was clear that a gift card would be considered a cash equivalent when it could be used for large retailers like Amazon.

In addition, another CMS rule (entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' published on December 31, 2018 (83 FR 67816, 67980)) characterizes Amazon gift cards as cash equivalents because they could be used for a variety of diverse purchases, which makes the gift card usable like cash (86 FR 5954).

Finally, in our January 2021 final rule adopting § 422.134, we did not specifically address gift cards from big-box stores nor did we discuss them in relation to the prohibition on cash equivalents in § 422.134(d)(2)(i). CMS has since received inquiries from various stakeholders requesting a definition of 'big-box store' in the context of MA R&I program gift cards.

Because of these considerations and to clarify the scope of prohibited cash equivalents for the purposes of MA Reward & Incentive programs, we are soliciting comment on whether CMS should further clarify the definition of "cash equivalent" as that term is used in § 422.134. CMS is particularly interested in stakeholder feedback on whether CMS should revise our MA R&I program regulation to include parameters for permissible gift cards being offered as MA reward items. We are interested in learning how MA plans interpret and implement our current guidance and whether stakeholders believe that more specific guidance on permissible gift card reward items is necessary. We welcome feedback on all aspects of this issue.

G. Section 1876 Cost Contract Plans and Cost-Sharing for the COVID-19 Vaccine and its Administration (§ 417.454)

Section 3713 of The Coronavirus Aid, Relief, and Economic Security (CARES) Act (2020) (Pub. L. 116–136) requires coverage of the COVID-19 vaccine and its administration at zero cost-sharing for enrollees of Traditional Medicare and Medicare Advantage. The CARES Act revised section 1861(s)(10)(A) of the Act to include among services provided at zero cost-sharing in the Medicare FFS program, the COVID-19 vaccine and its administration. As amended by section 3713 of the CARES Act, section 1852(a)(1)(B)(iv)(VI) of the Act prohibits MA plans from using cost-sharing that exceeds the cost-sharing imposed under traditional Medicare for a COVID–19 vaccine and its administration when the MA plan covers this Traditional Medicare benefit.

Cost plans are coordinated care plans and share many of the same features as Medicare Advantage plans but have a separate statutory authority (section 1876 of the Act) and are paid on

a reasonable cost basis, In addition, unlike with MA plans, enrollees in cost plans may receive services from original Medicare in addition to services from the cost plan's network; when they receive benefits from healthcare providers that are not contracted with the cost plan, cost plan enrollees are covered by original Medicare, with the same cost sharing and coverage as the Traditional Medicare program. The CARES Act did not include the zero cost-sharing provision for section 1876 cost contract plans (cost plans), so using its authority under section 1876(i)(3)(D) of the Act, which authorizes CMS to impose "other terms and conditions not inconsistent with [section 1876]" that are deemed "necessary and appropriate," CMS established a requirement for cost plans to use cost sharing that does not exceed the cost sharing in Traditional Medicare for a COVID-19 vaccine and its administration in an interim final rule, titled Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, which appeared in the **Federal Register** on November 6, 2020[89]. Because of the cost sharing used in Traditional Medicare per sections 1833(a)(1)(B) and 1861(s)(10)(A) of the Act, this is effectively a requirement to cover this benefit with zero cost sharing. In a newly adopted § 417.454(e)(4), we specified the timeline for coverage of a COVID-19 vaccine and its administration with zero cost-sharing for cost plans coverage of cost-sharing for cost plans that may not exceed cost sharing under Traditional Medicare as the "duration of the PHE for the COVID–19 pandemic, specifically the end of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Act, which is the PHE declared by the Secretary on January 31, 2020 and any renewals thereof." However, the CARES Act did not specify an end date for the zero cost-sharing requirement for MA plans and we believe that it is appropriate that enrollees in a section 1876 cost plan have the cost sharing protection for a COVID vaccine and its administration enrollees in the Medicare FFS program and in MA plans have when these cost plan enrollees get this benefit from healthcare providers that are in-network with the cost plan.

[89]See interim final rule with request for comments titled "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" CMS 9912 IFC, 85 FR 71142.

Therefore, we are proposing to replace the provision adopted at § 417.454(e)(4) in the November 2020 interim final rule with a new requirement that section 1876 cost plans cover without cost-sharing the COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act. This proposal is based on authority in section 1876(i)(3)(D) of the Act to add requirements for cost plans.

CMS believes that it is necessary and appropriate to ensure that cost plan enrollees, like other Medicare beneficiaries, are provided access to the COVID-19 vaccine and its administration without cost-sharing in-network. Requiring cost plans to comply with the same cost-sharing protections available to Medicare beneficiaries in traditional Medicare and those enrolled in MA plans would ensure equitable access to care and that cost is not a barrier for beneficiaries to receive the COVID-19 vaccine. CMS has extended to cost plans other statutory requirements related to cost-sharing via regulation for those services that the Secretary determines require a level of predictability and transparency for beneficiaries. For example, in a final rule which appeared in the **Federal Register** on April 15, 2011, CMS, using its authority under section 1876(i)(3)(D) of the Act, extended to cost plans the statutory requirements specifying that in-network cost-sharing for MA enrollees could not be higher than cost-sharing for traditional Medicare enrollees for chemotherapy administration services, renal dialysis services, and skilled nursing care in those cost sharing protections are § 417.454(e)(1) through (e)(3). We welcome comment on this proposal.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

Based on general feedback CMS has received from provider associations regarding the use of prior authorization (PA) by MA organizations and the submission and review of clinical documentation to support a request for coverage of a service subject to PA, we are proposing to

modify the requirement in §§ 422.566(d) and 422.629(k)(3) with respect to the expertise of the physician or other appropriate health care professional who must review an organization determination if the MA organization or applicable integrated plan (AIP), defined at § 422.561, expects to issue an adverse decision based on the initial review of the request. Pursuant to our authority under section 1856(b) of the Act to adopt standards to carry out the Part C program and in order to implement section 1852(g) of the Act regarding coverage decisions and appeals, CMS established procedures and minimum standards for MA plans to make organization determinations and reconsiderations regarding benefits. In addition, CMS adopted unified grievance and appeal procedures using authority in section 1859(f)(8)(B) of the Act to establish such unified procedures for D-SNPs; we limited the unified procedures to AIPs, a subset of D-SNPs, when adopting those procedures. These requirements are codified in our regulations at 42 CFR Part 422, subpart M. In addition, because cost plans must comply with the beneficiary appeals and grievance rights, procedures, and requirements at Part 422, subpart M, per §§ 417.600(b) and 417.840, these proposals apply to cost plan and healthcare prepayment plan appeals as well.

Specifically, section 1852(g)(1)(A) of the Act requires that a MA organization have a procedure for making determinations regarding whether an enrollee is entitled to receive a health service and the amount (if any) the individual is required to pay for such service and, further, that such procedures provide that determinations be made on a timely basis, subject to section 1852(g)(3) of the Act (which provides for expedited determinations and reconsiderations as part of the MA plan's appeal process). Section 1852(g)(2)(B) of the Act requires plan reconsiderations related to coverage denials that are based on medical necessity determinations to be made by a physician with appropriate expertise in the applicable field of medicine, and that the physician reviewer be different from the physician or other health care professional involved in the initial determination. While section 1852(g)(1)(A) of the Act does not specify who must conduct the initial medical necessity determinations, we interpret the reference in section

1852(g)(2)(B) of the Act to the physician involved in the initial determination to mean that MA plans must have appropriate health care professionals review initial determinations involving issues of medical necessity. This is an established interpretation of the statute and is reflected in existing regulations related to review of organization determinations. Specifically, the current regulation at § 422.566(d) states that if the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. The current regulation at § 422.629(k)(3) also applies the same requirement to AIPs with the additional requirement that the health care professional also have knowledge of Medicaid coverage criteria.

We are proposing to revise §§ 422.566(d) and 422.629(k)(3) to add to that existing requirement that the physician or other appropriate health care professional who conducts the review must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA organization or AIP issues an adverse organization determination decision. In other words, we are proposing that the existing regulation text with the more general requirement that the physician or other appropriate health care professional have sufficient medical and other expertise be replaced by a requirement linking the requisite expertise of the reviewer to the specific service that is the subject of the organization determination request. Under this proposal, the physician or other appropriate health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. This is the same standard set forth at § 422.590(h)(2) related to the

appropriate expertise applicable to physician review of reconsiderations. The rule at § 422.590(h)(2) interprets and implements the requirement in section 1852(g)(2)(B) of the Act that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity be made only by "a physician with appropriate expertise in the field of medicine which necessitates treatment" to mean a physician with an expertise in the field of medicine that is appropriate for the covered services at issue. The standard of requiring a reviewing physician's expertise to be appropriate for the specific service at issue is long-standing policy with respect to plan reconsiderations and we believe it is appropriate as well as practical to adopt this standard for the review of organization determinations by physicians and other appropriate health professionals in §§ 422.566(d) and 422.629(k)(3). Specifically, this proposed approach would strengthen clinical review in the organization determination process, while continuing to afford plans maximum flexibility in leveraging reviewer resources.

If this proposal is finalized, we expect MA organizations, including AIPs, to apply the standard of "expertise appropriate for the specific service at issue" at the organization determination level in the same manner as plans have applied this standard at the reconsideration level. As explained in the final rule establishing the Medicare+Choice program (65 FR 40170, 40288), published June 29, 2000, which later became the Medicare Advantage program, and in established sub-regulatory guidance, if the physician is not of the same specialty or subspecialty as the treating physician, the physician must have the appropriate level of training and expertise to evaluate the necessity of the requested drug, item, or service. This does not require the physician involved to be of the exact same specialty or sub-specialty as the treating physician. As an example, where there are few practitioners in a highly specialized field of medicine, a plan may not be able to retain the services of a physician of the same specialty or sub-specialty to review the organization determination. Plans will have discretion to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition. For example, if an enrollee is referred by a primary

care physician to a thyroid surgeon for a thyroid nodule removal, the health professional evaluating the request prior to the plan issuing a denial should be a doctor with thyroid expertise, but does not necessarily need to be a surgeon. As another example, if a plan intends to deny a request for a home nebulizer, the organization determination request should be reviewed by a health professional with respiratory expertise, such as a respiratory therapist.

If finalized, we believe this proposal will enhance the existing requirement for who is permitted to review organization determinations that deny coverage in whole or in part, while retaining plan flexibility and operational efficiency in selecting appropriate reviewers. We reiterate that this requirement applies when the MA organization or AIP expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request and does not limit the scope of reviewers where the plan approves coverage or determines that an item or service is medically necessary. From the perspective of enrollees and providers who request coverage on an enrollee's behalf or submit clinical documentation to support a coverage request, we believe this review standard will increase the likelihood of a thorough clinical review. Requiring expertise related to the requested service, as we are proposing, will enhance the overall decision-making process and the quality of the review conducted at the organization determination level, particularly when a prior authorization or other utilization management requirement on the requested item or service necessitates review of specific clinical documentation to support coverage. Further, we believe this proposal may reduce coverage denials at the organization determination level that could then be subject to the administrative appeals process. As a whole, we believe that this proposal strikes the appropriate balance between the proper clinical review of organization determinations and minimizing overall burden in the administration of the Part C benefit for MA plans and AIPs.

While the proposed requirement that the physician or other appropriate health care professional have expertise in the field appropriate to the requested service may result in AIPs and other MA organizations reallocating staff resources in certain cases to ensure that someone

with appropriate expertise is reviewing the request, we believe that the burden will be negligible and that this proposal will not require changes to AIPs and other MA organizations overall staffing. While performing a review of an organization determination request involves review of clinical documentation, this proposal would not impose any new information collection or recordkeeping requirements on AIPs or other MA organizations.

In the course of this rulemaking, we noticed the need for a technical correction in § 422.590(b)(1), which cross references the effectuation requirements in § 422.618. Section 422.590(b)(1) erroneously cites to § 422.618(a)(1), but it should cite to the effectuation requirements at § 422.618(a)(2) related to favorable decisions on payment requests. Thus, we propose to make the technical correction in this rule.

We welcome comments on this proposal and the technical correction.

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

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

Our current regulations at §§ 422.550 and 423.551, as well as our MA guidance under "Chapter 12 of the Medicare Managed Care Manual—Effect of Change of Ownership"[90] require that when a change of ownership occurs, as defined in the regulation, advance notice must be provided to CMS and the parties to the transaction must enter into a written novation agreement

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

that meets CMS' requirements. If a change of ownership occurs and a novation agreement is not completed and the entities fail to provide notification to CMS, the regulations at §§ 422.550(d) and 423.551(e) indicate that the existing contract is invalid. Furthermore, §§ 422.550(d) and 423.551(e) provide that if the contract is not transferred to the new owner through the novation process, the new owner must enter into a new contract with CMS after submission of an MA or Part D application, if needed.

The current regulation does not fully address what happens when the contract becomes "invalid" due to a change of ownership without a novation agreement and/or notice to CMS, or in other words, what happens to the existing CMS contract that was held by an entity that was sold. This presents an issue because CMS would still recognize the original entity as the owner, even if the contract is now held by a different entity. Therefore, we are proposing to revise §§ 422.550(d)(1) and 423.551(e)(1) to make it clear that in this case, the affected contract may be unilaterally terminated by CMS in accordance with §§ 422.510(a)(4)(ix) and 423.509(a)(4)(ix), which establishes that failure to comply with the regulatory requirements contained in part 422 (or part 423 if applicable) is a basis for CMS to terminate an MA or Part D contract. In addition, we are strengthening our enforcement authority regarding this process, with the proposed amendments to §§ 422.550(d) and 423.551(e). Pursuant to our authority under sections 1857 and 1860 of the Act, we propose to amend the regulations at §§ 422.550(d) and 423.551(e) to outline the process CMS will follow, including imposing applicable sanctions before terminating a contract that has a change in ownership without a novation agreement, in accordance with CMS requirements.

In the interest of protecting and effectively managing the MA and Part D programs, CMS, through the application process, must ensure that MAOs through their respective legal entities are deemed eligible to contract with CMS. Thus, any change in ownership from one legal entity to another requires CMS to determine whether the new organization continues to meet the regulatory requirements for operating a contract under the MA and Part D programs. If

this does not happen and a change in ownership from one legal entity to another occurs without CMS approval, it compromises our ability to ensure the integrity of the MA and Part D programs and further puts at risk our ability to monitor a contract's activity under the new legal entity, thereby putting enrollees at risk. We propose to provide an opportunity for organizations to demonstrate that the legal entity that is assuming ownership by way of novation is able to meet the requirements set forth by our regulations.

We propose to impose intermediate enrollment and marketing sanctions, as outlined in § 422.750(a)(1) and (a)(3) and § 423.750(a)(1) and (a)(3) on the affected contract, that will remain in place until CMS approves the Change of Ownership, (including execution of an approved novation agreement) or the contract is terminated. This may be completed in the following ways:

- If the new owner does not participate in the same service area as the affected contract, at the next available opportunity, it must apply for and be conditionally approved for participation in the MA or Part D program and within 30 days of the conditional approval (if not sooner) submit the documentation required under §§ 422.550(c) or 423.551(d) for review and approval by CMS (note that organizations may submit both the application and the documentation for the change of ownership concurrently); or

- If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions, submit the documentation required under §§ 422.550(c) or 423.551(d) for review and approval by CMS.

If the new owner is not operating in the same service area and fails to apply at the next opportunity, the existing contract will be subject to termination in accordance with §§ 422.510(a)(4)(ix) or 423.509(a)(4)(x). Or if the new owner is operating in the same service area and fails to submit the required documentation within 30 days of imposition of intermediate

sanctions, the existing contract will be subject to termination in accordance with §§ 422.510(a)(4)(ix) or 423.509(a)(4)(x).

This action would be subject to the past performance rules applicable under §§ 422.502(b)(1) or 423.503(b)(1).

We solicit comments on these proposals.

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

Sections 1857(g)(3)(A) and 1860D-12(b)(3)(E) of the Act provide CMS with the ability to impose Civil Money Penalties (CMPs) of up to $25,000 per determination (determinations are those which could otherwise support contract termination, pursuant to § 422.509 or § 423.510), as adjusted annually under 45 CFR part 102, when the deficiency on which the determination is based adversely affects or has the substantial likelihood of adversely affecting an individual covered under the organization's contract. Additionally, as specified in §§ 422.760(b)(2) and 423.760(b)(2), CMS is permitted to impose CMPs of up to $25,000, as adjusted annually under 45 CFR part 102, for each enrollee directly adversely affected or with a substantial likelihood of being adversely affected by a deficiency. CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted annually[91] for each affected enrollee or per determination, however CMS does not necessarily apply the maximum penalty amount authorized by the regulation in all instances because the penalty amounts under the current CMP calculation methodology are generally sufficient to encourage compliance with CMS rules.

On December 15, 2016, CMS released on its website, the first public CMP calculation methodology for calculating CMPs for MA organizations and Part D sponsors starting with referrals received in 2017. On March 15, 2019, CMS released for comment a proposed CMP

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

calculation methodology on its website that revised some portions of the methodology released in December 2016. Subsequently, on June 21, 2019, CMS finalized the revised CMP calculation methodology document, made it available on its website, and applied it to CMPs issued starting with referrals received in contract year 2019 and beyond.[92]

On January 19, 2021, CMS published a final rule in the **Federal Register** titled "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" (86 FR 5864). In that final rule, CMS finalized a policy, effective beginning in CY 2022, to update the minimum CMP penalty amounts no more often than every three years. Under this policy, CMS updates the CMP penalty amounts by including the increases that would have applied if CMS had multiplied the minimum penalty amounts by the cost-of-living multiplier released by the Office of Management and Budget (OMB)[93] each year during the preceding three-year period. CMS also tracks the yearly accrual of the penalty amounts and announces them on an annual basis.

The intent of the minimum penalty increase policy was to establish the CMP calculation methodology document in regulation to ensure consistency and transparency with CMP penalty amounts. Although parts of the regulations at §§ 422.760(b)(3) and 423.760(b)(3) have set standards for CMP penalties, in hindsight, CMS believes that other parts of the regulations unnecessarily complicated CMS's approach to calculating CMPs, which has the effect of limiting CMS's ability to protect beneficiaries when CMS determines that an organization's non-compliance warrants a CMP amount that is higher than would be normally be applied under the

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

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

CMP methodology. In addition, although CMS always has had the authority to impose up to the maximum authorized under sections 1857(g)(3)(A) and 1860D-12(b)(3)(E) of the Act, parts of the minimum penalty increase policy may have inadvertently given the impression that CMS was limiting its ability to take up to the maximum amount permitted in statute and regulation. This was not the intent of the rule. For example, there may be instances where an organization's non-compliance has so substantially adversely impacted one or more enrollees, that CMS would determine it necessary to impose the maximum CMP amount, or an amount higher than the amount set forth in the CMP methodology guidance to adequately address the non-compliance. In order to clarify its ability to adequately protect beneficiaries and encourage compliance, CMS proposes to modify its rules pertaining to minimum penalty amounts.

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

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

We solicit comment on these proposals.

K. Call Center Interpreter Standards (§§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A))

CMS is proposing to amend §§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A) to establish standards for interpreter services utilized by MA organizations and Part D sponsors in connection with their toll-free customer call centers. CMS relies on the Secretary's authority at sections 1857(e)(1) and 1860D-12(b)(3)(D) of the Act to adopt additional contract terms and conditions as the Secretary may find necessary and appropriate, and not inconsistent with the statute, to adopt these additional requirements for MA organizations and Part D sponsors. CMS also relies on the authority in sections 1852(c)(1) and 1860D–4(a)(1)(B) of the Act, under which MA organizations and Part D sponsors must disclose detailed information about plans, to establish call center requirements. These proposed interpreter standards will ensure adequate and appropriate access to information for non-English speaking and Limited English Proficiency (LEP) Medicare beneficiaries, such that the information disclosure requirements for MA organizations and Part D sponsors are met and enrollment in MA and Part D plans is accessible for these groups.

Specifically, we propose to require MA organizations and Part D sponsors to use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

CMS has consistently stated that MA organizations and Part D sponsors should use appropriate interpreters to ensure that non-English speaking and LEP beneficiaries have access to assistance. On January 2, 2008, CMS released an HPMS memo, "Best Practices for Addressing the Needs of Non-English Speaking and Limited English Proficient (LEP) Beneficiaries," which suggested that Part D sponsors and MA organizations review additional HHS guidance on developing an effective plan for language assistance for LEP beneficiaries. This guidance, titled

"Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," appeared in the **Federal Register** on August 8, 2003 (68 FR 47311) and provided the following criteria to determine the competency of interpreters: demonstrate proficiency in and ability to communicate information accurately in both English and in the other language; have knowledge in both languages of any specialized terms or concepts peculiar to the recipient's program or activity and of any particularized vocabulary and phraseology used by the LEP person; and understand and follow confidentiality and impartiality rules. Additionally, since 2010, CMS has annually encouraged MA organizations and Part D sponsors to review and use the Office of Minority Health's (OMH) National Standards on Culturally and Linguistically Appropriate Services (CLAS), originally published in 2001 and most recently updated in 2018.[94] The CLAS standards include a requirement to provide competent language assistance services. Most recently, in our December 16, 2021 HPMS memo titled "2022 Part C and Part D Call Center Monitoring – Timeliness and Accuracy & Accessibility Studies," we recommended that MA organizations and Part D sponsors use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology. We selected these criteria in our guidance because they are similar to requirements for interpreters under 45 CFR 92.101(b)(3)(i)(A)-(C), when an interpreter is required as a reasonable step to ensure meaningful access to programs or activities by LEP individuals under 45 CFR 92.101(b)(3)(i), which

[94]CMS includes this reminder regarding OMH's CLAS standards in our annual HPMS memo detailing the methodology of our call center monitoring studies. For example, see our December 9, 2010 HPMS memo titled "2011 Part C and Part D Call Center Monitoring and Guidance for Providing Services to Limited English Proficient Beneficiaries;" our December 16, 2013 HPMS memo titled "2014 Part C and Part D Call Center Monitoring and Guidance for Timeliness and Accuracy and Accessibility Studies;" our November 16, 2016 HPMS memo titled "2017 Part C and Part D Call Center Monitoring and Guidance for Timeliness and Accuracy and Accessibility Studies;" and our December 16, 2021 HPMS memo titled "2022 Part C and Part D Call Center Monitoring - Timeliness and Accuracy & Accessibility Studies."

implements section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, (Pub. L 111-148).[95] We note that we did not adopt in our guidance, and do not intend to adopt in this proposed rule, the standard for requiring an interpreter under 45 CFR 92.101(b)(1). Rather, we intend to continue to require that Part D sponsors and MA organizations provide an interpreter for non-English speaking and LEP individuals whenever such an individual contacts the toll-free customer call center under 42 CFR §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii).

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 appeared in the **Federal Register** on April 15, 2011 (76 FR 21431), CMS adopted provisions at §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) to require MA organizations and Part D sponsors to provide interpreters for non–English speaking and LEP individuals who call the plan's toll-free customer call center. In the time since CMS created this requirement for MA organizations and Part D sponsors, there has been a significant increase in timely access to interpreters. For example, CMS data show that interpreters were being made available timely by MA and Part D plans during 66 percent and 60 percent, respectively, of the calls we monitored in 2011; 82 percent and 81 percent, respectively, in 2015; and 88 percent and 86 percent, respectively, in 2021.

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

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[95]Recipients of Federal financial assistance are separately obligated to comply with Federal civil rights laws that require recipients to take reasonable steps to ensure meaningful access to their programs and activities by LEP individuals, including through provision of language assistance services that may require interpreters. These laws, enforced by the HHS Office for Civil Rights, include Section 1557 of the Affordable Care Act (42 U.S.C. 18116 and implementing regulation at 45 CFR Part 92) (Section 1557), which prohibits, inter alia, discrimination on the basis of race, color, national origin, sex, age, and disability in health programs and activities receiving Federal financial assistance; and Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq. and implementing regulation at 45 CFR Part 80) (Title VI), which prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving Federal financial assistance. Regulations implementing Section 1557 set forth specific requirements related to provision of language assistance services, including requirements for interpreter and translation services, when they are required as a reasonable step to ensure meaningful access to programs or activities by limited English proficient individuals. See 45 CFR Part 92 for additional information.

for the Elderly," which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) (the January 2021 final rule), CMS codified its standards for evaluating compliance by MA and Part D plans with the requirement to provide interpreters for calls to the plans' toll-free call centers by amending §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii). The amendments added requirements that interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller. These requirements strengthened enrollees' and prospective enrollees' access to interpreters when they call a plan, and thus to information about how to access Medicare-covered benefits.

Building on our previous regulatory proposals to establish and strengthen MA and Part D enrollee access to plan interpreter services, we propose to codify requirements for minimum qualifications for interpreters available to non-English speaking and LEP individuals at MA and Part D call centers. To accomplish this, we are proposing to modify § 422.111(h)(1)(iii)(A) to require MA organizations' interpreters for LEP individuals to meet certain minimum qualifications. As proposed in new paragraphs (A)*(1)* through *(3)* these qualifications include, respectively:

- Adhering to generally accepted interpreter ethics principles, including confidentiality;
- Demonstrating proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and
- Interpreting effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

We propose to establish the same requirements for Part D sponsor interpreters by modifying § 423.128(d)(1)(iii)(A) and adding proposed new paragraphs (A)*(1)* through (A)*(3)* that mirror the proposed changes to § 422.111(h).

We note that on August 4, 2022, HHS published a Notice of Proposed Rulemaking regarding Section 1557 of the Affordable Care Act, which would codify a definition of qualified interpreter similar to what we are proposing here.

We solicit comments on this proposal.

L. Call Center Teletypewriter (TTY) Services (§§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B))

We are proposing to make a technical change to §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B), which require that MA organizations and Part D sponsors, respectively, connect 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes. Our proposed change is intended to remove any ambiguity that might result from our use of the term "TTY operator." The specific standards found at §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B) were intended to require that that the caller reach a live person and confirm that said person is able to assist with general Medicare questions or questions about the plan's Part C or Part D benefits within a specific period of time. When an MA organization or Part D sponsor operates their own TTY device and thereby creates a direct TTY to TTY communication, the plan customer representative is also the TTY operator. However, where MA organizations and Part D sponsors utilize telecommunications relay systems, a TTY operator serves as an intermediary between the caller and the plan's customer service representative and is not able to answer the caller's questions about plan benefits.

To ensure that someone utilizing TTY services is connected to a plan customer representative within 7 minutes, we propose to modify §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B) to instead require the plan's call center establish contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

We solicit comment on this proposal.

M. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294)

1. Overview and Summary

We propose to add into regulatory text our longstanding prohibition of midyear benefit changes, previously referred to as midyear benefit enhancements (MYBEs) for MA and Part D plans. Specifically, we propose to add regulatory text prohibiting changes to non-drug benefits, premiums, and cost sharing by an MA organization starting after plans are permitted to begin marketing prospective contract year offerings on October 1 (consistent with § 422.2263(a)) of each year for the following contract year and until the end of the applicable contract year. Similarly, we also propose to codify into regulation our longstanding policy prohibiting Part D sponsors from making midyear changes to the benefit design or waiving or reducing premiums, bid-level cost sharing (for example, the cost sharing for an entire formulary tier of Part D drugs), or cost sharing for some or all of a Part D plan's enrollees starting after plans are permitted to begin marketing prospective contract year offerings on October 1 (consistent with § 423.2263(a)) of each year for the following contract year and until the end of the applicable contract year.

Finally, we propose to require Part D sponsors to: (1) refund incorrect collections of premiums and cost sharing, and (2) recover underpayments of premiums and cost sharing. We also propose to establish both a lookback period and timeframe to complete overpayments and underpayment notices, as well as a de minimis threshold for such refunds and recoveries. We solicit comments regarding the addition of similar requirements in MA, specifically establishing a lookback period and de minimis threshold for refunding incorrect collections.

2. Medicare Advantage Prohibition on Midyear Benefit Changes (§ 422.254)

In our proposed rule titled, "Medicare Program; Establishment of the Medicare Advantage Program" (69 FR 46865), which appeared in the **Federal Register** on August 3, 2004, and is hereinafter referred to as the "August 2004 MA proposed rule," we acknowledged that in the previous Medicare+Choice program, organizations were permitted to offer MYBEs to

existing benefit packages. We proposed to discontinue this policy, noting how we believed that it would no longer be appropriate to allow MA organizations to offer new plans or change an existing plan's benefits midyear because such revised (or new) MA plans would not reflect the bids which were approved during the normal approval process (as set forth in 42 CFR Part 422, Subpart K). We explained how MYBEs are de facto adjustments to benefit packages for which bids were submitted by MA organizations based on their estimated revenue requirements. Specifically, we expressed concern that allowing MYBEs could render the bid meaningless (69 FR 46899).

In our final rule titled, "Medicare Program; Establishment of the Medicare Advantage Program" (70 FR 4640), which appeared in the **Federal Register** on January 28, 2005, and is hereinafter referred to as the "January 2005 MA final rule," we adopted the MYBE policy described in the August 2004 MA proposed rule with modifications in response to comments from MA organizations requesting flexibility regarding MYBEs in order to improve enrollee experiences or adjust for unforeseen errors, under certain circumstances. Specifically, we adopted a limited MYBE policy to (1) permit a MYBE to be effective no earlier than July 1 of the contract year, and no later than September 1 of the contract year; (2) prohibit MA organizations from submitting MYBE applications later than July 31 of the contract year; and (3) require 25 percent of the value of the MYBE to be retained by the government. The policy also required the MA organization to submit a revised bid and supporting documentation about how revenue requirements were overstated in the bid submitted for the contract year. (70 FR 4640) However, we noted that this was an interim policy for the initial years of the competitive bidding system and that we would review the continuing need for the policy.

Subsequent to the January 2005 MA final rule, we issued the proposed rule titled, "Medicare Program; Prohibition of Midyear Benefit Enhancements for Medicare Advantage Organizations Offering Plans in Calendar Year 2007 and Subsequent Calendar Years" (71 FR 52014), which appeared in the **Federal Register** on September 1, 2006, and is hereinafter

referred to as the "September 2006 MA proposed rule." There, we proposed that, beginning with CY 2007, MA organizations would not be permitted to make any midyear changes in benefits, premiums, or cost sharing, even under the circumstances in which these types of changes were permitted previously. We finalized this policy in the final rule titled, "Medicare Program; Prohibition of Midyear Benefit Enhancements for Medicare Advantage Organizations" (73 FR 43628), which appeared in the **Federal Register** on July 28, 2008, and is hereinafter referred to as the "July 2008 final rule."

While previous rules referred to these changes as "midyear benefit enhancements," or MYBEs, we are proposing to instead use the term "midyear benefit changes" to better clarify that all changes (enhancements or reductions) to non-prescription drug benefits, premiums, and cost sharing are prohibited for MA plans, consistent with the scope of our prior rulemaking. However, we are not proposing to prohibit MA plans from revising plan rules, such as prior authorization or referral policies, or from making network changes; the rules in § 422.111(d) regarding notice to enrollees about changes in plan rules are not proposed to be changed. Please see section III.D. of this proposed rule for our proposal to revise the rules in § 422.111(e) concerning notice of a change in an MA plan's provider network. Additionally, this proposal, if finalized, would not prohibit MA plans from covering required changes or additions to basic benefits, that is Part A and Part B benefits that all MA plans must cover, when those changes or additions to basic benefits are the result of a change in the law, such as newly enacted legislation, or rulemaking or a National Coverage Determination; such changes are required to be made by MA plans, subject to section 1852(c)(5) of the Act and § 422.109 which provide for the Medicare FFS program to cover certain changes in Part A and Part B benefits. Our proposal encompasses other changes in MA non-drug, premiums and any cost sharing outside of required changes or exceptions we have noted here. Consequently, we hereinafter refer to these alterations as "midyear benefit changes" (MYBCs).

Although we finalized the policy in the July 2008 final rule and have accordingly enforced it ever since, we now propose to add regulatory text explicitly prohibiting MYBCs and specifying when such changes will be prohibited. Specifically, we propose to clarify in regulatory text that any changes to non-prescription drug benefits, cost sharing, and premiums are prohibited starting after plans are permitted to begin marketing prospective contract year offerings on October 1 of each year for the following contract year (consistent with § 422.2263(a)) and through the end of the applicable contract year. This means that after marketing is permitted to begin for the 2024 contract year, MA organizations must offer the benefits described in approved bids through the end of the 2024 contract year. In other words, MA organizations are prohibited in this scenario from changing the benefits, cost sharing and premiums in their approved bids from October 1, 2023 until December 31, 2024, except for modifications in benefits required by law.

Consistent with our current practice as described in the July 2008 final rule, prohibiting changes after marketing is permitted to begin provides MA organizations the flexibility to make changes during the bidding process when permitted by CMS to remain in compliance with the requirements set forth at § 422.254(b), while also maintaining the integrity of the bidding process.

We note that per § 422.2263 following the start of marketing on October 1 of each year, MA organizations may begin to market and publicize their plan offerings for the following contract year, such that organizations may compare their approved plans against competitors in order to make advantageous changes. As we noted the August 2004 and September 2006 MA proposed rules, allowing MYBCs undermines the integrity of the bidding process as it allows MA organizations to alter their benefit packages after the bidding process is complete. Further, MA organizations may use MYBCs to misrepresent their actual costs and noncompetitively revise their benefit packages later in the year (69 FR 46899, 70 FR 4301, 71 FR 52016).

Altering an approved plan to include new benefits after marketing has started may also give MA organizations an unfair advantage over competitors when beneficiaries are selecting their plans during the initial coverage elections period (ICEP). We articulated in the July 2008 final rule that we believe newly age-eligible enrollees are attractive to MA organizations because of their relatively low utilization, as these individuals are new to the program and tend to be healthier (73 FR 43631). Therefore, to prevent MA organizations from inappropriately changing bids to appeal to low-utilization enrollees, an MA organization must provide the benefits described in the MA organization's final plan benefit package (PBP) (as defined in § 422.162(a)) until the end of the applicable contract year. The July 2008 final rule reiterated these points. Despite the issuance of the July 2008 final rule, however, we have continued to receive inquiries from MA organizations requesting changes to PBPs after the contract year has begun.

We note that MYBCs of this nature would also violate the uniformity requirements set forth at § 422.100(d)(ii), which requires that an MAO must offer their plan to all beneficiaries in a service area "at a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2)." Altering the non-prescription drug benefits, premiums, or cost sharing midyear violates this requirement, even if the new benefit, premium, or cost sharing is offered to all of the plan's enrollees, as some enrollees would have paid for such benefits, premiums, or cost sharing already, and would not be eligible for reimbursement of these costs. In other words, some plan enrollees would have paid higher or lower amounts for the same benefits or services than other enrollees who paid depending on when the MYBC was put in effect.

On May 22, 2020, we issued guidance in a Health Plan Management System (HPMS) memorandum titled "Information Related to Coronavirus Disease 2019 – COVID-19" (hereinafter referred to as the "2020 COVID-19 guidance," and available at https://www.cms.gov/files/document/covid-19-updated-guidance-ma-and-part-d-plan-sponsors-may-22-2020.pdf) which specified changes in policy for MA Organizations following the

declaration of the COVID-19 Public Health Emergency (PHE). Due to the extraordinary nature of the PHE and its impact on Medicare eligible individuals and the disabled and elderly population generally, the 2020 COVID-19 guidance allowed for relaxed enforcement of the prohibition on MYBCs, with certain limitations. Specifically, MYBCs would be allowed when such MYBCs are: (1) provided in connection with the COVID-19 PHE; (2) beneficial to enrollees; and (3) provided uniformly to all similarly situated enrollees. Additionally, we permitted MA organizations to implement additional or expanded benefits that address issues or medical needs raised by the COVID-19 PHE, and provided examples like covering meal delivery or medical transportation services to accommodate the efforts to promote social distancing during the COVID-19 PHE. We further noted in our January 14, 2022 memo entitled "Coronavirus Disease 2019 (COVID-19) Permissive Actions Extended in Contract Year 2022" that we would exercise our enforcement discretion until the conclusion of the COVID-19 PHE. Despite the current COVID-19 guidance, MA organizations have continued to request changes to approved plan bids which are not consistent with the parameters specified in such guidance.

While our proposed addition to the regulation text is not intended to supersede the 2020 COVID-19 guidance (should it remain in effect through the 2024 calendar year), we propose to add regulatory text to solidify longstanding policy to prohibit MYBCs starting after the plan has begun marketing prospective contract year offerings on October 1 of each year for the following contract year and until the end of the applicable contract year as a means to provide clarification for MA organizations and maintain the integrity of the bidding process. As discussed previously, this prohibition includes exceptions for changes in benefits required by applicable law.

Employer Group Waiver Plans (EGWPs) exclusively enroll the members of the group health plan sponsored by the employer, labor organization (that is, union) or trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations; these plans generally have "800 series" MA contracts with CMS. These EGWPs are not currently

subject to this prohibition on MYBCs under existing CMS waivers for EGWPs. However, an MA organization is subject to the prohibition on MYBCs if the MA organization offers an MA plan that that enrolls both individual beneficiaries and employer or union group health plan members, (that is, a plan open to general enrollment); for those types of plans, the employer or union sponsor may make mid-year changes to offer or change only non-MA benefits that are not part of the MA contract (that is, are not basic benefits or MA supplemental benefits). (*See* 73 FR 43630 and Chapter 9, section 20.3, of the Medicare Managed Care Manual, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c09.pdf.)

Because this proposal would add regulatory text regarding the MYBC policy which has already undergone notice and comment rulemaking, and does not change the scope of that prior non-codified rule, this provision is technical in nature, and there is no paperwork burden. Additionally, this provision will not impact the Medicare Trust Fund.

We solicit comment on these proposals.

3. Part D Prohibition on Midyear Benefit Changes (§ 423.265)

Section 1860D-11(d) of the Act grants CMS the authority to review information pertaining to Part D sponsors' proposed plans and negotiate terms and conditions of the proposed bid and proposed plan with Part D sponsors. Section 1860D-11(e) of the Act grants CMS the authority to approve Part D sponsors' proposed plans. To implement sections 1860D-11(d) and (e) of the Act, we proposed regulations at § 423.272 in our proposed rule titled "Medicare Program; Medicare Prescription Drug Benefit" (69 FR 46631), which appeared in the **Federal Register** on August 3, 2004 (hereinafter referred to as the "August 2004 Part D proposed rule"). We finalized these regulations in our final rule titled "Medicare Program; Medicare Prescription Drug Benefit" (70 FR 4193), which appeared in the January 28, 2005 issue of the **Federal Register** (hereinafter referred to as the "January 2005 Part D final rule").

In response to comments to our August 2004 Part D proposed rule regarding the authority to enter into bid-level negotiation with Part D sponsors, and as was discussed in section III.M.2.

of this proposed rule, we stated in our January 2005 Part D final rule that in order to maintain the integrity of the bidding process, we believed it was not appropriate to allow either MA organizations or Part D sponsors to waive premiums or offer midyear benefit enhancements, as they would be de facto adjustments to benefit packages for which bids were submitted earlier in the year. We also stated that these adjustments would be de facto acknowledgement that the revenue requirements submitted by the plan were overstated, and further, that allowing premium waivers or midyear benefit enhancements would render the bid meaningless (70 FR 4301).

As noted in section III.M.2. of this proposed rule, we previously referred to these changes as "midyear benefit enhancements," or MYBEs, and it stands to reason that midyear benefit changes, whether enhancements or reductions, are equally problematic from the perspective of bid integrity. Therefore, we hereinafter refer to these alterations as "midyear benefit changes," or MYBCs.

Additionally, section 1860D-11(e)(2)(C) of the Act requires that the bid reasonably and equitably reflect the revenue requirements of the expected population for the benefits provided under the plan. Therefore, in addition to indicating that the plan bid was overstated and rendering the bid meaningless, waiving or reducing the premiums, cost sharing, or both, that are reflected in the approved bid would indicate that the amounts provided in the bid were not necessary for the provision of coverage.

We draw a distinction here between changes in "bid-level" cost sharing (for example, the cost sharing associated with an entire tier of drugs) and changes in the cost sharing for an individual drug (for example, when such drug moves from one already approved tier of the benefit to another already approved tier of the benefit). As is discussed further in section III.Q. of this proposed rule, section 1860D-4(b)(3)(E) of the Act, as codified at § 423.120(b)(5),[96]

[96]We propose organizational changes to the existing regulations to streamline them and improve their clarity, which would include two subparagraphs on approval of changes and provision of notice to appear, respectively, at § 423.120(e) and (f).

requires that Part D sponsors provide appropriate notice before any removal of a covered Part D drug from a formulary and "any change in the preferred or tiered cost-sharing status" of such a drug. Thus, the statute contemplates midyear changes in cost sharing of individual formulary drugs. Consequently, since the beginning of the Part D program, we have allowed formulary changes that result in changes to the cost sharing for individual drugs (for example, moving a single drug to a different cost-sharing tier), but have declined to permit Part D sponsors to change their benefit designs or waive or reduce premiums, "bid-level" cost sharing (for example, the cost sharing associated with an entire tier of drugs), or cost sharing (for some or all enrollees) once plans are permitted to market for the following contract year (on October 1, consistent with § 423.2263(a)) on the grounds that such activities would be inconsistent with the CMS-approved bid.

Additionally, section 1860D-2(a) of the Act defines qualified prescription drug coverage to mean standard (Defined Standard or Actuarially Equivalent Standard) prescription drug coverage or alternative prescription drug coverage (with at least actuarially equivalent benefits) and access to negotiated prices in accordance with section 1860D-2(d) of the Act. In our proposed rule titled, "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (74 FR 54633), which appeared in the October 22, 2009 issue of the **Federal Register**(hereinafter referred to as the "October 2009 proposed rule") we further interpreted section 1860D-2(a) of the Act as requiring the provision of uniform premium and benefits. We codified these requirements in our regulations at § 423.104(b) in our final rule titled, "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (75 FR 19677), which appeared in the **Federal Register** on April 15, 2010.

In addition to violating the bid requirements, as we noted in the preamble of the October 2009 proposed rule, a Part D sponsor's waiver of cost sharing midyear also violates the uniform benefit requirements, because doing so results in plans not providing the same coverage to all

eligible beneficiaries within their service area (74 FR 54690). The CMS-approved benefit cannot be varied for some or all of the plan's enrollees midyear, as that would violate the uniform benefit provisions set forth in § 423.104(b). Even if the plan changes the benefit midyear for all of the plan's enrollees, this still violates the uniform benefits provision because some of the plan's enrollees would still have paid for benefits prior to the change. We note that during the COVID-19 PHE, CMS provided for specific flexibilities by Part D sponsors to ensure adequate pharmacy access that would otherwise violate the uniform benefit provisions. CMS exercised its enforcement discretion to temporarily permit Part D sponsors to fully or partly waive cost sharing for covered Part D drugs with medically accepted indications for COVID-19.

To clarify these points for all parties, we propose to codify in regulation our longstanding subregulatory policy at new paragraph § 423.265(b)(5) which would require that once a Part D sponsor is permitted to market prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), that is, as of October 1, it shall not change, and therefore, must provide, the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182(a)) for the contract year without modification, except where a modification in benefits is required by law.

Additionally, we have been monitoring compliance with this policy via our Part D Bid review and approval process, consistent with § 423.272. Consequently, there is no additional paperwork burden associated with codifying this longstanding subregulatory policy.

We solicit comment on this proposal.

4. Failure to Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts (§§ 423.293 and 423.294)

As was described in section III.M.3. of this proposed rule, Part D sponsors' waiver of cost sharing or premiums would violate the uniform premium and benefit requirements of section 1860D-2(a) of the Act and § 423.104(b). Similarly, Part D sponsors' incorrect collections of cost sharing and premiums also could have the effect of making the benefit non-uniform.

The current regulatory language at § 423.104(b) mirrors the language at § 422.100(d)(1) and (2)(i) with regard to uniform premiums and cost sharing. However, although the MA program adopted language at § 422.270 to address incorrect collections of premiums and cost sharing in the January 2005 MA final rule, the regulations in Part 423 do not address Part D sponsor requirements regarding incorrect collections of premiums and cost sharing. We intend to bring the Part D requirements into alignment with the existing MA requirements for incorrect collections, as well as establish new requirements regarding failure to collect premiums and cost sharing amounts. Therefore, for incorrect collections, we propose to codify requirements at a new § 423.294 that would be similar to the MA program requirements at § 422.270. We also propose to codify new requirements regarding failure to collect premiums and cost sharing amounts at § 423.294. Finally, we solicit comment regarding adding a similar policy to add new requirements for MAOs regarding failure to collect premiums and cost sharing in § 422.270.

Our proposed Part D requirements would require a Part D sponsor to make a reasonable effort to collect monthly beneficiary premiums under the timing established in § 422.262(e) (made applicable to Part D premiums in § 423.293(a)(2)) and ensure collection of cost sharing at the time a drug is dispensed. If for some reason the Part D sponsor fails to collect or ensure collection in a timely manner, the Part D sponsor would be required to make a reasonable effort to bill for and recover the premium or cost sharing amount after the fact. Any adjustments to the premium or cost sharing amount that occur based on subsequently obtained information would be made within the timeframe for coordination of benefits as established at § 423.466(b), which is 3 years from the date on which the monthly premium was due or on which the prescription for a covered Part D drug was filled. A Part D sponsor could decline to attempt to recover an amount if it is below a de minimis amount, as detailed below.

Our proposed Part D requirements would also require a Part D sponsor to make a reasonable effort to identify any amounts incorrectly collected from its Medicare enrollees, or from others on behalf of affected enrollees. Sponsors would have to issue refunds during the

same 3-year timeline applicable to recoveries, as described previously, and need not issue refunds if they are below a de minimis amount.

Our proposed Part D requirements would differ from the existing requirements at § 422.270 in the following ways. The first modification to our proposed requirements for Part D sponsors is that we propose to clarify that the 3-year lookback period established in § 423.466(b) for coordination of benefits applies to retroactive claim or premium adjustments that result in refunds and recoveries at § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively. Currently, a Part D sponsor is required to process retroactive claims adjustments within 45 days of receiving complete information, per § 423.466(a), and there is no requirement for the timing of retroactive premium adjustments. While § 423.466(b) allows 3 years for coordination of benefits, there is currently no limit in the regulation for how far back retroactive premium adjustments or claims adjustments unrelated to coordination of benefits must be made. For example, if a Part D sponsor in 2022 identifies an error in their prior years' drug pricing files that resulted in beneficiaries being charged incorrect cost sharing from 2015 to 2020, the current regulation might require them to refund and/or recover amounts for prescriptions beneficiaries received as long as seven years ago. This is not only inconsistent with our coordination of benefits requirements, which would only require adjustments for the past 3 years, but is potentially confusing to beneficiaries. By proposing to establish a 3-year lookback period in § 423.294(b)(2) and (4) and § 423.294(c)(2), we would align the timeframe established in § 423.466(b) for coordination of benefits with the timeframe for premium adjustments and claims adjustments unrelated to coordination of benefits. Not only would this 3-year period coincide with the timeframe established in § 423.466(b) for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs) and other entities, including beneficiaries and others paying on the beneficiaries' behalf, but it would also align with the timeframe for redeterminations in § 423.1980(b) and (c). A Part D sponsor would not be required to make a premium or claims

payment adjustment if more than 3 years has passed from the date of service, just as a Part D sponsor is required to coordinate benefits for a period of 3 years.

In section IV.N. of this proposed rule, we are proposing to codify at § 423.44(d)(1)(v) current policy that excepts certain prescription drug plan (PDP) members from being disenrolled for failure to pay plan premiums. Additionally, as also discussed at section IV.N. of this proposed rule, we propose at revised § 423.44(d)(1)(v) a disenrollment exception if the Part D sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer. We also (1) expect Part D sponsors to issue collection notices and, (2) consistent with the requirements at § 423.44, require Part D sponsors to make a reasonable attempt at collection, notwithstanding the requirements at § 423.44 for involuntary disenrollment. Nonetheless, we would not expect a Part D sponsor to disenroll a Part D enrollee for such Part D sponsor's failure (when the plan made the error) to collect the proper payment and subsequent failure to collect an underpayment. Section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual also provides that we expect a Part D sponsor to have billed the Part D enrollee prior to the start of the grace period *for the actual premium amount due* (emphasis added), with such notice/bill specifying the due date for that amount.

Additionally, specific to cost sharing, under current regulations at § 423.566(b)(5), a decision on the amount of cost sharing for a drug constitutes a coverage determination. If a claim adjudicates at an incorrectly low amount, or if other actions by a Part D sponsor result in the Part D enrollee being asked to pay an incorrectly low cost-sharing amount, such adjudication or action is a coverage determination. If the Part D sponsor becomes aware of the error, the Part D sponsor would reopen the previously adjudicated coverage determination consistent with the reopening rules at §§ 423.1980 through 423.1986. If the Part D sponsor issues an adverse revised determination, the notice must state the rationale and basis for the reopening and revision and any right to appeal.

Second, at § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively, we propose to clarify that the 45-day timeframe in § 423.466(a) applies to the processing of refunds and recoveries for both claims and premium adjustments. This would make the timeframes for the refund or recovery of premium adjustments the same as for claims adjustments and for refunds and recoveries related to the low-income subsidy program, which under § 423.800(e) are the same as the requirements of § 423.466(a). In other words, whenever a Part D sponsor receives, within the 3-year lookback period, information that necessitates a refund of enrollee overpayment of premiums, cost sharing, or both, or recovery of underpayments of premiums, cost sharing, or both, the Part D sponsor would be required to issue refunds or recovery notices within 45 days of the Part D sponsor's receipt of such information. Nothing in this proposal would alter the requirements of § 423.293(a)(4) with respect to the options a Part D sponsor must provide Part D enrollees for retroactive collection of premiums.

We note we are not proposing any changes to the Medical Loss Ratio (MLR) requirements under §§ 422.2420(c) and 423.2420(c), which provide that uncollected premiums that could have been collected still count as revenue.

The final difference between our proposed requirements for Part D sponsors and existing Part C requirements is that we propose to apply a de minimis amount, calculated per Prescription Drug Event (PDE) transaction or, for premium adjustments, per month, for these refunds and recoveries. As proposed at § 423.294(b) and (c)(1), if a refund or recovery amount falls below the de minimis amount set for purposes of § 423.34(c)(2) for low income subsidies (currently at $2 for 2022), the Part D sponsor would not be required to issue a refund or recovery notice. For instance, if a sponsor in 2024 discovered that it had charged incorrect premiums amounts to certain beneficiaries for a 12-month period from January through December of 2022 and the de minimis amount for 2024 is $2, the sponsor would not have to issue recovery notices to any beneficiary who owed $24 or less total for the 12-month period. This proposal clarifies that the existing coordination of benefits (COB) requirements in § 423.466 encompass payment

adjustments. As such, the proposed timeframe for the proposed requirements to refund or recover incorrectly collected cost sharing and premium amounts would not result in any additional costs to Part D sponsors, Part D enrollees, or the government. Conversely, because there was previously no historical limit or threshold for such refunds and recoveries, establishing both a 3-year lookback period and de minimis amount would remove significant administrative burden on plan sponsors and the government, particularly in circumstances where the amount to be refunded or recovered is less than the postage required to provide a refund or recovery notice. Consequently, this provision would not impact the Medicare Trust Fund, and there would be no additional paperwork burden, as recovery notices are already required under § 423.466, and § 423.293 already provides a process for the retroactive collection of premiums.

Current MA regulations set forth at § 422.270 do not contain requirements for MA organizations to refund or recover incorrect collections of cost-sharing or premiums with regard to a de minimis amount or a lookback period. On the contrary, § 422.270(b) states that an MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf. With regard to timing of recovering underpayments when an enrollee is not at fault, § 422.262(h) states an enrollee may make payments by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. We solicit comments on adding requirements regarding a de minimis amount and lookback periods for recovering or refunding incorrect collections in MA to that mirror proposed requirements in Part D.

We are also proposing a technical change to the regulation text related to the Part D retroactive collection of monthly beneficiary premiums. We propose to amend § 423.293(a)(4) by replacing “Medicare Advantage organization” with “Part D sponsor” to be consistent with the terminology used in the rest of § 423.293.

We solicit comment on these proposals.

5. Summary of Proposals and Comment Solicitation

In summary, we are proposing to:

● Add § 422.254(a)(5) to add regulatory text regarding the requirement that starting after an MA organization is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 422.2263(a)), it may not change, and therefore must provide, the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 422.162(a)) for the contract year without modification, except where a modification in benefits is required by law. This proposed prohibition on changes would apply to cost sharing and premiums as well as benefits;

● Add § 423.265(b)(5) to codify the requirement that starting after a Part D sponsor is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), it may not change, and therefore, must provide, the benefits described in its CMS-approved PBP (as defined at § 423.182) for the contract year without modification, except where a modification in benefits is required by law;

● Make a technical correction at § 423.293(a)(4) to replace "Medicare Advantage organization" with "Part D sponsor"; and

● Add new § 423.294 to codify requirements regarding failure to collect, and incorrect collections of, enrollee premiums and cost sharing for Part D sponsors, including:

++ Specifying in proposed § 423.294(a) that failure to collect premiums and cost sharing, or incorrect collections of premiums or applicable cost sharing, violates the uniform benefit provisions at § 423.104(b);

++ Applying a 3-year lookback period for the identification of applicable refunds and recoveries at the proposed § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively;

++ Applying a 45-day period to issue applicable refunds and recovery notices at the proposed § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively;

++ Specifying at proposed § 423.294(b)(3) the refund methods for amounts incorrectly collected and other amounts due; and

++ Specifying at proposed § 423.294(b) and (c)(1) a de minimis amount for applicable refunds and recoveries.

We solicit comment regarding adding new requirements (specifically adding a de minimis amount and lookback period) in the MA regulations regarding failure to collect premiums and cost sharing in § 422.270 to align with the proposed changes for Part D sponsors described in this section of the proposed rule.

We solicit comment on these proposals and policy questions.

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

1. Overview and Summary

We are proposing to amend the language in § 422.502 and § 423.503 to codify CMS's authority to decline to consider a substantially incomplete application for a new or expanded Part C or D contract. We are also proposing to codify criteria for determining that an application is substantially incomplete.

Since we began our contracting efforts under the Medicare Modernization Act of 2003 in 2005 in preparation for the statute's 2006 effective date, we have established strict deadlines for the initial submission of applications for an entity to qualify as an MAO or Part D sponsor for a new contract, expansion of a service area of an existing contract, or to offer an MA SNP and the resubmission of materials needed to cure identified deficiencies. These deadlines are established annually in our Parts C and D applications, in accordance with §§ 422.501 and 423.502. Consistent with that operational policy, we do not review applications that are submitted after the established deadline. Entities submitting applications after the deadline do not receive a new or expanded Part C (either a general MA contract or approval to offer a SNP) or D contract for the following benefit year. An entity missing the deadline also does not receive a notice of intent to

deny under §§ 422.502(c)(2) or 423.503(c)(2) and is not entitled to a hearing under §§ 422.660 or 423.650.

CMS noted in the final rule which appeared in the **Federal Register** on April 15, 2011 titled "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes" (76 FR 21431), hereafter referred to as the April 2011 final rule, that, in order to meet the submission deadline, some entities had submitted applications that were so lacking in required information as to fail to constitute a valid submission (76 FR 21527). If permitted to proceed with such an application, the entity would be able to complete their application by taking advantage of two later opportunities (including the period following the notice of intent to deny) to cure deficiencies. These "placeholder" applications would allow entities more time to submit complete applications than applicants that submitted complete applications by the application deadline. We stated in the preamble to the April 2011 final rule that we considered this an abuse of the application review process and have therefore treated such substantially incomplete applications as invalid since the enactment of the April 2011 final rule.

In the April 2011 final rule, we stated that we believed that substantially incomplete applications were submitted in part because of confusion about our authority to enforce the application deadline (76 FR 21527). This confusion was likely a result of the then-effective provisions of §§ 422.502(c)(2)(i) and 423.503(c)(2)(i), which stated that CMS would provide an applicant a notice of intent to deny when the entity "has not provided enough information to evaluate the application." We stated that we had intended this language to afford an entity that had made a good faith effort to complete an application the opportunity to provide materials necessary to cure discrete application deficiencies, not to provide an unintended protection and additional time to entities that submitted "placeholder" applications. In order to correct this misunderstanding and to allow us to enforce our application submission deadline, CMS amended the regulation to remove the quoted language in §§ 422.502(c)(2)(i) and 423.503(c)(2)(i). Since

that time, we have treated substantially incomplete applications as invalid applications that are not entitled to a notice of intent to deny or a hearing under §§ 422.502(c)(2) or 423.503(c)(2) or entitled to a hearing under §§ 422.660 or 423.650. While we notify organizations that submit substantially incomplete applications that we consider their application to be substantially incomplete and therefore invalid, that notification is for informational purposes only and is not a notice of intent to deny under §§ 422.502(c)(2) and 423.503(c)(2).

CMS is proposing to codify its longstanding policy with respect to substantially incomplete applications.

2. Discussion (§§ 422.502 and 423.503)

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

We also propose at §§ 422.502(a)(3)(ii) and 423.503(a)(4)(ii) to codify our definition of a substantially incomplete application as one that does not include responsive materials to one or more sections of its MA or Part D application, respectively. Pursuant to §§ 422.501(c) and 423.502(c), CMS requires entities seeking to qualify as an MAO (or to qualify to offer a SNP) and/or Part D sponsor to submit an application in the form and manner required by CMS. Applications for service area expansions are subject to the same rules and review processes as we treat the expansion of a plan service area as a new application for a new area. We prescribe the form and manner in an application published annually. This application is subject to the Paperwork Reduction Act review process. The form and manner vary somewhat from year to

year, but generally include several sections that require an entity to demonstrate compliance with specific categories of program requirements. For instance, Part D applications for new Part D contracts include: (1) a series of attestations whereby the applicant agrees that it understands and complies with various program requirements; (2) a contracting section that requires entities to demonstrate compliance with Part D requirements by submitting certain first tier, downstream, and related entity contracts and network pharmacy templates; (3) a network section that requires entities to submit lists of contracted pharmacies that meet geographic and other access requirements; (4) a program integrity section that requires entities to submit documentation that they have documented and implemented an effective compliance program as required by § 423.504(b)(vi); and (5) a licensure and solvency section that requires entities to meet applicable licensure and fiscal solvency requirements. MA applications require substantially similar information related to the operation of an MA plan, and SNP applications include additional sections related specifically to SNP requirements for the type of SNP the applicant seeks to offer. Consistent with past practice, CMS proposes to treat an application that does not include required content or responsive materials for one or more of these sections as substantially incomplete. In our assessment, applications that fail to include significant amounts of responsive materials, including failing to include required content or responsive material for any section of the application, in materials submitted by the application submission deadline are merely submitting placeholder applications that do not merit additional opportunities to meet CMS requirements.

An example of a Part D application that would be incomplete and therefore excluded from further consideration under the proposed rule is one that failed to upload a retail pharmacy list that would allow CMS to determine whether it met pharmacy access requirements. This would include failure to submit a list at all, submitting a list containing fictitious pharmacies, or submitting a list that contained so few pharmacies that CMS could only conclude that no good faith effort had been made to create a complete network. CMS would also deem as substantially

incomplete any application that failed to submit any executed contracts with first tier, downstream, or related entities that the applicant had identified as providing Part D services on its behalf.

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

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

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

has ruled that such determinations were not contract determinations entitled to hearings under §§ 422.660 and 423.650.

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

We solicit comment on this proposal.

3. Summary of Proposals

In summary, we are proposing to:

- Add §§ 422.502(a)(3) and 423.503(a)(4) to codify CMS's policy of not evaluating or issuing a notice of determination as described in §§ 422.502(c) or 423.503(c) when an entity submits a substantially incomplete application;

- Specify at the proposed §§ 422.502(a)(3)(ii) and 423.503(a)(4)(ii) that a substantially incomplete application is one that does not include responsive materials to one or more sections of the application; and

- Specify at the proposed §§ 422.502(a)(3)(iii) and 423.503(a)(4)(iii) that a determination that an entity submitted a substantially incomplete application is not subject to the appeals provisions of Part 422 and 423, subpart N.

We solicit comment on these proposals.

O. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

1. Standing Request for Translated Materials and Materials in Accessible Formats Using Auxiliary Aids and Services

In accordance with our authority under sections 1851(h), 1851(j), 1852(c), 1860D-1(b)(1)(B)(vi), 1860D-4(a), and 1860D-4(l) of the Act, §§ 422.2267(a)(2) and 423.2267(a)(2) of the regulations require MA organizations and Part D sponsors to translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. This threshold is based on the Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (67 FR 41455 through 41472, published in June 2002) that implemented Executive Order 13166 (signed in August 2000). In addition, per § 417.428, cost plans with contracts under section 1876 of the Act must follow the same marketing and communication regulations; we apply the same standards to cost plans under this regulation based on our authority in section 1876(i)(3)(D) of the Act. Each fall, we release an HPMS memorandum announcing that plans can access in the HPMS marketing review module a list of all languages that are spoken by 5 percent or more of the population for every county in the U.S.[97] In the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drugs Benefit Program; Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency final rule, which appeared in the May 9, 2022 **Federal Register** (87 CFR 27704) (hereinafter referred to as the May 2022 final rule), we also adopted a requirement that MA and Part D plans use a

[97]CMS released the contract year 2023 version of this HPMS memorandum titled, "Contract Year 2023 Translated Model Materials Requirements and Language Data Analysis" on September 23, 2022. This memorandum can be retrieved at: https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-wk-4-september-19-23

multi-language insert (MLI), which informs the reader, in the top fifteen languages used in the U.S., as well as any additional non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area, that interpreter services are available for free. In accordance with §§ 422.2267(e)(31) and 423.2267(e)(33), the MLI must be included with all CMS required materials provided to current or prospective enrollees. As discussed in the May 2022 final rule, 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 limited English proficiency are aware of and are able to access interpreter services therefore provides a clear path for this portion of the population to properly understand and access their benefits (87 FR 27821).

In addition, MA organizations and Part D sponsors must comply with section 504 of the Rehabilitation Act of 1973, section 1557 of the Affordable Care Act, and implementing regulations at 45 CFR part 92. The regulations at 45 CFR 92.102(b) require plans to provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. Section 92.102(b)(1) defines the auxiliary aids and services for plans to provide to enrollees. For written materials this includes but is not limited to braille, large print, data/audio files, relay services, and TTY communications. We further explained the obligation of plans to provide accessible communications for individuals with disabilities in an August 30, 2017, Health Plan Management System memorandum titled, "Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557)."[98]

[98]CMS Office of Hearings and Inquiries, "Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557), August 30, 2017. Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3.

However, CMS has learned from oversight activities, enrollee complaints, and stakeholder feedback that enrollees often must make a separate request each time they would like a material in an alternate language or need auxiliary aids and services. In addition, during CMS program audits and oversight activities we have found that special needs plans (SNPs) do not always translate individualized care plans (ICPs) into enrollees' preferred languages, even when the enrollee has expressed a preference for translation as part of completing the health risk assessment. To address these issues, we are proposing here, based on our authority under the Medicare statute, to adopt regulations to impose additional Medicare marketing and communications standards on plans to ensure access to important information and materials for individuals who have limited English proficiency or need auxiliary aids or services.

The materials required under §§ 422.2267(e) and 423.2267(e) and ICPs are vital to how individuals access services and make decisions about their health care. These materials furnish important information about coverage and benefits under Medicare health and drug plans. We believe this proposal will make it easier for beneficiaries 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.

The U.S. Census Bureau's 2019 American Community Survey (ACS) 1-year estimates show that 12.2 percent of individuals 65 years of age and older speak a language other than English in the home.[99] Nearly 8 percent of Medicare beneficiaries are individuals with limited English proficiency, many of whom need an interpreter or other language assistance to communicate effectively.[100] The U.S. Census Bureau's 2019 American Community Survey 1 year estimate also finds that 2.3 percent of the population is blind or low vision and 3.6 percent

[99]Refer to https://data.census.gov/cedsci/table?q=language&tid=ACSST1Y2019.S1603.
[100]Refer to https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.

are deaf or have hearing loss, with 13.7 percent of adults over 65 reporting hearing loss or deafness, and 6 percent of adults over age 65 reporting blindness or low-vision.[101] Communication and language barriers are associated with decreased quality of care and poorer health outcomes. In addition, individuals with limited English proficiency are less likely to have routine health visits, more likely to defer needed health care, and more likely to leave the hospital against medical advice.[102] Effective communication is critical to providing high-quality care. Reliance on unqualified individuals to interpret medical information can lead to misunderstandings, poor outcomes, or even death.[103]

We believe that it is a substantial burden for enrollees to have to request each material in an alternate language or request auxiliary aids and services for each material and that requiring enrollees to do so could impede access to care. It is also possible that enrollees may require both auxiliary aids and services for materials and an alternate language (for example Spanish braille). In addition, to ensure the ICPs are developed in consultation with the enrollee as required at § 422.101(f)(1)(ii), it is important that ICP materials be provided in the enrollee's preferred language and, where appropriate, in an accessible format using auxiliary aids and services. Studies consistently show the negative health outcomes that patients with limited English proficiency experience due to the barriers they encounter when interacting with their doctors and care team members, accessing interpreters, and addressing insurance concerns. These outcomes are further exacerbated by vulnerable patients often not knowing their right to have qualified interpreters and other language access provisions at no extra cost.[104] We have become attuned to this issue through our work with Medicare-Medicaid Plans (MMPs). In 2019, CMS conducted a review of MMPs to learn how they capture, record, and use enrollees' language preferences and any need for auxiliary aids and services. We found that MMPs use multiple enrollee touch points

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[101]Refer to https://data.census.gov/cedsci/table?q=https%3A%2F%2Fdata.census.gov%2Fcedsci%2Ftable%3Fq%3DS1810%26tid%3DACSST1Y2019.S1810%26hidePreview%3Dfalse&tid=ACSST1Y2019.S1810.

[102]Refer to https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.2.435.

[103]Refer to https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.

[104]Refer to https://www.healthaffairs.org/do/10.1377/forefront.20200724.76821/full/.

to capture this information, including welcome calls, health risk assessments, nurse advice lines, and other interactions associated with member services, enrollment, prescription services, appeals and grievances, and care management. To collect and store this information, MMPs have taken steps such as establishing centralized email accounts within their organizations to capture all translation and auxiliary aid and service requests they receive and to ensure greater consistency and completion of requests, developing database reports that list their enrollees and any identified language or auxiliary aid or service preferences, and storing the information in their eligibility system.

As a result, we believe that there are many ways for MA organizations and Part D sponsors to learn of an enrollee's need for auxiliary aids and services and language preferences and maintain this information. The CMS Guide to Developing a Language Access Plan can provide MA organizations and Part D sponsors with helpful information to ensure that persons with limited English proficiency have meaningful access to services.[105] In addition, the Improving Communication Access for Individuals Who are Blind or Have Low Vision brochure can similarly assist organizations in developing policies to better serve these individuals.[106] We encourage plans to educate enrollees on the availability of translated materials and accessible formats using auxiliary aids and services through such avenues as enrollee newsletters, advertising, or other educational forums. MA plans may use a reward program, as permitted under § 422.134, to provide rewards as a means to encourage enrollees to provide information regarding their need for an alternate language or auxiliary aids and services; in our view, providing this information to the MA plan promotes improved health and the efficient use of healthcare resources (as required by § 422.134 for reward programs) as it ensures that materials and information are adequately furnished to be understood and used by the enrollee in understanding and accessing covered benefits.

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[105]Refer to https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.
[106]Refer to https://www.cms.gov/files/document/omh-visual-sensory-disabilities-brochure-508c.pdf.

We would like to minimize barriers to enrollees receiving materials in alternate languages and accessible formats using auxiliary aids and services and remove any ambiguity associated with MA and Part D plan responsibilities for providing materials in alternate languages and accessible formats using auxiliary aids or services and for SNPs to provide ICPs in alternate languages and accessible formats using auxiliary aids and services. Therefore, we propose to re-designate the paragraphs at §§ 422.2267(a)(3) and 423.2267(a)(3) as §§ 422.2267(a)(5) and 423.2267(a)(5) and add new paragraphs at §§ 422.2267(a)(3) and 423.2267(a)(3) to require MA organizations and Part D sponsors to provide materials to enrollees on a *standing basis* in any non-English languages that is the primary language of at least 5 percent of the individuals in a plan benefit package service area as defined under §§ 422.2267(a)(2), 423.2267(a)(2) and proposed §§ 422.2267(a)(4) and 423.2267(a)(4), which are is discussed later in this section, and in any accessible formats using auxiliary aids and services upon receiving a request for the materials in another language or using auxiliary aids and services or otherwise learning of the enrollee's preferred language or need for an accessible format using auxiliary aids and services. This means that once a plan learns of an enrollee's preferred language and/or need for auxiliary aids and services – whether through an enrollee requesting a material in a preferred language or using auxiliary aids and services, during a health risk assessment, or another touch point – the plan must provide required materials in that language and/or accessible format using auxiliary aids and services as long as the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide required materials in a different manner. We have also proposed language at §§ 422.2267(a)(3) and 423.2267(a)(3) to extend this requirement to the individualized plans of care described in § 422.101(f)(1)(ii) for SNP enrollees. The proposed requirement would allow enrollees to avoid having to submit a request to receive required materials in a preferred language and/or using auxiliary aids and services each time the MA or Part D plan distributes a required material. We note that plans are responsible for providing materials in both a preferred format and using auxiliary aids and services when needed (for example Spanish braille). These

modifications at §§ 422.2267 and 423.2267 and other requirements at Parts 422 and 423 regarding translation obligations and auxiliary aids are in addition to plan obligations under 45 CFR Part 92 that govern meaningful access for individuals with limited English proficiency and effective communication for individuals with disabilities. MA and Part D plans must comply with both the rules at § 422.2267 and § 423.2267 and the non-discrimination requirements in 45 CFR Part 92. Where one set of regulations imposes a higher or different standard but it is not impossible for the plan to comply with both, the plan must comply with both. Because cost plans, per § 417.428, are subject to the regulations in part 422, subpart V, these requirements also apply to cost plans.

There are no information collections related to creating a standing request for translated materials or materials using auxiliary aids and services. We believe the burden associated with these proposed requirements is exempt from the requirements of PRA as defined in 5 CFR § 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We believe most cost plans, MA organizations, and Part D sponsors have translators on staff or access them via contractors because of existing translation and auxiliary aid requirements.

2. Require FIDE SNPs, HIDE SNPs, and Applicable Integrated Plans to Translate Materials into the Medicare Translation Standard Plus Additional Medicaid Languages

Over 1.8 million individuals dually eligible for the Medicare and Medicaid programs speak a language other than English at home or do not speak English fluently.[107] In addition, dual eligibility is a strong predictor of poorer outcomes in an array of Medicare programs,[108] and dually eligible beneficiaries are far more likely than other Medicare beneficiaries to be from racial or ethnic minority groups (48 percent vs. 22 percent). Many dually eligible beneficiaries

[107]Refer to https://www.resourcesforintegratedcare.com/language_preferences/. .
[108]Refer to https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs

have low health literacy yet need to navigate a more complex system of coverage than non-dually eligible beneficiaries.

Per the definition of specialized MA plans for special needs individuals in § 422.2, all SNPs must be MA-PDs that comply with both Part 422 and Part 423 requirements. Sections 422.2267(a)(2) and 423.2267(a)(2) require dual eligible special needs plans (D-SNPs), like all other MA-PD plans, to translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. We propose to amend §§ 422.2267 and 423.2267 with a new paragraph (a)(4) that requires that FIDE SNPs and HIDE SNPs, as defined at § 422.2, and applicable integrated plans (AIPs), as defined at § 422.561, translate all Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into any languages required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard at § 422.2267(a)(2). Generally, we expect that the Medicaid translation requirements would be the regulatory standard at § 438.10; however, a State may impose a higher or more stringent translation requirement on its Medicaid managed care plans than is required by § 438.10, so we believe referring to the capitated Medicaid managed care contract rather than § 438.10 is appropriate for this proposed new requirement. Specifically, § 438.10(d)(3) requires that entities make written materials that are critical to obtaining services available in the prevalent non-English languages in the service area. Section 438.10(a) defines prevalent as a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient. Section 438.10(d)(1) requires that the State establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. Under the definitions for FIDE SNP, HIDE SNP, and AIP, each of these types of plan has a companion or affiliated Medicaid managed care plan, which would itself be subject to § 438.10 and the applicable State's translation requirements for Medicaid materials described in § 438.10. We

propose to extend the translation standards applicable to the Medicaid materials used by FIDE SNPs, HIDE SNPs, and AIPs to the Medicare materials used by those plans to ensure that the dually eligible enrollees in all FIDE SNPs, HIDE SNPs, and AIPs receive all of the materials necessary for accessing and understanding all of their benefits (both Medicare and Medicaid) in a language that the enrollees understand.

For example, if current §§ 422.2267 and 423.2267 only require translation into Spanish for Medicare materials but the State Medicaid agency requires translation into Chinese as well as English and Spanish, then our proposed revisions to §§ 422.2267 and 423.2267 would also require that the affected FIDE SNP, HIDE SNP, or AIP translate the Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into Chinese as well as Spanish.

These modifications at §§ 422.2267 and 423.2267 do not create exceptions to other laws that govern translation of written materials provided to enrollees that we have previously described. Rather, our intent is to make it easier for dually eligible beneficiaries who are enrolled in FIDE SNPs, HIDE SNPs, or AIPs to understand the full scope of Medicare and Medicaid benefits available through such D-SNPs, which would increase their ability to make informed health care decisions. It would also reduce the likelihood of an enrollee receiving materials in different languages (for example, some in English and some in Spanish) depending on whether the materials are governed by Medicare or Medicaid requirements.

We are considering applying the proposed new requirement to additional or different groups of D-SNPs, such as limiting the proposal to AIPs or to organizations with D-SNP-only contracts as described under § 422.107(e), or expanding the requirement to all D-SNPs and D-SNP look-alikes (that is, the MA plans that meet the standards in § 422.514(d)) during a period before the D-SNP look-alike plan is nonrenewed or terminated. We decided to focus our proposal on all FIDE SNPs and HIDE SNPs, as defined at § 422.2, and AIPs, as defined at § 422.561, because these plans have capitated contracts with State Medicaid agencies and must already translate Medicaid materials to comply with their Medicaid managed care contracts, and

would likely either have staff that are capable of translating materials into these languages or contract with organizations to perform these translations. In addition, an increasing number of dual eligible individuals are in FIDE SNPs, HIDE SNPs, and AIPs where the same organization provides coverage of both the Medicare and Medicaid services for the enrollee.

We understand that our proposal would require some FIDE SNPs, HIDE SNPs, and AIPs to translate the Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into additional languages. We believe that the benefit gained by the ability for more enrollees to receive all materials in their preferred language outweighs this burden. As described previously in this section, these enrollees are far more likely than other Medicare beneficiaries to be from racial or ethnic minority groups or have low health literacy yet need to navigate a more complex system of coverage than non-dually eligible beneficiaries. As a result, to ensure health equity for this population we have proposed including a broad range of D-SNP types but are excluding those D-SNPs that only coordinate with Medicaid services. We welcome comments on our proposal and these potential alternatives we are considering.

3. Exclude Member ID Cards from New Paragraphs Proposed at §§ 422.2267(a)(3) and (a)(4) and §§ 423.2267(a)(3) and (a)(4)

In addition to the proposals described earlier in this section, §§ 422.2267(e)(30)(vi) and 423.2267(e)(30)(vi) currently exclude the member ID card from the translation requirement under §§ 422.2267(a)(2) and 423.2267(a)(2). We propose to amend the member ID card provision at §§ 422.2267(e)(30)(vi) and 423.2267(e)(30)(vi) to expand the exclusion for member ID cards to include the new paragraphs proposed in this section, §§ 422.2267(a)(3) and (a)(4) and §§ 423.2267(a)(3) and (a)(4), respectively.

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

We are proposing a number of changes to Subpart V of both 422 and 423 regulations. These changes include requiring third parties to submit marketing materials, notifying enrollees annually that they can opt out of plan business calls; limiting the ability of plans and agents to

contact prospective enrollees beyond six months from the time they submit a Scope of Appointment (SOA) or Business Reply Card (BRC); requiring website provider directories be searchable by all required elements (for example, name, phone number, address); adding "effect on current coverage" to the Pre-enrollment Checklist (PECL), as well as requiring agents to discuss the PECL during an enrollment call; requiring plans to list benefits at the beginning of the Summary of Benefits and in a specified order; labeling the non-renewal notice as standardized rather than a model, consistent with CMS's guidance instructions; limiting the requirement to record calls between third-party marketing organizations (TPMOs) and beneficiaries to marketing (sales) and enrollment calls; clarifying that the prohibition on door-to-door contact without a prior appointment still applies after collection of a BRC or SOA; prohibiting marketing of benefits in a service area where those benefits are not available; prohibiting the marketing based on information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, costs that dually eligible beneficiaries are not responsible to pay, or other unrealized costs of a Medicare beneficiary; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell; requiring MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS; modifying the TPMO disclaimer to add State Health Insurance Programs (SHIPs) as an option for beneficiaries to obtain additional help; placing discrete limits on the use of the Medicare name, logo, and Medicare card; prohibiting the use of superlatives (for example, words like "best" or "most") in marketing unless the material provides documentation to support the statement, and the documentation is for the current or prior year; and clarifying the requirement to record calls between TPMOs and beneficiaries such that it is clear that the requirement includes virtual connections such as Zoom and Facetime.

Sections 1851(h), 1851(j), and 1852(c) of the Act, which address Medicare Part C, provide CMS the authority to review marketing materials, develop marketing standards, and

ensure that marketing materials are accurate and not misleading. These provisions also provide CMS with the authority to prohibit certain marketing activities. Section 1856(b)(1) of the Act provides CMS the authority to add additional standards to the MA program that the Secretary determines are necessary for CMS to carry out the program. In addition, sections 1876(i)(3)(D), 1857(e)(1) and 1860D-12(b)(3)(D) of the Act provide CMS the authority to adopt additional contract terms for cost plans, MA plans, and Part D plans when necessary and appropriate. Likewise, section 1860D-1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) of the Act for approval of marketing materials and application forms for Part D plan sponsors. Section 1860D-4(l) of the Act applies certain prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations. In addition, under section 1852(c) and 1860D-4(a) of the Act, CMS can require organizations to provide certain materials to Medicare beneficiaries concerning MA and Part D plan choices. These statutory provisions help ensure Medicare beneficiaries are informed and protected when making an election to enroll in an MA (including MAPD) or Part D plan. We believe the changes proposed in this regulation strengthen CMS' ability to ensure MA and Part D marketing to beneficiaries is not misleading, inaccurate, or confusing. Additionally, under 42 CFR 417.428, most marketing requirements in subpart V of part 422 apply to section 1876 cost plans as well. (87 FR 1899).

In accordance with regulations at §§ 422.2261(a) and 423.2261(a), MA organizations and Part D Sponsors (MA organizations/Part D Sponsors) must submit all marketing materials, all election forms, and certain designated communications materials for CMS review. Sections 422.2261(a)(3) and 423.2261(a)(3) prohibit third-party and downstream entities from submitting materials directly to CMS, unless specified by CMS. Following an operational change in May 2021, CMS began permitting TPMOs to submit certain marketing materials. In cases where a TPMO document only markets one MA organization/Part D sponsor, there would be no change for the TPMO, meaning they would still send the document in through the MA organization/Part

D sponsor who would submit it into HPMS. For TPMOs that develop materials for more than one MA organization/Part D sponsor, the TPMO would submit the material directly to CMS. Based on CMS' operational change we are proposing to require TPMOs, as defined at §§ 422.2260 and 423.2260, to submit their marketing materials developed for multiple MA organizations and Part D sponsors (and their specific plans) to CMS through HPMS. Specifically, we are proposing to remove §§ 422.2261(a)(3) and 423.2261(a)(3), which as implemented prohibited TPMOs from submitting materials the TPMO alone developed, and modifying §§ 422.2261(a)(2) and 423.2261(a)(2) to require that where marketing materials have been developed by a TPMO for multiple plans, the TPMO must submit those materials that the TPMO has designed and developed to CMS, and such submission may only occur after the TPMO receives the prior approval of each of the MA organizations or Part D sponsors on whose behalf the materials were designed and developed by the TPMO.

The HPMS is CMS' system of record for marketing materials. In the January 19, 2021 final rule, we modified §§ 422.2261(a)(3) and 423.2261(a)(3) to provide CMS the flexibility to allow third parties to submit materials directly to CMS in the future (86 FR 5998). CMS made this modification in anticipation of changes to HPMS. CMS released an updated marketing module in HPMS in May of 2021. Prior to this release, third-party materials were submitted into HPMS, but the TPMO was required to send materials to an MA organization or Part D sponsor and have the MA organization or Part D sponsor submit the materials on the TPMO's behalf. System changes in 2021 permitted third parties and downstream entities, such as TPMOs, to submit materials directly to CMS following the receipt of prior approval from at least one MA organization or Part D sponsor. The January 19, 2021 final rule enabled the agency to allow submission by third parties and downstream entities because of the timing and uncertainty of the revamped HPMS marketing module.

Since issuing the January 19, 2021 final rule, we have modified HPMS so that TPMOs may submit materials that are being used for multiple MA organizations, Part D sponsors, or

plans. We are now proposing to require, rather than permit, TPMOs submit to CMS any material that the TPMO develops for multiple MA organizations and Part D sponsors that meets the definition of marketing and that TPMOs receive prior approval, by each MA organization or Part D sponsor, of the material being submitted on behalf of each of the MA organization or Part D sponsor. Failing to require submission may result in these materials not being subject to CMS review. Thus, we are proposing to remove §§ 422.2261(a)(3) and 423.2261(a)(3) and modify §§ 422.2261(a)(2) and 423.2261(a)(2) to add that TPMOs must submit their materials designed on behalf of and with prior approval from the applicable MA organizations or Part D sponsors.

CMS is proposing to add a new (xix) to § 422.2262(a)(1) and a new (xviii) to § 423.2262(a)(1) to address the use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card. CMS is aware of concerns from external stakeholders about marketing activities and documents that appear to be from Medicare, CMS, or the Federal Government. Through beneficiary complaints and CMS surveillance activities, over the years, we have seen the word "Medicare" in names of store fronts (that is, The Medicare Store), on notices or postcards where "Medicare" is in large font while disclaimers are miniscule, and in television advertisements where a beneficiary could think that the advertising is coming from CMS. We have also seen logos, which are very similar to the Health and Human Services (HHS) logo on websites and print materials. These logos have featured circles with writing around the circle and a bird, wings or other images that appear to be the same image used by the Federal Government. In addition to the store front, postcards, and television advertisements, there are also numerous third-party internet sites with "Medicare" in the URL or a logo similar to the HHS logo, potentially causing a beneficiary to click on a private site when they intend to go to Medicare.gov or are seeking official Medicare information or access. Often, it appears as if the materials urging the beneficiary to "take action" are from Medicare or that these third parties represent Medicare or the Federal Government. With the increase of third parties in the marketplace, based on CMS' surveillance and complaints

received, especially through 1-800-MEDICARE, we are concerned that an increasing number of beneficiaries are being misled into believing the entity they are contacting is Medicare or the Federal Government. One specific example, provided by a Medicare beneficiary, is a postcard with the beneficiary-named address with "Medicare Notice" in large, bold letters at the top along with "Personal & Confidential" and "Important Medicare Information." This postcard also had a "Medicare Information" box listing a "Customer ID", formatted to look like an official Medicare beneficiary number. This misleading postcard appeared to be an official document disseminated by the Federal Government. In our review of complaints received through 1-800 MEDICARE, CMS discovered other examples of beneficiaries who mistakenly believed they were calling Medicare rather than a private MA or Part D plan or its agent or broker, likely based on the receipt of a flyer using the word "Medicare" in a way that conveyed to the beneficiary that they must call the telephone number on the mailer. These complaints illustrate that the use of the Medicare name is at times confusing and misleading to Medicare beneficiaries.

A top CMS priority, consistent with sections 1851(h)(2) and 1860D-01(b)(1)(B)(vi) of the Act and CMS's implementing regulations at §§ 422.2262 and 423.2262, is to ensure that MA organizations and Part D sponsors disseminate information to beneficiaries that is accurate and not misleading. We are therefore concerned that the use of the term "Medicare" in situations like those described above erroneously leads beneficiaries to believe that Medicare-related communications or advertising are disseminated or endorsed by Medicare or the Federal Government, when in actuality such communications are being disseminated by the MA organizations/Part D sponsors themselves, or by entities operating on behalf of the MA organizations or Part D sponsors. Although the types of plan communications described above that feature the word "Medicare" typically include disclaimers that state the information presented is not connected to or endorsed by the Federal Government or the Medicare program, these disclaimers are often tiny, difficult to read, and are mixed in with other CMS required disclaimers as well as plan-developed, non-required, disclaimers. While CMS already prohibits

inaccurate or misleading information under §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), we believe it is important to specifically prohibit the misleading use of the Medicare name, CMS logo, and products or information issued by the Federal Government(including the Medicare card) in §§ 422.2262(a)(1) and 423.2262(a)(1). We are not including the Medicare Part D mark, as CMS gives Part D sponsors contractual permission to use the mark. By adding a new (xix) and (xviii) we are firmly and clearly prohibiting the improper use of these terms and logos. Therefore, we propose adding a new paragraph (xix) to § 422.2262(a)(1) and a new (xviii) to § 423.2262(a)(1) which specifically prohibits the use of the Medicare name, CMS logo, or official products, including the Medicare card, in a misleading manner.

Since CMS contracts with MA organizations and Part D sponsors, CMS holds these organizations accountable for the actions of their first tier, downstream and related entities, per §§ 422.504(i) and 423.505(i). If CMS determines that the Medicare name, CMS logo, or official products like the Medicare card, have been used in a misleading manner by a first tier, downstream or related entity (FDR), CMS would address the issue with the MA organization or Part D sponsor on whose behalf the FDR was operating and hold the sponsoring organization accountable for the misleading information.

In our January 2021 final rule, we prohibited plan use of unsubstantiated statements except those used in taglines and logos in 42 CFR 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii). Prior to the January 2021 final rule, we had prohibited the use of unsubstantiated superlatives and pejoratives, except when used in logos and taglines, through our Medicare Communications and Marketing Guidance. We now propose to further restrict the use of superlatives by prohibiting all superlatives unless substantiating supporting data is also provided with the material and essentially adopt a regulation that builds upon our prior guidance. We are proposing this for all superlatives, including those used in logos and taglines. Previously, CMS generally required plans to provide substantiating data to support the use of a superlative. However, that substantiating information was only provided to CMS, resulting in the beneficiary seeing the

superlative without no context. Currently, the beneficiary has no knowledge of how the superlative is determined, potentially misleading the beneficiary to believe a statement which may be partially or mostly true, but lacking context and important specificity. For example, an MA plan may advertise that it has the *largest* network, which on a national basis may be accurate. However, when looking at a particular service area, this MA plan may have the smallest network. Permitting the use of superlatives without specific information explaining the basis or context, is potentially misleading to beneficiaries so we have reconsidered the scope of §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) as previously finalized.

CMS believes it is critical to provide either actual data or information, such as reports or studies, that forms the basis for a superlative statement in order for beneficiaries to review and understand the context and reference point for the superlative. This documentation and/or data can be referenced through footnotes explaining the basis, noting the source, with enough information for a beneficiary to locate, or providing the actual comparison done to determine the superlative. For example, if a plan stated that they have the lowest premiums, the plan would need to state their premium and the premiums of other plans in the service area, or reference a study, review or other documentation that supports the superlative and with which the beneficiary can make accurate comparisons between plans.

We are also proposing to add a requirement that the supportive documentation and/or data be based on current data. Our proposed regulation text requires that the supportive documentation or data must reflect data, reports, studies, or other documentation to have been published either in the existing contract year or the prior contract year. For example, a health plan could not make the statement in CY 2022 that they have the largest provider network in an area using 2018 data. Rather, in CY 2022, the statement that a health plan has the largest network in an area must be supported by documentation and/or data published as of January 1, 2021 or later. Data and the underlying situations can be dynamic and change over time, therefore, CMS is proposing that recent data, meaning the current or the prior contract year data,

are the only data that may be used to substantiate superlatives. We believe any data older than the prior contract year may be misleading, given the age of the data and the potential of the data to have changed. Based on this, we propose to modify paragraphs §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) to prohibit the use of superlatives, unless sources of documentation and/or data supportive of the superlative is also referenced in the material and to provide that such supportive documentation and/or data must reflect data, reports, studies, or other documentation that has been published in either the current contract year or prior contract year.

In §§ 422.2263(b) and 423.2263(b) we propose adding a new (8) which prohibits organizations from advertising benefits not available in a service area, unless doing so is unavoidable in a local market. This prohibition is codifying our previous guidance, as previously outlined in section 30.1 of the 2016 Medicare Marketing Guidelines (MMG)[109], providing that marketing activities should be limited to a plan's service area unless doing so was unavoidable, such as advertising in a local newspaper that may be distributed outside a service area. In cases where marketing outside a service area was unavoidable, CMS's guidance provided that the plan's service area be disclosed.

Over the past few years, CMS has seen a significant increase in national marketing which promotes benefits such as dental, vision, and money back on a beneficiary's Social Security check. While many of these benefits are available to a large number of beneficiaries, they are not available in all service areas or to all Medicare beneficiaries in the amounts often advertised. For example, in 2021 there were national advertisements that claimed a beneficiary "could get up to $144 back" on their Social Security check, which would be accomplished through a reduction in the beneficiary's Medicare Part B premium. A premium reduction of this magnitude would have covered most of the standard 2021 Part B premium of $148.50. However, the number of counties or states where one or more available plans offered the advertised Part B premium

[109]https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2016-Medicare-Marketing-Guidelines-Updated.pdf

reduction of $144 was small. In fact, for CY 2021, Florida and Puerto Rico were the only states or territories that had plans with a reduction of $140 or more, and in CY 2022 the only states or territories that had plans with a reduction of $140 or more were California, Florida and Puerto Rico. Further, although there were plans available in these states, the plans offering the $140 or more buy down were not available in all counties. Since beneficiaries in more than 60% of states only have access to plans that offer a Part B premium reduction of $99.00 or less (CY 2022), advertising on a national or even regional level that a beneficiary can get up to the full amount or even close to the full amount is potentially misleading. And although over 30% of states and territories offer Part B premium reduction of $100 or more, this reduction is not available in all counties in each State and territory. These national advertisements publicize that a beneficiary can get up to a certain dollar amount (for example, $144) even if there are no plans available in that state that offer $144 or any dollar amount close to $144. CMS believes that if a plan offering "up to" the top dollar amount is advertised as available for enrollment, then such a plan offering that top dollar amount should be available to beneficiaries who are receiving or exposed to the advertisement where they reside; otherwise we believe it is potentially misleading to potential enrollees. A beneficiary calling, based on an advertisement touting up to $144 back, would expect that plans would be available that would provide a reasonable Part B premium reduction. However, the actual reduction may be minimal, anywhere from $1 to $25, significantly far from the "up to" advertised amount; or in other cases, there may not even be a Part B premium reduction in that particular service area. We believe this practice - touting a reduction far greater than what is available has the effect of getting beneficiaries to contact the company, hoping for financial assistance, only to be told there is little to no Part B premium reduction - is a misleading tactic that is more likely designed to attract a beneficiary's attention so that the beneficiary will call the number and then, be subject to additional marketing and potentially switched to a plan not that is not well suited to meet the beneficiary's health care needs.

A similar issue exists for other MA benefits such as dental, vision, and hearing as well as Part D benefits, non-formulary medications and over-the-counter medications. There have been national advertisements that promote plans with high benefit amounts for certain benefits (for example, up to $2,500 in dental benefits). CMS believes advertising up to a $2,500 dental benefit on a national level is misleading when some markets may not even have access to a plan with dental or others only have access to a plan with limited dental (for example, $500). While many beneficiaries have access to MA plans with some level of additional dental, vision and hearing benefits, advertising benefits up to a large dollar amount (for example, $2,500) is misleading when the MA plan options available to a beneficiary provide a significantly lower value benefit (for example, $500).

CMS has seen advertisements which market up to $144 dollars back on the beneficiaries' Social Security check, or thousands of dollars in hearing, dental and vision, to entice a beneficiary to call the 1-800 number possibly believing they can receive the maximum amount of benefits advertised. CMS has listened to recorded calls between a beneficiary and an agent in which the beneficiary starts off by asking about how to get $144 back in their Social Security check. Based on its review of recorded calls[110], CMS has learned that once the beneficiary places a call to the advertised number, the agent may market a plan that does not provide a Part B premium reduction at all or that offers a premium reduction at a much lower level than the advertised dollar value, or a plan with more limited dental, hearing or vision than was advertised. Once the agent or broker has the beneficiary on the line, the beneficiary is either put in a position of trying to end the call or listening to an agent sell a plan in which the beneficiary was not interested, potentially leading the beneficiary into enrolling in a plan that does not offer the advertised benefits. Because of the initial call, which was based on unavailable benefits, the beneficiary may end up enrolling in a plan that does not best meet the health care needs of the

[110]CMS has retained the recordings of these calls. The calls include sensitive information, and as such, we feel it would be inappropriate and illegal to include them as part of this public record.

beneficiary. In this situation, the beneficiary may have benefited by staying in their existing plan, and may even have stayed enrolled in their existing plan, if not for the advertisement urging the beneficiary to call to "get the money they deserve."

As mentioned above, when a plan advertises benefits which are not available to beneficiaries in the service area where the advertisement airs, that type of marketing is misleading. We believe that beneficiaries should only receive marketing that advertises benefits actually available to the beneficiary where the beneficiary resides (that is, in a service area that covers where the advertisements air). Therefore, we are proposing a new (8) at §§ 422.2263(b) and 423.2263(b) that provides that MA organizations and Part D sponsors may not engage in marketing that advertises benefits that are not available to beneficiaries in the service area where the marketing appears unless unavoidable in a local market.

We are also proposing a new (9) at §§ 422.2263(b) and 423.2263(b) that prohibits marketing unless the names of the MA organizations or Part D sponsors that offer the benefits are being advertised are clearly identified. In cases where the MA organization or Part D sponsor uses a specific marketing name, as identified in HPMS, that marketing name can be used in place of the MA organization or Part D sponsor name. CMS has seen an increase in the marketing of benefits, through television, websites, and mailers that mention additional benefits such as dental, vision, hearing, as well as low or zero-dollar premiums. These advertisements do not identify which product(s), plan(s), or specific plan(s) benefits are being advertised, but rather act as a lead generator to obtain beneficiary contact information. When a beneficiary calls, returns a flyer, or clicks on a link on a webpage, the advertising entity (which may be either an MA organization, a Part D sponsor, or a TPMO) may be able to obtain a beneficiary's contact information, which is then used by that entity for unlimited future calls or for providing that information to other entities that then contact the beneficiary. One particular internet site[111]

[111]HPMS is the system of record for storing marketing websites submitted to CMS for review and approval.

requires an individual to enter their name, email address, and phone number prior to looking at any plan information. The disclaimer at the bottom of the ad (and often in much smaller font) states "By entering my contact information and clicking "Next" above, I consent to receive e-mails, telephone calls, text messages and artificial or pre-recorded messages from…licensed insurance agents or their affiliates and third-party partners, regarding health insurance products and services including Medicare Advantage Plans and/or Prescription Drug Plans, at the e-mail address and telephone number provided above, including my wireless number (if provided), using an automated telephone dialing system." By "automated telephone dialing system," the language seems to be referring to what are commonly referred to as robo-calls. In order for the beneficiary to get any information, they are forced to agree to be contacted not just once based on the initial inquiry, but for unlimited calls, texts, and emails from the internet site they visited, as well as any other company to whom the internet site gave or sold the beneficiary's information. We do not believe beneficiaries realize or want their contact information to be provided to other entities just because the beneficiary wanted to get information about available plans from one internet site. We believe that many of the unsolicited contact complaints that CMS has received (through 1-800-MEDICARE, online complaint system, anecdotally from stakeholders, etc.) are the result of a beneficiary inadvertently or unknowingly agreeing to having their personal information provided or sold to others entities, who then call the beneficiary and market MA products.

CMS believes there are specific, important reasons for advertisements to contain MA organization and Part D sponsor names. First of all, we believe including the names in the advertisement will help the beneficiary understand that they are calling a plan or a plan representative and not Medicare, the government, or a non-partisan entity. Adding the names provides information to put the beneficiary in control of whether they even want to contact the agent because by having the name on an advertisement, the beneficiary can research the MA organization or Part D sponsor, including their Star Ratings and complaints, or discuss the plan

with relatives or friends whom they trust to help make health care decisions. The beneficiary can then make a more informed decision on whether they want to contact the agent to learn about that particular plan. Without knowing the plan name, the beneficiary may find themselves in a position of listening to an agent (especially if that agent is in the beneficiary's home) market a plan that the beneficiary is not interested in joining.

Not only does this proposed policy assist beneficiaries, it will also assist CMS and MA organizations and Part D sponsors to ensure the marketing reflects the appropriate MA organizations and Part D sponsors. CMS is proposing to require TPMO-developed marketing to be submitted into HPMS and currently permits TPMOs to submit marketing materials into HPMS. Under our proposal, once submitted, each MA organization or Part D sponsor would decide whether they want the TPMO to use that marketing piece on their behalf. If an MA organization or Part D sponsor "opts into" the piece, the TPMO may then use it on their behalf and marketing those organizations. If the MA organization or Part D sponsor "opts out" of the marketing piece, then the TPMO would not have permission to market *those specific organizations*. By requiring MA organization and Part D sponsor names both CMS and the organization would then be able to ensure that only those MA organizations and Part D sponsors who opted into the TPMO using the piece are being advertised in that piece. And if CMS determines a piece is misleading, we will then be able to identify the organizations from the advertisement, compare them to the ones that opted in and address the issue with those organizations who opted into the TPMO piece. This will allow CMS to quickly notify the MA organization or Part D sponsor of the issues, have the organization resolve the issues, and get the misleading materials out of circulation quickly.

Therefore, we are proposing a new (9) at § 422.2263(b) to prohibit MA organizations from marketing any products or plans, benefits, or costs, unless the MA organization or marketing name(s) (as listed in HPMS of the entities offering the referenced products or plans) are identified in the marketing material. We are also proposing a new (9) at § 423.2263(b) to

prohibit Part D sponsors from marketing any products or plans, benefits, or costs, unless the Part D sponsor or marketing name(s) (as listed in HPMS of the entities offering the referenced products or plans) are identified in the marketing material.

In addition, we propose to set requirements on how the names of the sponsoring organization are displayed or identified in marketing materials. In reviewing television, print, and online marketing, the disclaimers are often small, not displayed long enough, read too fast, or are difficult to find. We propose adding requirements in this new paragraph (9) to ensure the information is visible. We propose adding that print advertisements must have MA organization, Part D sponsor, or marketing names in 12-point font and may not be solely in the disclaimer or fine print. We use the phrase "fine print" as it is generally defined to mean printed matter in small type or in an inconspicuous manner. For television, online, or social media-based advertisements, we propose that these names must either be displayed during the entire advertisement in the same font size as displayed benefits and phone numbers, or be read within the advertisement at the same pace as advertised benefits or phone numbers. For radio or other advertisements that are voice-based only, we propose that these names must be read at the same speed as the phone number. To implement these new requirements, we are proposing new paragraphs (b)(9)(A), (B), and (C), respectively.

We are proposing to add a new (10) to §§ 422.2263(b) and 423.2263(b) to address the marketing of "savings" for beneficiaries. As part of our marketing surveillance and reviews, CMS has seen advertisements touting that a beneficiary can save $9,000 or more on their prescription drugs, or over $7,000 in health care expenses if they join a particular MA plan or Part D plan. In the example referring to savings for prescription drugs, this advertisement included a small disclaimer stating that the "savings" figure is based on the usual and customary price someone without prescription drug insurance would pay. In other examples, MA organizations, Part D sponsors, or TPMOs are marketing dual eligible Special Needs Plans (D-SNPs) that provide "savings" of over $7,000. In this situation, the "savings" described in the

advertisement refers to the Part B Medicare premium and copay amounts that are covered by Medicaid for fully dual-eligible beneficiaries or are the costs saved through the Prescription Drug savings program, which is based on income. However, with both of these examples, most beneficiaries are not saving the advertised amount of money because they would never have incurred many of those out-of-pocket expenses. Specifically, a beneficiary that already has prescription drug coverage (such as a current Part D plan or other creditable prescription coverage from before the individual became eligible for Medicare) would not save $9,000 in out-of-pocket costs by switching to the advertised plan because they already had coverage for their drugs through a different plan. This advertised "savings" is only applicable if the beneficiary currently had no drug coverage, meaning they had to pay for all of their drugs out of pocket. Likewise, the above example of advertisements marketing D-SNPs, the advertisements generally have very small, fine print that says the individual may need to be income eligible or Medicare and Medicaid eligible in order to receive the advertised savings. However, since dual eligible beneficiaries already have Medicaid coverage or are already in a dual plan they are not saving the full $7,000 because they never paid the full $7,000 in their old or existing plan. Further, if the beneficiary is eligible to have Medicaid pay certain costs on the beneficiary's behalf (such as payment of Part B premiums) or is protected from paying cost sharing by § 422.504(g)(1)(iii), the advertised savings are not unique to the advertised plan in any way.

We believe that these commercials and other types of advertising (for example, direct mailers) are techniques that TPMOs, MA organizations, and Part D sponsors use to entice a beneficiary into calling a 1-800 number for plan X, mistakenly believing that she or he will save thousands of dollars by switching plans, as identified in the examples above. To address our concerns about beneficiaries being misled, we propose to add a new paragraph (b)(10) at §§ 422.2263 and 423.2263 to prohibit MA organizations and Part D sponsors from including information about savings available to potential enrollees that are based on a comparison of

typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

Next, we propose adding a new paragraph (A) to §§ 422.2264(a)(2)(i) and 423.2264(a)(2)(i) to add to the current prohibition of door-to-door solicitation. Business Reply Cards (BRC) and other types of documents where the beneficiary requests additional information are intended to allow the agent to reach out to the beneficiary via telephone, email, or direct mail. One particular agent asked CMS if the BRC gives them the legal right to visit a beneficiary's home unannounced. We do not believe a beneficiary filling out a BRC necessarily indicates a beneficiary's intention give permission for an agent to show up unannounced, at their home, requesting to market MA or Part D plans to that beneficiary. CMS considers this activity to be door-to-door solicitation. Therefore, we propose adding a new (A) to §§ 422.2264(a)(2)(i) and 423.2264(a)(2)(i) which provides that contacting a beneficiary at his or her home is considered to be door-to-door solicitation unless an appointment at the beneficiary's home at the applicable date and time was previously scheduled.

Currently, regulations at §§ 422.2264(b) and 423.2264(b) permit MA organizations and Part D sponsors to contact existing members, and to a limited extent, former members, as plan business. In §§ 422.2264(b) and 423.2264(b) we define plan business activities to include calling current members to discuss Medicare products. In addition, in §§ 422.2264(b)(2) and 423.2264(b)(2), we currently require that MA organization and Part D sponsors provide beneficiaries an opportunity to opt out of being contacted concerning plan business. However, we have interpreted and implemented this regulation as requiring MA organizations and Part D sponsors to present the opt-out opportunity one time, regardless of how many subsequent contacts an enrollee receives. We are proposing, in §§ 422.2264(b)(2) and 423.2264(b)(2), a change that would require each MA organization and Part D sponsor to provide the opt-out information to all its enrollees, regardless of plan intention to contact, at least annually in writing, instead of just one time. Over time, beneficiaries may realize that having plans contact

them regarding marketing is not necessary. Beneficiaries, by only receiving the opt-out option once under current regulations, may fail to realize that they have the option to opt out at any time. By requiring a written annual notification from plans, our proposed new requirement will ensure beneficiaries are reminded that they may decide at any time to opt out of being contacted by their MA organization/Part D Sponsor about plan business.

Therefore, we are proposing MA organizations/Part D Sponsors provide beneficiaries with additional notice, in an annual written communication, about their ability to opt out of being contacted about plan business. We are deferring to plans on how best to communicate this, as we believe that they are in the best position to develop appropriate language based on the plan business they conduct. In addition, we are not proposing the specific written format that plans must utilize when communicating this information during the year, nor specifying when the plan must provide this information during each contract year. MA organizations/Part D sponsors may provide this opt-out notification as a single letter, in a welcome packet, or another method of written communication. The enrollee's decision to opt out of contacts for purposes of plan business will remain in effect until an enrollee chooses to opt in. We solicit comment on whether CMS should expand the existing and proposed notice requirements in some fashion as a way to ensure that Medicare beneficiaries are not marketed MA/Part D plans in a way that is similar enough to cold calling that it should be prohibited.

Our regulations at §§ 422.2264(c) and 423.2264(c) regulate what is permitted at sales and educational events as well as conduct that is prohibited at these events. Currently, MA organizations and Part D sponsors, including agents and brokers, may not market specific MA/Part D plans or benefits at educational events. However, CMS currently permits MA organizations and Part D sponsors participating in educational events to set up future personal marketing appointments and to collect beneficiary contact information including Scope of Appointment forms (SOAs) at educational events. Our regulations also permit marketing events

to immediately follow an educational event, provided the beneficiary is made aware of the change and is given an opportunity to leave prior to the beginning of the marketing event.

In 2018, prior to the implementation of §§ 422.2264(c) and 423.2264(c), the MCMG prohibited many of these activities, such as holding marketing events following an educational event, distributing SOA cards, and setting up future individual marketing appointments. Since the January 2021 final rule, CMS' review of marketing to beneficiaries has expanded. We have reviewed complaints about confusing and misleading marketing tactics received through 1-800-MEDICARE and have heard from industry groups concerned about the changes in our policy regarding educational events. Since the 2021 final rule, complaints to CMS have increased alleging unsolicited contact. We believe that some of these complaints may be attributed to the collection (and later use) of contact information or SOA cards at educational events.

We are proposing, in §§ 422.2264(c) and 423.2264(c), to reinstate the prohibition on accepting SOA cards or the collection of beneficiary contact information at educational events. Section 1851(j)(1) of the Act prohibits sales and marketing to take place at educational events. Such events are meant to provide information on how Medicare works including the options of Original Medicare, Medigap plans, Part C, and Part D. These events are aimed at informing beneficiaries on what Medicare covers and the different options a beneficiary has when they are Medicare-eligible or are looking at the options they have to switch the way they receive their Medicare benefits. In other words, these events are meant to provide generic information about the different options, rather than to persuade beneficiaries to enroll in any type of plan (for example, MA-PD or Medigap) or in a plan offered by any specific sponsoring organization.

Although the collection of beneficiary information through SOAs or BRCs was previously permitted, we now believe that collection of contact information at educational events should not be permitted. As mentioned in our May 2022 final rule, the number of marketing complaints has increased significantly over the past few years. Specifically, a significant portion of these complaints involve unsolicited contact. A likely contributor to these contacts is a

beneficiary not realizing the contact form provides permission to be called by an agent at some time in the future. CMS has also heard from beneficiary groups requesting that CMS reinstitute the beneficiary protections from the MCMG that were not included in the January 2021 final rule regarding educational events.

The beneficiary attends an educational event to learn about Medicare, unlike a sales event where a beneficiary has decided that they want to look further into a plan to enroll. Collecting contact information at educational events potentially unduly pressures a beneficiary into providing their personal information. Agents passing out SOA cards, possibly watching beneficiaries fill them out, and then collecting these cards can put a beneficiary in an uncomfortable position of having to decide whether they want to oblige or draw attention by declining. This especially may be the case if the beneficiary feels like they should provide this information in exchange for attending the educational event, which could include the provision of a meal and helpful question and answer opportunities in addition to general information. We believe the beneficiary needs to be in charge of and control whether they want to be contacted, by whom, and in what form. Therefore, to ensure such decisions remain with the beneficiary, we propose to amending the regulations that list the activities that are permissible to include in educational events (§§ 422.2264(c)(1)(ii) and 423.2264(c)(1)(ii)) by removing the paragraphs that authorizes obtaining beneficiary contact information, including Scope of Appointment forms.

The current regulations at §§ 422.2264(c)(1)(ii)(C) and 423.2264(c)(1)(ii)(C) also permit agents to set up future personal marketing appointments at educational events. Similar to SOAs and contact information, we believe that beneficiaries should be in charge of with whom they speak, when they meet with an agent, and what products they want to discuss with that agent. In the case of educational events, the beneficiary generally attends the event to learn about Medicare, not to facilitate a sales meeting where the beneficiary is urged to enroll in a plan. Once an agent speaks with a beneficiary at an educational event, the beneficiary may feel

pressured into setting up a marketing appointment. The "on the spot" request at an educational event does not provide the beneficiary enough time to consider whether they want an someone to come to their home and market a plan to them for the purpose of enrollment. We believe that an educational event should be solely for education; not lead generation or future marketing opportunities for agents. Therefore, we also propose removing §§ 422.2264(c)(1)(ii)(C) and 423.2264(c)(1)(ii)(C), which currently permit organizations and agents to set up future marketing appointments at educational events.

CMS is also concerned about marketing events directly following an educational event. As stated above, educational events are meant to provide information on how Medicare works, including the options of Original Medicare, Medigap plans, Part C, and Part D, not meant to persuade beneficiaries to enroll in a plan. Beneficiaries attending an educational event directly followed by a marketing event may feel pressured into staying for the marketing event at the conclusion of the educational event. For example, an agent may hold an educational event providing free meals and desserts, which is directly followed by a marketing event. Beneficiaries may feel pressured into staying for the marketing event because of the offer of a free meal at the event that follows the educational event. Although our current regulations require there be an opportunity to leave prior to the sales event, we do not regulate how long that needs to be, nor do we prescribe what the agent can or cannot say regarding the sales event. Beneficiaries may feel obligated to stay for a variety of reasons, including not having enough time to gather their belongings or feeling awkward leaving when others are staying, adding additional pressure to stay and possibly enroll in an MA or Part D plan, especially when they only came to the event to learn about Medicare and the options available to them. Furthermore, attending a marketing event right after an educational event may raise the risk of beneficiaries being confused that the benefits of an MA or Part D plan in general are actually unique to the specific plan options that are being marketed. For example, a factual and impartial statement like, "It is important to consider your out-of-pocket costs and which drugs you take when

deciding on your enrollment options" in the educational event could be followed up in the marketing event that uses the same phrasing and terms in describing a specific plan's benefits. The beneficiary might conflate these issues if the educational and marketing meetings are held so close in time.

When CMS permitted marketing events to immediately follow educational events, we were concerned about beneficiaries having to go to two separate events at different times, potentially in two different places. Over the past few years, there has been a significant increase in the use of technology. The COVID-19 pandemic resulted in fewer face-to-face communications and more technology-based marketing, such as Zoom calls and live events on the internet. If a beneficiary attends an educational event and wants further information about a specific MA or Part D product, the beneficiary can go to a marketing event or ask for a one-on-one appointment either in person or through communications technology. Although there are still many beneficiaries that may not have significant knowledge about digital technology, we believe the number of beneficiaries that understand the technological options will increase. The use of technology has provided more options for beneficiaries, and with the increase in technology education CMS is proposing, the need for sales events to follow educational events because of travel considerations will become less important.

By separating educational events from the marketing events, beneficiaries are afforded the time to consider all their questions and options. The beneficiary can reach out to the agent if and when they want to hear more about the particular plan the agent is selling. CMS believes this proposal to separate marketing from educational events will alleviate the pressure a beneficiary may feel to stay for a marketing event and will protect beneficiaries from undue pressures to enroll in a plan for which they may not be interested or a plan that does not best meet their health care needs. Based on this, we are proposing to prohibit marketing events from taking place within 12 hours of the educational event in the same location. We are proposing changes to §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) to read, "Marketing events are prohibited

from taking place within 12 (twelve) hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings." We believe a 12-hour window is important to ensure beneficiaries are not pressured into attending a sales event. This will usually give beneficiaries until the next calendar day, providing sufficient time to think about the impartial and factual information provided at the educational event. We are concerned that a short window, such as 10-15 minutes, will not provide beneficiaries with enough time to finish conversations, pack their belongings, and leave the facility prior to the sales event starting. If a beneficiary is unable to leave during the break, we are concerned that the beneficiary may be "guided" to the sales event or pressured into attending by being told the event won't last long or that there will be no pressure to join, or will be made to feel obligated to go to the sales event. CMS believes the best way to protect beneficiaries by being pressured into attendance would be for the sales event to be at a different time, with a sufficient amount of time between the two events. We also believe it is necessary to limit this new requirement to when the sales event is in the same location as the educational event. This ensures that an agent or broker can hold a sales event the same day as an educational event, provided the sales event is in a different location. If an agent wishes to have a sales event three miles from an educational event, we do not want to limit the ability of the agent or broker to do so. Therefore, we are proposing to revise paragraph (c)(2)(1)(1) of §§ 422.2264 and 423.2264 to prohibit marketing events from taking place within 12 hours of an educational event, at the same location.

Sections 1851(j)(2)(A) and 1860D-4(l)(2) of the Act require an advance agreement with a prospective enrollee on the scope of the marketing appointment, which must be documented. Our regulations at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) reiterate this requirement, designating this requirement as a Scope of Appointment. Both the statute and the regulations require an advance agreement between the beneficiary and the agent. Previously, we interpreted this standard of agreement in advance in our MCMG guidance as meaning as 48 hours prior the appointment when practicable. We propose codifying our previous marketing (MCMG)

guidance by prohibiting personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary. However, we are not proposing to include "when practicable*"* in the proposed regulation. We believe "when practicable" nullifies the purpose of the 48 hour timeframe, given the many reasons that might be cited for why waiting the full 48 hours is not "practicable," such as the beneficiary living an hour away, the beneficiary wanting to discuss the products immediately following the signing of the SOA, the beneficiary may feel pressured by the agent to discuss the product immediately, or the beneficiary needs to arrange to have the person that helps them with health care decisions available at the meeting. The reasons for why a meeting must occur within the 48 hour timeframe are numerous and subjective, meaning what is practicable for one person may not be practicable for another, thus we are concerned about our ability to enforce the regulation if we include "when practicable" in requiring advance agreement at least 48 hours before the meeting. In addition, given today's technology and the fact that we permit SOAs to be completed via telephone, electronically, or in paper form, obtaining a SOA 48 hours prior to the appointment should not present a significant burden for either beneficiaries or the plan representatives and agents that engage in these meetings. Therefore, we are proposing to add "At least 48 hours" before the word "Prior" to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to read, "At least 48 hours prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies)."

Regulations at §§ 422.2264(c)(3)(iii) and 423.2264(c)(3)(iii) prohibit an MA organization/Part D sponsor, including their agents and brokers and other first tier and downstream entities, from marketing a health care product during a personal marketing appointment beyond the scope agreed upon by the beneficiary. Sections §§ 422.2274(g)(1) and 423.2274(g)(1) require that MA organizations/Part D sponsors ensure TPMOs acting on their behalf adhere to any requirements that apply to the plan itself. Therefore, the requirement for noting the scope of a personal marketing appointment (that is, the SOA) is applicable to TPMOs.

Currently, CMS requires permission to be granted and completed, concerning the products that will be discussed, prior to the marketing discussion. The existing regulations do not stipulate a timeframe in which the beneficiary may be contacted after an SOA is completed or an expiration date after which the SOA is invalid.

CMS also is aware that MA organizations, Part D sponsors and TPMOs encourage beneficiaries to fill out business reply cards (BRC) or similar mechanisms so the MA organization/Part D sponsor or TPMO has permission to contact the beneficiary at a later date. BRCs are different from SOAs in that the SOA must have the products to be discussed on the document, while many times the BRC is simply obtaining contact information (that is, name, phone number, address, email). While SOAs are required, BRCs are not required. However, we have the same concerns with BRCs as we do with SOAs, BRCs often are open-ended, allowing an MA organization, Part D sponsor or TPMO to contact a beneficiary at any point in the future. For example, a beneficiary could fill out a BRC in October of 1 year and be contacted by the MA organization/Part D sponsor or TPMO 24 months later, well beyond the timeframe that the beneficiary would reasonably expect to be contacted about their plan choices and decision-making when they filled out the card.

CMS is proposing to modify the current regulations at §§ 422.2264(c)(3)(iii)(A), 422.2264(c)(3)(iii)(B), 423.2264(c)(3)(iii)(A) and 423.2264(c)(3)(iii)(B) to limit the validity of the SOAs and BRCs in §§ 422.2264(c)(3)(iii)(A) and 423.2264(c)(3)(iii)(A), and the SOAs in §§ 422.2264(c)(3)(iii)(B) and 423.2264(c)(3)(iii)(B), to six months from the beneficiary's signature date or the beneficiary's request for more information. BRCs and requests for additional information are not applicable to paragraph (B) because CMS does not have the authority to regulate how long a BRC is valid for non-MA/Part D products. A beneficiary's permission to allow contact by an MA organization/Part D sponsor or a TPMO is not, and should not be, open-ended. Beneficiaries who request information regarding MA organizations/Part D sponsors are requesting information at that present time. Since the purpose of the SOA or BRC

is for beneficiaries to discuss plan products applicable for the present or following contract year, having the SOA or BRC expire after 6 months satisfies that purpose, and would prevent agents from using it in perpetuity and thus avoiding the statutory and regulatory prohibitions on unsolicited contact and cold calling. If a beneficiary wants the agent tied to the SOA or BRC to continue contacting them beyond 6 months, the agent may secure and document that permission through a new SOA, BRC, or similar mechanism.

In accordance with § 422.2265(b)(4), MA organizations are required to have a searchable provider directory on their website. The current regulations do not identify the elements by which the provider directory can be searched, leaving that up to each organization. We are proposing to modify § 422.2265(b)(4) by requiring the organization's provider directory be searchable by every element, such as name, location, and specialty, required in CMS' model provider directory. We believe this proposal is necessary to assist beneficiaries in finding particular providers. For example, if an organization only provides a beneficiary with the ability to search by location, the beneficiary would have significant difficulties finding a particular specialty or a particular provider. In section III.A.3. of this proposed rule, we are proposing to add two new requirements to § 422.111(b)(3)(i) that organizations must include providers' cultural and linguistic capabilities and identify certain providers waived to treat patients with MOUD in their provider directories. As adopted and with our proposed revisions, § 422.111(b)(3)(i) requires organizations to include these two new elements in their provider directories, therefore, our proposed modification to § 422.2265(b)(4) would require the organization's provider directory be searchable by these two new elements. By requiring website provider directories be searchable by every element, our proposal would ensure that a beneficiary would be able to locate specific provider specialties, as well as providers by names, addresses, or other elements the organization has listed in the online provider directory. Therefore, we propose to modify § 422.2265(b)(4) to require the directory be searchable by every element.

CMS is also proposing to modify the pre-enrollment checklist (PECL) requirements at §§ 422.2267(e)(4) and 423.2267(e)(4). First, we are proposing to add new paragraphs at §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), to add "Effect on current coverage" to the list of references currently provided within §§ 422.2267(e)(4)(i) – (vii) and 423.2267(e)(4)(i) – (vii). Second, we are proposing to update §§ 422.2267(e)(4) and 423.2267(e)(4) to require that plans review the PECL with the prospective enrollee during telephonic enrollments.

The PECL contains important information prospective enrollees need to know prior to enrolling in an MA or Part D plan. It ensures beneficiaries understand important documents and what information is in such documents, such as the Evidence of Coverage, which provides all costs, benefits, and plan coverage. The PECL also includes information designed to help beneficiaries, such as a reminder to make sure their doctors, pharmacies, and prescriptions are either in the plan's network or covered in their formulary. Finally, the existing PECL reminds beneficiaries of certain plan rules, formularies, and out-of-network services are not covered except for emergency and urgently needed care, and that benefits and costs may change on January 1 of each year.

In §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), we propose to add "Effect on current coverage" to the list of information that must be referenced as part of the PECL. Over the past 2 years, CMS has been doing an in-depth review of 1-800-MEDICARE complaints. Our reviews revealed numerous beneficiary complaints that they were not aware their current coverage, such as an existing MA plan, a Medigap plan, or their Tri-care plan would end once they enrolled in an MA plan. Thus, CMS is proposing to add effect on current coverage to the list of information that plans must provide to prospective enrollees in the PECL, as we believe it will provide additional education to beneficiaries on the implications of choosing an MA or Part D plan and ensure beneficiaries are fully aware that this selection will cause their existing coverage to end.

In §§ 422.2267(e)(4) and 423.2267(e)(4), we are also proposing that the PECL be reviewed with the prospective enrollee during telephonic enrollments as well as provided when

hard-copy enrollment forms are provided. As previously mentioned, the PECL provides information necessary for beneficiaries to understand the details of the plan for which they are enrolling. Although the PECL must be provided with an enrollment form, CMS' review of telephonic enrollments revealed that the neither the PECL nor its substance was being conveyed to beneficiaries during the enrollment process. Specifically, complaints received by 1-800-MEDICARE included beneficiaries who called 1-800-MEDICARE to inform the Agency via the toll-free line that agents failed to inform the beneficiary that their doctors were not in the MA plan's network, were inaccurately told that there would be no costs, or were inappropriately told that their existing coverage would not be affected by enrolling into a new MA or Part D plan. During CMS' review of the telephonic enrollment audio recordings between beneficiaries and agents, it was clear that some beneficiaries were confused that their current coverage would be ending. It also was clear that some were misled by the agent and were told that their existing benefits would not change, and others were never informed by the agent that enrollment into an MA or Part D plan would cancel the beneficiary's current coverage. There also were cases where the agent failed to go over the beneficiary's current providers or Part D drugs. In addition, few, if any, calls with agents included explanations that all of the benefits and cost sharing for the plan could be found in the plan's Evidence of Coverage.

By requiring the PECL to be reviewed with prospective enrollees as part of telephonic enrollments, we hope to ensure that beneficiaries are better informed about the details surrounding the plan for which they are enrolling. Under this proposal, MA organizations and Part D sponsors would decide whether they require their contracted agents and brokers to read the PECL in its entirety or to require that each item contained on the PECL be discussed. It is CMS' expectation that the agent ensures the beneficiary understands the items in the PECL. Agents may do this by receiving an affirmative answer to whether the prospective enrollee understands the information provided, as well as asking the prospective enrollee if she or he has any questions. CMS believes that an actual review of the PECL elements with prospective

enrollees will decrease inaccurate information and misunderstandings, resulting in fewer 1-800-MEDICARE complaints and higher beneficiary satisfaction.

Therefore, CMS is proposing to add the reference to "Effect on current coverage" to §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii) and requiring, in §§ 422.2267(e)(4) and 423.2267(e)(4), that the PECL be reviewed with the prospective enrollee during telephonic enrollments.

CMS also is proposing a change to § 422.2267(e)(5)(ii)(A) to require Summary of Benefits medical benefits be listed in the top half of the first page and in the order currently listed in §§ 422.2267(e)(5)(ii)(A)(1) through 422.2267(e)(5)(ii)(A)(10). Currently, § 422.2267(c)(2) states that model materials, like the Summary of Benefits, must follow CMS' order of content when specified. This existing regulation permits CMS to specify the order of content presented in MA required model materials. CMS has already specified the order of information on medical benefits in the Summary of Benefits instructions, mirroring the regulatory list of medical benefits provided at § 422.2267(e)(5)(ii)(A)(1) through (10). By requiring all plans to list certain benefits in the same location and in a specified order, beneficiaries will be able to more easily compare benefits across different plans and in a more standardized way. The ability for beneficiaries to review and compare benefits across different MA Plans will assist beneficiaries in making a more informed health care choice.

We are also proposing a change to 42 CFR §§ 422.2267(e)(10) and 423.2267(e)(13), which provides that the non-renewal notice is a model communications material through which plans must provide the information required under §§ 422.506 and 423.507, respectively. Per §§ 422.2267(c) and 423.2267(c), model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. Modifications to model materials, including the non-renewal notice, can be made at the MA organization's/Part D sponsor's discretion within certain limits outlined in §§ 422.2267(c) and 423.2267(c). Our current non-renewal document and accompanying instructions do not permit

plan changes, except where noted, to the non-renewal notice. To ensure accuracy and consistency, we are proposing to update §§ 422.2267(e)(10) and 423.2267(e)(13) to specify that the non-renewal notice is a "standardized communications material" so that it is clear these materials must be used without modifications except where noted. This is necessary to ensure that the vital information contained in the non-renewal notice about a beneficiary's alternative healthcare options and the timing for the plan to make a selection are conveyed in a way that CMS has determined is accurate and understandable. Beneficiaries receiving the non-renewal notice are provided a Special Enrollment Period (SEP) (as per § 422.62(b)(1)) with deadlines to make new health care decisions. This notice provides beneficiaries with this information, as well as other plans available to them. As a model notice, MA organizations/Part D sponsors would be able to place this vital information anywhere in the document, potentially highlighting their other plan options, instead of providing equal prominence to all health care choices. Our proposal would eliminate that possibility.

In the May 2022 final rule, CMS implemented a Third Party Marketing Organization (TPMO) disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41). The required disclaimer states, "We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1-800-MEDICARE to get information on all of your options." We currently require TPMOs that represent more than one MA or Part D plan in a given service area, but do not represent all plans, to verbally convey the disclaimer within the first minute of a sales call, electronically convey the disclaimer when communicating with a beneficiary via email or online chat, or prominently display the disclaimer on their website, and to include the disclaimer on all marketing materials. We are proposing to modify this disclaimer to add State Health Insurance Programs (SHIPs) as a source of information for beneficiaries. We are also proposing that an additional disclaimer requirement, which would require all TPMOs to list names of the MA organizations or Part D sponsors with which they contract in the applicable service area.

Although TPMOs may contract with one or more MA organizations and Part D sponsors, they do not necessarily contract with all available options in a service area. When a beneficiary contacts a TPMO that does not contact with all MA organizations or Part D sponsors in a particular service area, the beneficiary may not know that the TPMO does not sell or represent all of the available options. To ensure beneficiaries in this situation are aware that other options exist, the disclaimers at §§ 422.2267(e)(41) and 423.2267(e)(41) require TPMOs to notify the beneficiary that a complete list of plans could be obtained from 1-800-MEDICARE or Medicare.gov. We are proposing to modify §§ 422.2267(e)(41) and 423.2267(e)(41) to provide that TPMOs in this situation also notify beneficiaries that they may contact their local SHIP for more information. SHIPs are another resource that beneficiaries can contact to obtain unbiased information on all available health and drug plan options. We believe adding SHIPs to this disclaimer provides beneficiaries with important and unbiased information regarding other sources of assistance.

In addition, CMS is proposing that TPMOs disclose the names of the MA organizations or Part D sponsors with which they contract. This ensures that beneficiaries are aware of all of their choices when communicating a TPMO. In CMS's review of hundreds of sales, marketing, and enrollment audio calls, CMS found over 80% of the calls only mentioned one plan option from one MA organization. The audio reviews CMS conducted also showed that agents rarely, if ever, informed the beneficiary that there were multiple plans available in the service area. Although the agent may have researched other plans on behalf of the beneficiary the agent was assisting, information about those plan options was rarely communicated to the beneficiary, and thus the beneficiary may not have known about their other options to make an informed decision about the plan that best meets the beneficiary's needs.

CMS is proposing to revise the existing TPMO disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41) to require TPMOs that do not contract with every available MA organization or Part D sponsor in a service area to include a list the MA organizations or Part D sponsors with

which they do contract in the beneficiary's service area. In addition, because the existing TPMO disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41) does not apply to TPMOs that contract with every MA organization or Part D sponsor in a given service area, CMS is also proposing to revise §§ 422.2267(e)(41) and 423.2267(e)(41) to include a new disclaimer for TPMOs that do contract with every MA organization or Part D sponsor in the service area. This new disclaimer would need to be provided within the first minute of the call, as required for TPMOs that do not contract with MA organization or Part D sponsor in a service area. As with the existing TPMO disclaimer, this new disclaimer would need to be electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means, prominently displayed on the TPMO's website, and included in any TPMO marketing materials, including print materials and television advertising.

Therefore, we propose modifying §§ 422.2267(e)(41) and 423.2267(e)(41), to require two disclaimers. The first disclaimer, which applies to TPMOs that do not sell for all MA organizations or Part D sponsors in a service area, would read, "We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are [insert list of MA organizations or Part D sponsors]. Please contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program to get information on all of your options." The second disclaimer, for those TPMOs that sell for all MA organizations or Part D sponsors in a service area, would read, "We offer the following plans in your area [insert list of MA organizations or Part D sponsors]. You can always contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program for help with plan choices."

We are proposing a technical change to § 423.2267(e) to add new paragraphs (e)(43) and (e)(44), to include the comprehensive medication review (CMR) written summary which, in accordance with § 423.153(d)(1)(vii)(B), Part D sponsors must provide to all MTM program enrollees who receive a CMR, as well as the safe disposal information that, in accordance with

§ 423.153(d)(1)(vii)(E), Part D sponsors must provide to all plan enrollees targeted for MTM. As noted in the January 2021 final rule (86 FR 5984), we intended § 423.2267(e) to be a complete list of all required materials and content. The CMR written summary and safe disposal information are materials that Part D sponsors are already required to provide under existing regulations at 42 CFR §§ 423.153(d)(1)(vii)(B) and (E), and were inadvertently omitted from this section during the previous rulemaking. Because MA-PDs must comply with Part D regulations per § 422.500, this proposal regarding the MTM and safe disposal instructions will also apply to MA-PDs.

Based on our review of complaints and audio calls, we are concerned about the level of oversight that MA organizations and Part D sponsors provide over their contracted agents and brokers. In our review of complaints and discussions with MA organizations and Part D sponsors, MA organizations and Part D sponsors appear to be reactive instead of proactive in addressing inappropriate agent and broker behavior. CMS has received complaints through 1-800-MEDICARE as well as other CMS staff. Once a complaint is received, the complaint is provided to the applicable MA organization or Part D sponsor to review, investigate, and take appropriate action. However, this method of oversight is more reactive, and requires organizations and sponsors to respond to issues that CMS has already been made aware. As a result, we are concerned that inappropriate behavior by agents and brokers is not being sufficiently addressed and corrected by MA organizations and Part D sponsors. In §§ 422.2272 and 423.2272, we propose requiring sponsoring organizations have an agent and broker monitoring and oversight plan that ensures agents and brokers are adhering to CMS requirements and that the MA organization or Part D sponsor is actively monitoring and reporting agents and brokers to CMS who are not compliant with CMS requirements.

We believe a thorough oversight and monitoring plan will assist in identifying and stopping poor performing agents and brokers more quickly, whether they are independent, captive, or employed agents or brokers. To that end, CMS requires MA organizations and Part D

sponsors to oversee the agent and brokers with which they contract (§§ 422.2274(c) and 423.2274(c)). A proper oversight program includes the review of internal grievances, 1-800-MEDICARE complaints, random samplings of past audio calls, listening to sales/marketing/enrollment calls in real-time, secretly shopping in-person education and sales events, and secretly shopping web-based education and sales events. These types of activities will improve the overall marketing and sales activities of plans. MA organizations and Part D sponsors should be able to identify areas where agents and brokers have not been adequately trained, agents and brokers who may not fully understand the product offerings, and agents and brokers who improperly market to beneficiaries. MA organizations and Part D sponsors can then quickly act, such as tailored training or disciplinary measures, based on the specific issues for each agent or broker. Once an MA organization or Part D sponsor identifies the non-compliance, the MA organization or Part D sponsor would then be required to report that agent or broker non-compliance to CMS. This will assist plans and sponsors in gauging the scope of marketing issues, and help plans and sponsors in developing methods to stop inappropriate agent and broker activity. Therefore, we are proposing to add a new (e) to §§ 422.2272 and 423.2272 to read, "Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS."

Section 1856(b) of the Act provides CMS the authority to publish regulations creating standards for organizations to carry out the MA program. CMS is proposing to adopt, at a new paragraph (c)(12) of §§ 422.2274 and 423.2274, additional standards for agents and brokers in their marketing of MA and Part D plans to beneficiaries to require that sponsoring organizations ensure that agents and brokers discuss specific topics and information with beneficiaries prior to enrollment. We believe that adopting these standards is consistent with and achieves a similar goal as the statutory requirement in section 1851(j)(2)(D) of the Act that compensation to agents and brokers create incentives for agents and brokers to enroll beneficiaries in the plan that best meets their health care needs. For an agent or broker to ensure the beneficiary is in a plan that

best meets their needs, the agent or broker needs to obtain enough information to determine the health care needs of the beneficiary. If the agent or broker fails to have sufficient information to ensure that he or she is enrolling the beneficiary in a plan that best meets the beneficiary's health care needs, but is compensated for enrolling the beneficiary in a plan, we believe that section 1851(j)(2)(D) of the Act is undermined. CMS is concerned that agents and brokers too often fail to adequately determine the kind of health plan into which a beneficiary wishes to enroll, such as a plan that offers a lower premium and higher copays, one that has specific providers in their network, or one that provides coverage for a certain durable medical equipment. Therefore, in §§ 422.2274(c) and 423.2274(c), we are proposing that all agents and brokers (employed, captive, and independent agents) go through a CMS-developed list of items that must be asked and/or discussed during the marketing and sale of an MA plan or Part D plan.

CMS has listened to hundreds of marketing and enrollment audio calls. In the majority of these calls (over 80 percent), agents and brokers failed to ask pertinent questions to help a beneficiary enroll in a plan that best meets his or her needs. CMS listened to calls where the agent or broker only asked about primary care providers and prescription drugs. There were also calls that CMS listened to where the agent or broker only discussed "extra benefits" such as dental and vision. During many of the calls CMS reviewed, the agent or broker failed to ask important questions, such as whether there was a specialist that the beneficiary wished to see (or currently sees) and whether that specialist was in the plan's network, whether the beneficiary would prefer lower copays and a higher premium or vice versa, which hospitals the beneficiary preferred, or whether the beneficiary wanted dental and hearing benefits. Some calls were under twenty (20) minutes in length. This short time period led CMS to question whether an agent or broker could have realistically obtained the necessary information from the beneficiary in order to adequately determine their needs and wants, review available options, and complete the enrollment.

In order to properly assist a beneficiary in choosing a Medicare health and/or drug plan, the agent or broker must have sufficient information about the beneficiary's needs and goals. We do not believe a beneficiary can be enrolled in a plan that best meets his or her needs when, for example, an agent or broker fails to ask the beneficiary about their current providers, including specialists and preferred hospitals or other facilities. To ensure a beneficiary's needs are reviewed, CMS is proposing to add a new (12) to §§ 422.2274(c) and 423.2274(c), requiring an MA organization or Part D sponsor ensure that the agent's/broker's sales call goes over each CMS required question or topic, including information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs. CMS would provide in sub-regulatory guidance more detailed questions and areas to be covered based on these general topics.

If agents and brokers are required to ask beneficiaries certain questions, or cover certain topics, prior to beginning the enrollment process, we expect that beneficiaries will be more knowledgeable about the plans that are available to them, and thus better able to make an informed choice. We are not proposing that agents or brokers would be required to read standardized questions or statements regarding the topics discussed here. Rather, we are proposing that certain required topics are addressed, prior to the enrollment, whether it be asking questions about the medications the beneficiary takes or covering topics such as the premium the beneficiary will be charged for the plan. We propose to add a new (12) to §§ 422.2274(c) and 423.2274(c) which will read, "Ensure, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health

care services, premiums, benefits, and specific health care needs." or "Ensure, prior to an enrollment CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), premiums, and other services (such as over-the-counter medications and other incentives)."

Currently in §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii), TPMOs must record all calls with beneficiaries. This regulation was put into effect to ensure that TPMOs, including agents and brokers, were appropriately marketing to beneficiaries. As stated above, CMS's experience with reviewing complaints and in listening to recorded calls revealed many instances where agents and brokers have failed to provide enough information, confused beneficiaries, and, most concerning, provided inaccurate information about plan benefits. In other cases, these entities led beneficiaries to believe the beneficiaries were calling Medicare rather than an insurance agent. This requirement for recording all calls with beneficiaries was proposed on January 6, 2022, and finalized in the May 2022 final rule; we had received few pertinent comments prior to the rule being finalized. However, following this rule, CMS has heard from trade organizations, plans, as well as individual agents regarding the obligation to record all calls. Many of these post-final rule questions and comments centered around whether "smaller" agent companies had to record conversations. Some of the comments received after the final rule requested clarification on whether all calls really needed to be recorded.

CMS is not proposing to change the requirement that TPMOs, including agents and brokers, regardless of their size, must record calls. However, we are proposing to limit calls that must be recorded from all calls to only those calls regarding sales, marketing, and enrollment. CMS believes the current requirement is too broad because under the current requirement calls placed to merely set up an in-person meeting, make sure the beneficiary received the plan welcome packet, or ask non-marketing questions, such as when the plan will be effective, must

all be recorded. We believe this is an unnecessary burden since our goal is to obtain call recordings to ensure the marketing, sales, and enrollment activities conducted by agents, brokers and TPMOs meet the applicable regulatory requirements. Therefore, we are proposing to modify §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to limit the calls that must be recorded to the complete duration of marketing, sales, and enrollment calls. The definition of marketing in §§ 422.2260 and 423.2260 will apply to new paragraph (g)(2)(ii) and we intend the words "sales" and "enrollment" to include the plain meaning of those terms.

In addition to modifying §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to only require marketing, sales, and enrollment calls to be recorded, we are also proposing to add language to clarify the platform(s) of calls which much be recorded. Since implementing the May 2022 final rule, we have received questions asking whether technology-based meetings (for example, Zoom meetings) need to be recorded. CMS considers meetings taking place on Zoom, Facetime, Skype, or other technology-based platforms to be the same as telephonic calls with the same concerns as telephonic calls. Technology is changing the way people interact and Medicare beneficiaries aging into the program are more likely to have experienced newer technologies and may be more comfortable using technology. In addition, during the COVID-19 pandemic, many beneficiaries learned to use different technologies to keep in touch with people. Moreover, because of the pandemic, many agents and brokers have moved to using these newer technologies, holding meetings through web-based technologies.

Based on the reasons stated above, we propose to modify §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to read "Record all marketing, sales, and enrollment calls, including calls occurring via web-based technology, in their entirety."

Finally, in §§ 422.2274(g) and 423,2274(g), we are proposing to add a new paragraph (4) to address issues with TPMOs distributing beneficiary contact information to multiple entities, in any manner, including selling this information. When a beneficiary calls a 1-800 number from a direct mail flyer, a television advertisement, or an internet advertisement, the beneficiary most

likely believes they are only calling – and requesting contact with - the entity that answers the call. However, some of these entities, in quickly read disclaimers or through disclaimers in very small print, that actually inform the beneficiary that their information may be sold to other entities. The contact information (name, address, phone number) obtained by these entities is then sold to one or more field marketing organizations and/or agents/brokers. In turn, these other entities then call the beneficiary, using the initial incoming call and the contact information obtained by the TPMO from that incoming call, as a form of permission to reach out and contact the beneficiary.

When a beneficiary calls a company based on an advertisement, CMS asserts that the beneficiary is only expecting to connect with that particular company, not to have return calls made to their personal home or cell number from other companies. Through environmental scanning efforts, however, CMS has learned that the selling and reselling of beneficiary contact information is happening as described here and that beneficiaries are unaware that by placing the call or clicking on the web-link they are unwittingly agreeing for their contact information to be collected and sold to other entities and providing consent for future marketing activities.

We do not believe beneficiaries knowingly give their permission to receive multiple calls from multiple different entities on the basis of a single call made by a beneficiary. We believe beneficiaries intend in these scenarios that their information will be received only by one entity, that being the plan that will ultimately receive the beneficiary's enrollment request. Additionally, providing a quickly-read disclaimer or providing a disclaimer in very small print or in an inconspicuous place when that disclaimer indicates that a beneficiary's contact information may be provided or sold to another party, are considered misleading marketing tactics because these entities are using beneficiary data and contact information in a manner in which the beneficiary did not intend. Organizations that require the beneficiary to agree to allowing their contact information to be resold prior to speaking with a representative or having access to any information are another example of this. In these situations, a beneficiary initiates contact with

one organization and then ends up receiving calls from multiple other unrelated entities. In light of the statutory prohibition on unsolicited contact (§§1851(j)(1)(A) and 1860D-04(l)(1)), and the regulatory interpretation of that prohibition (§§422.2264(a)(3) and 423.2264(a)(3)), this practice goes beyond the scope of what we consider permissible. Therefore, we are proposing to add a new (4) to §§ 422.2274(g) and 423.2274(g) to read, "Personal beneficiary data collected by a TPMO may not be distributed to other TPMOs."

We solicit comment on these marketing and communications proposals and whether the proposed regulatory changes will sufficiently achieve the goals we have outlined of protecting beneficiaries.

Q. Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

1. Overview and Summary

We propose regulatory changes regarding (1) obtaining approval to make changes to a formulary already approved by CMS--including extending the scope of immediate substitutions; and (2) providing notice of such changes.

In section III.Q.2.b. of this proposed rule, Approval of Changes to Approved Formularies, we propose to codify longstanding sub-regulatory guidance and terminology (such as classification of changes as either maintenance or non-maintenance) that specify when and how Part D sponsors obtain approval to make negative formulary changes and the enrollees to whom these changes would apply. Section III.Q.2.b.(3). of this proposed rule includes our proposal to permit Part D sponsors that meet certain requirements to immediately substitute a new interchangeable biological product for its corresponding reference product; a new unbranded biological product for its corresponding brand name biological product; or a new authorized generic for its corresponding brand name equivalent. Section III.Q.2.b.(3). of this proposed rule also includes a proposal for a third category of negative formulary changes defined as immediate negative formulary changes.

Currently, we exempt Part D sponsors that make immediate generic substitutions under the regulation from providing transition supplies; we now propose in section III.Q.2.b.(3). of this proposed rule to exempt Part D sponsors making any immediate negative formulary changes (that is, all types of immediate substitutions and also market withdrawals) from providing transition supplies. We also propose to conform our regulations to provide that the same timing rules would apply for all immediate negative formulary changes, that is they all could take place at any time.

Section III.Q.3. of this proposed rule proposes to align our regulatory requirements for appropriate advance notice of formulary changes to guidance and longstanding operations, including streamlining certain requirements.

2. Approval of Changes to Approved Formularies

a. Background: Statutes, Regulations, and Longstanding Operational Implementation of Changes to Approved Formularies

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.[112] Section 1860D-11(e)(2)(D) of the Act specifically predicates approval on a finding by the Secretary that plan design, including formulary and tiered formulary structure, is not likely to substantially discourage enrollment by certain Part D eligible individuals. Section 1860D–4(c)(1)(A) of the Act calls for "a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate."[113]

We have taken a number of steps to implement the approval process. For instance, under § 423.272(b)(2)(i), CMS does not approve a bid for which the plan design and benefits

[112]Section 1860D–4 of the Act on beneficiary protections for qualified prescription drug coverage includes requirements for beneficiary access such as the development and application of formularies. For instance, under section 1860D–4(b)(3)(B) of the Act, the pharmacy and therapeutic committee of each Part D sponsor must base clinical decisions on certain scientific evidence and standards of practice, while subparagraphs (C) and (G) of section 1860D-4(b)(3) of the Act require formularies to include drugs within certain categories and classes.

[113]See discussion in the January 2005 Part D final rule (70 FR at 4299).

(including any formulary and tiered formulary structure) or utilization management program are likely to substantially discourage enrollment by certain individuals. There are also regulations specific to the development and content of formularies. For example, § 423.120(b)(1) requires Part D sponsors to establish pharmacy and therapeutic committees to develop and review formularies as specified, and § 423.120(b)(2) requires provision of an adequate formulary.

Each year we undertake a multi-step process to review and approve all formularies submitted by Part D sponsors as part of their annual bid packages. We review each formulary, and associated utilization management tools, to ensure that they do not discourage enrollment by beneficiaries with certain types of disease states. We do this by utilizing formulary review checks such as: provision of drugs across different classes and categories per §§ 423.120(b)(2)(i), (ii), and (iv) and 423.272(b)(2); consistency with best practice formularies currently in widespread use; clinical merit per § 423.120(b)(1)(v); and treatment guidelines for disease states in § 423.120(b)(2)(iii). As part of the process, we reach out to Part D sponsors when necessary to provide an opportunity to address any issues identified during our review prior to final approval.

The statute contemplates changes to approved formularies: section 1860D-4(b)(3)(E) of the Act specifies that Part D sponsors may remove a covered Part D drug or change its preferred or tiered cost-sharing status after providing appropriate notice. We understand that the statute does not contemplate a static formulary. Prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, evidence-based clinical guidelines, and opportunities for improving safety and quality in prescription drug use at a lower cost will inevitably occur over the course of the year.

Realizing that implementing new developments may require formulary changes, we support formulary changes that would allow enrollees to quickly benefit from the latest clinical research, new potentially lower-cost options, or possibly result in better health outcomes. For instance, § 423.120(b)(5)(iii) permits Part D sponsors to immediately remove drugs from their

formularies when Food & Drug Administration (FDA) deems them unsafe and drug manufacturers remove them from the market. Similarly, § 423.120(b)(5)(iv) permits a Part D sponsor that adds an equivalent generic drug, and otherwise meets requirements, to immediately remove a brand name drug or change its preferred or tiered cost-sharing status. In addition, 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** (hereinafter referred to as the April 2018 final rule), we reduced the time for advance direct notice of certain formulary changes from 60 to 30 days.

That said, as discussed at section III.M. of this proposed rule, midyear changes to the Part D benefit can violate uniformity and undermine the integrity of bids. And despite the statute's contemplation of changes in the tiered or preferred cost sharing status of a specific drug, which accords with the goal of providing an opportunity for Part D sponsors to respond to new information specific to a particular drug by making changes that could result in better treatment for enrollees, the statute does not contemplate allowing plans to make large scale changes to their formularies after they have undergone the robust approval process described above. Permitting large scale formulary changes midyear could lead to "bait and switch" concerns. During open enrollment, beneficiaries decide whether to enroll (or remain) in particular plans based on the benefit, including drugs offered on the formulary and tier placement, and as represented to them by the Part D sponsor. Formulary stability is extremely important so that enrollees maintain access to the benefit they chose. Moving too often from one drug to a different drug for non-clinical reasons could also pose undue threats to enrollee health. Indeed, the current regulation, § 423.120(b)(6), prohibits Part D sponsors from removing drugs or making changes to preferred

or tiered cost-sharing status between open enrollment up through the first 60 days of the contract year except as specified.[114]

To balance the need for a rigorously vetted, stable formulary against the need to permit formulary changes that respond to developments such as new drug therapies and knowledge, we have, since the start of the program, permitted certain drug-specific changes to approved formularies.

Our process for reviewing and approving changes to approved formularies can be broken out into several categories, each of which is subject to a different level of CMS review and/or approval. Consistent with existing Chapter 6 of the Prescription Drug Benefit Manual (PDBM), we are proposing to codify our process for review and approval of changes to approved formularies.

b. Proposed Provisions for Approval of Formulary Changes

In this rule, we propose to define several types of formulary changes, adopt rules for CMS approval of negative formulary changes, revise requirements for implementation of certain formulary changes that may be made immediately, and update and streamline our notice requirements. As part of this proposal, we are proposing organizational changes to the existing regulations to streamline them and improve their clarity.

(1) Proposed Definitions

In our existing guidance in PDBM Chapter 6, we use the term "negative formulary change" and categorize negative formulary changes as either "maintenance" or "non-maintenance." Our policies with respect to the form of sponsor submission, means of CMS approval, and which individuals are considered to be affected by an approved formulary change differ as between "maintenance" and "non-maintenance" negative formulary changes. We now

[114]Section 423.120(b)(6) exempts § 423.120(b)(5)(iii) and (iv), which permit Part D sponsors to immediately remove drugs deemed unsafe by FDA or withdrawn by their manufacturers or make immediate generic substitutions as specified.

propose to codify our existing policy with respect to negative changes to approved formularies, including when and how notice must be provided to "affected enrollees."

In § 423.100 we propose to define negative formulary changes as the following changes with respect to a Part D drug: (1) removing the drug from a formulary; (2) moving the drug to a higher cost-sharing tier; or (3) adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limits (QL) requirements for the drug. We would note that QL restrictions would not include safety edits described at § 423.153(c)(2) to prevent unsafe or inappropriate dosing of drugs. CMS does not require such edits to be submitted to CMS as part of the formulary. Accordingly, we propose that negative formulary changes do not include safety-based claim edits which are not submitted to CMS. (See section IV.W.2. of this proposed rule on Codifying Current Part D Transition and Continuity of Care Policies for the proposal to define safety-based claim edits.) Negative formulary changes would, however, include adding PA, ST, or QL to apply to a drug for the first time, making existing applicable PA or ST requirements more restrictive, or making QL edits more restrictive by reducing allowances (for instance, reducing a daily dose from two tablets per day to one tablet per day) unless the reduction is a safety edit as described above.

In § 423.100, we propose to update the definition of "affected enrollee" to reference beneficiaries affected by all negative formulary changes instead of just removal or change in preferred or tiered cost-sharing status.

PDBM Chapter 6 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 such as shortages and determining appropriate payment such as coverage under Part B or Part D). 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.

Consistent with our current manual policy and operations, we propose 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 PA, ST, or QL requirements (other than those meeting the requirements of immediate substitutions currently permitted and that we propose to permit below); (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 intend 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.

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 propose 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.

To these two longstanding categories of negative formulary changes, maintenance and non-maintenance, we would introduce in § 423.100 a third category to capture negative formulary changes that fall within certain parameters and that may be made immediately. We propose 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 note, however, that while such changes may be made immediately, Part D sponsors retain the option to implement such changes as maintenance changes. This means, 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 30 days before they occur.

To effectuate our proposal, discussed in section III.Q.2.b.(3). of this proposed rule, to permit certain immediate substitutions in the case of authorized generics, interchangeable biological products, and unbranded biological products, we propose 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 biological product, or an unbranded biological product of a biological product.

Finally, we propose to move 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 that lists State Pharmaceutical Assistant Programs (SPAPs), entities providing other prescription drug coverage, prescribers, network pharmacies, and pharmacists as specified.

(2) Proposed Approval and Implementation of Maintenance and Non-Maintenance Changes

We propose to codify our existing practice with respect to CMS review and approval of negative formulary changes. Specifically, we propose 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 would maintain our existing requirements for immediate implementation of certain formulary changes for immediate substitutions and market withdrawals at § 423.120(e)(2), with some modifications, as discussed in section III.Q.2.b.(3). of this proposed rule.

We propose 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 from CMS within 30 days of submission. We propose 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 propose 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).

As discussed further in section III.Q.2.b.(3). of this proposed rule, we also propose revisions to our current requirement at § 423.120(b)(6), which prohibits Part D sponsors from making certain changes between the beginning of the annual election period until 60 days after the beginning of their contract year to reference negative formulary changes and to appear at § 423.120(e)(4).

(3) Immediate Negative Formulary Changes

Under current regulations at § 423.120(b)(5)(iv), a Part D sponsor meeting certain requirements can add a new equivalent generic drug to its formulary and immediately remove a brand name drug or change its preferred or tiered cost-sharing and then provide retrospective direct notice to affected enrollees. Such generic substitutions are exempt from the transition process under § 423.120(b)(3)(i)(B) and are not subject to the limitation on when formulary changes may take place under § 423.120(b)(6). In addition, under current regulations at § 423.120(b)(5)(iii), Part D sponsors can immediately remove drugs deemed unsafe by FDA or withdrawn from sale by their manufacturers. As a matter of operations, CMS has most recently not required Part D sponsors to submit negative change requests for immediate generic substitutions. (Instances of drugs removed when FDA deems them unsafe or a drug manufacturer withdraws them from sale are infrequent.)

Our current immediate generic substitutions policy has generated the question of whether Part D sponsors can immediately substitute drugs in other circumstances, such as substituting an

authorized generic for its brand name equivalent. A central goal of our formulary policy is to provide flexibility to Part D sponsors to substitute a drug when such substitution poses minimal risk to disrupting an enrollee's drug therapy. For this reason, we are proposing in this rule to broaden the scope of permitted immediate substitutions so that Part D plans can make such substitutions not only in the case of a generic equivalent, but also in the case of authorized generics and for certain biological products. We propose to permit immediate substitution of authorized generics for the brand name product under the same terms that are currently permitted for generic equivalents. By generic equivalents, we mean drugs approved under an Abbreviated New Drug Application (ANDA) in accordance with section 505(j) of the Federal Food, Drug, and Cosmetic Act that are therapeutically equivalent to a brand name drug. Authorized generics, as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act, are marketed under their corresponding brand name drug's New Drug Application (NDA)[115] and are the exact same drug product as their corresponding brand name drugs. We therefore propose to revise the regulation to define an authorized generic drug at § 423.4 and to include the immediate substitution of authorized generics at § 423.120(e)(2)(i).

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. At the time of this writing, there is at least one interchangeable biological product[116] and there is also an unbranded biological product marketed under the same license. Other licensed interchangeable biological products may become available in Part D in the future. Accordingly, we believe it is appropriate to expand our policy to include interchangeable and unbranded biological products when immediate

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[115]See FDA website entitled "FDA List of Authorized Generic Drugs" at: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs#:~:text=The%20term%20%E2%80%9Cauthorized%20generic%E2%80%9D%20drug,product%20as%20the%20branded%20product. Accessed April 26, 2022: "Because an authorized generic drug is marketed under the brand name drug's New Drug Application (NDA), it is not listed in FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book)."

[116]Semglee® (insulin glargine-yfgn).

substitution would not disrupt existing therapy. 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 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 beneficiaries, CMS, or other specified entities, we weighed the need to maintain the continuity of a plan's formulary for beneficiaries who sign up for 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. 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 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."[117] FDA noted on a webpage for consumers that this is similar to how generic drugs are routinely substituted for brand name drugs.[118]

All 50 states now permit or require substitution of interchangeable biological products for prescribed biological products when available, 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.[119] 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

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[117]PHSA § 351(i)(3) (42 U.S.C. 262(i)(3)).

[118]See "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..

[119]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.

provide flexibility that could to lead to better management of the Part D benefit that does not impede State pharmacy practices, we propose at § 423.120(e)(2)(i) to permit Part D sponsors meeting the applicable requirements to immediately substitute a reference biological product on its formulary with the corresponding interchangeable biological product. In support of that proposal, we also propose 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 (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 Public Health Service Act (42 U.S.C.§ 262(i)(3) and 262(k)(4)).[120] 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.

In addition to interchangeable biological products, unbranded biological products have recently become available. In the frequently asked questions of FDA's "Purple Book Database of Licensed Biological Products," available at https://purplebooksearch.fda.gov/faqs#9, FDA describes an "unbranded biologic" or "unbranded biological product" as an approved brand name biological product that is marketed under its approved biologics license application (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 are proposing to permit Part D sponsors to immediately substitute a brand name drug with its authorized generic version, we similarly propose at § 423.120(e)(2)(i) to permit immediate substitution, as specified, of unbranded biological products for corresponding brand name biological products. We would further propose 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

[120]See sections 351(i)(3) and 351(k)(4) of the PHSA (42 U.S.C. 262(i)(3) and 262(k)(4)). For information current as of this writing, see "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

marketed under a brand name. We also propose at § 423.4 to define "unbranded biological products" as biological products marketed under a licensed section 351(a) or 351(k) BLA without a brand name on its label.

We are not proposing to permit Part D sponsors to immediately substitute biosimilar products. 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. Nevertheless, we encourage Part D plan sponsors to offer more biosimilar products on their formularies.

To reflect the fact that this regulation as proposed would then permit immediate switches for more types of drugs than generic drugs, we propose to refer to all of these changes as "immediate substitutions" rather than "immediate generic substitutions," and drugs eligible to be immediately substituted as "corresponding drugs" as defined in § 423.4.

Additionally, through use of the plural tense ("negative formulary changes"), we intend in our proposed description of immediate substitutions in §423.120(e)(2)(i) to make clear that a Part D sponsor that otherwise meets our requirements that adds a corresponding drug and chooses to retain, rather than remove, the drug currently on its formulary may apply more than one negative formulary change to that drug (for instance, add an interchangeable biologic product to the formulary and both move the reference product currently on the formulary to a higher cost-sharing tier and add prior authorization requirements).

Our proposal would exempt negative immediate changes that meet our requirements from the negative change request and approval process discussed earlier in III.Q.2., but would require Part D sponsors to submit such changes in their next required or scheduled CMS formulary updates. We also propose to renumber § 423.120(b)(6) to appear at § 423.120(e)(4). That section currently requires that, other than immediate generic substitutions or instances in which a plan removes a drug deemed unsafe by FDA or withdrawn from sale by a manufacturer, Part D sponsors cannot remove a covered Part D drug from its formulary or make any change in the

preferred or tiered cost-sharing status of a formulary drug between the beginning of the annual election period until 60 days after the beginning of their contract year. We propose to revise this provision to refer to negative formulary changes and exempt all immediate negative formulary changes—be they immediate substitutions or market withdrawals.

As noted earlier, the current regulation exempts Part D sponsors that make immediate generic substitutions from the regulatory requirement to provide transition supplies. The regulations do not specify that such an exemption exists for drugs deemed unsafe by FDA or withdrawn from sale by their manufacturers. We now propose to include market withdrawals as well as all types of immediate substitutions: § 423.120(b)(3)(i)(B) would exempt Part D sponsors making any immediate negative formulary changes from providing transition supplies of such affected drugs.

(4) Relation to Inflation Reduction Act of 2022

Section 11001 of the IRA amended section 1860D–4(b)(3)(I)(i) of Act to require the inclusion on a plan's formulary of selected drugs for which a maximum fair price is in effect with respect to the plan year. Section 1860D-4(b)(3)(I)(ii) of the Act specifies that nothing in clause (i) shall be construed as prohibiting a Part D sponsor from removing such a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation. We propose to identify § 423.120(e)(2)(i) as the successor regulation to §423.120(b)(5)(iv) for purposes of section 1860D-4(b)(3)(I)(ii) of the Act.

3. Notice Requirements

a. Background: Statutes, Regulations, and Guidance on Notice of Changes

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 Part D drug from a formulary or changing the preferred or tiered cost-sharing status of such a drug. We implemented this statute in regulations issued at the start of the program in the January 2005 Part D final rule and updated in the April 2018 final rule. We consider various

forms of advance notice to be appropriate in different situations, and in some cases our current regulations reflect these distinctions, such as in the case of permitted immediate generic substitutions (which we propose earlier to broaden to include other substitutions of corresponding drugs), where advance general notice is appropriate so long as direct notice is provided at a later time.

In this section of the proposed rule, we are proposing various changes to update and streamline the requirements that apply to the provision of notice of formulary changes and to propose revised requirements for appropriate advance notice of such changes. These proposals will bring our regulations into better alignment with our longstanding practice as reflected in PDBM Chapter 6.

b. Alignment of Approval and Notice Policy

We propose a series of changes to our notice requirements, both to reorganize and streamline them, as well as to provide for faster implementation of all formulary changes (other than negative formulary changes), such as moving a drug to a lower cost-sharing tier or making a utilization management tool less restrictive.

First, we propose 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 are also proposing to retain at § 423.120(f)(1) an alternative option for Part D sponsors to provide an affected enrollee who requests a refill 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 propose 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 would require information on the steps that enrollees may take to request coverage determinations and exceptions. Our current model documents already largely provide advance general notice of such changes. Section 423.120(f)(5)(ii) as proposed would further state 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 propose to revise and renumber the existing regulation to specify that, except for negative immediate changes, negative formulary changes require at least 30 days advance notice. Consistent with our proposal for approval of maintenance changes, 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. 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.

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 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 propose to update § 423.128(d)(2)(iii), to require online notice of negative formulary changes. As we observed in our April 2018 final rule (83 FR 1607 and 1608), online postings that are otherwise consistent with our requirements for notice to "other specified entities

(currently described in § 423.120(b)(5) and, as discussed in section II.W.2.b.(1). of this proposed rule, proposed to be defined in § 423.100) may constitute sufficient notice of formulary changes. Consistent with this observation and that § 423.128(d)(2)(ii) requires an online formulary to be updated monthly, our proposed revisions would clarify that the requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

As suggested in PDBM, Chapter 6, § 30.3.4.2, sponsors may elect to provide other specified entities an annual notice providing information on the sponsor's formulary change policy (that is, timing of notice, methods of communication with beneficiaries, and any electronic notices providers may receive at the point-of-sale regarding formulary status) and the sponsor's website where these entities can verify the formulary status of particular drugs.

c. Notice of Negative Immediate Changes

Consistent with our existing requirements for immediate generic substitutions (which we propose above to broaden to include other corresponding drugs), we propose 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 propose at § 423.120(f)(4) to maintain our current requirements for the contents of the direct written notice, but reorganize and renumber them for clarity. We also propose to revise the regulation at § 423.120(f)(4)(iv) to require information on appropriate alternative drugs that treat the same condition in the same or a lower cost-sharing tier in addition to retaining the long standing requirement for information on expected cost-sharing. We are providing more flexibility by removing the requirement that the alternative drugs must be in the same therapeutic category or class: while alternative drugs are likely to be, they might not necessarily be in the same therapeutic category or class based on a plan's classification system. Therefore, we are increasing flexibility with the understanding the Part D sponsor's P&T committee would identify clinically appropriate formulary alternatives at the time the

formulary change is being evaluated.

We further propose that the contents of the written notice would be the same regardless of when the notice must be provided. That is, for notices of maintenance and non-maintenance changes, which must be provided to affected enrollees at least 30 days in advance per § 423.120(f)(1), and for notices of negative immediate changes, which can be provided after the changes take effect per § 423.120(f)(3), the content of the written notice would remain largely the same. Consistent with existing requirements, the notice proposed in § 423.120(f)(4) would contain the name of the affected drug, the type of negative formulary change being made and why, alternatives and expected cost sharing, and for immediate substitutions, how an affected enrollee can obtain a coverage determination or exception.

Lastly, we propose to make conforming amendments to cross citations in §§ 423.104(d)(2)(iv)(A)(*6*) and 423.128(e)(6) as applicable that we have moved the bulk of our discussion on changes to the formulary from § 423.120(b)(5) and (6) to § 423.120(e) and (f).

4. Conclusion

We would like to take this opportunity to note that sections §§ 423.2265(c)(1)(v) and 423.2265(c)(1)(ii) respectively require Part D sponsors each year to provide a Formulary to current enrollees along with an Annual Notice of Change, for which the model language instructs enrollees to review the drug list to confirm continued coverage for their drug. However, while we do not require plans to identify specific formulary changes impacting enrollees for the next contract year, several years of experience have shown that educating beneficiaries about formulary changes helps reduce beneficiary confusion and complaints at the start of the plan year. We encourage plans, particularly those with significant formulary or benefits changes due to PBM transition, plan crosswalks, contract consolidations, or other reasons to engage in beneficiary education and outreach regarding formulary changes.

In the process of proposing the regulatory changes described in this section, we realized that the burden associated with these policies was not accurately captured in PRA package CMS-10141. This package attributed a number of hours for each plan to provide notice to CMS and other entities for removal of drugs from the Part D formulary, however, the package did not properly estimate burden at the level of granularity associated with the complete scope of negative changes, negative change requests, or providing notice to affected enrollees. In section VII.B.6. of this proposed rule, we describe burden associated with our policies related to negative formulary changes as we propose to codify them. We note that while we make this correction to the PRA package, we believe that Part D sponsors have been following the guidance provided in PDBM chapter 6 and annual formulary operations memoranda. CMS monitors negative change request submission and changes to HPMS formularies as a matter of standard operations, and we have received few complaints from beneficiaries stating they have been subject to formulary changes without proper notice. Thus, we believe that Part D sponsors have been complying with the enrollee notice component of current policy. The model notice letter for enrollees affected by negative formulary changes will be included with the associated updates to PRA package CMS-10141. With respect to impact of the current policy to the Medicare Trust Fund, Part D sponsors have been able to make negative changes to their formularies, subject to CMS guidance and oversight, since the start of the Part D program. We therefore assume that there is no net impact to the Medicare Trust Fund as a result of codifying existing policy related to negative formulary changes. We also assume there is no net impact to the Medicare Trust Fund as a result of the proposed policy permitting immediate substitution of new interchangeable biological products; unbranded biological products; and authorized generics since when the initial immediate substitution policy was adopted, there was no net impact expected, as discussed in the April 2018 final rule.

In summary, we propose regulatory changes on how to obtain approval to make changes to a formulary already approved by CMS and to provide notice of such changes. In regards to

approval, we propose to codify, with some revisions, longstanding sub-regulatory guidance and terminology specifying when and how Part D sponsors can obtain approval to make negative formulary changes and the enrollees to whom these changes would apply. Specifically, we propose to codify our existing practice with respect to CMS review and approval of negative formulary changes by proposing in § 423.120(e) that Part D sponsors may not make any negative formulary changes to the CMS-approved formulary except as specified in the regulation. We would codify longstanding policy at proposed § 423.120(e)(3)(i), to permit each Part D sponsor that has submitted a maintenance change request to assume that CMS has approved its negative change request if it does not hear back from CMS within 30 days of submission, and at § 423.120(e)(3)(ii) to specify that that Part D sponsors must not implement any non-maintenance changes until they receive notice of approval from CMS. We also propose 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)(i).

In support thereof, we would define "negative formulary changes" in § 423.100 to Part D drugs to include drug removals, moves to higher cost-sharing tiers, and adding or making more restrictive PA, ST, or QL requirements. We would specify that negative formulary changes can be classified in one of three categories, which we also propose to define in that same section as:

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

- "Immediate negative formulary changes", a newly coined term that would compass all types of immediate substitutions or market withdrawals under § 423.120(e)(2)(i) or (ii) respectively.

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

We propose in respective §§ 423.120(b)(3)(i)(B) and 423.120(e)(4) to conform our regulations to provide that the same transition and timing rules would apply for all immediate negative formulary changes: as proposed all immediate negative formulary changes could take

place at any time (previously this exception only applied to immediate generic substitutions and market withdrawals) and Part D sponsors would not need to provide a transition supply therefor (previously we only specified in regulation that this exception applied to immediate generic substitutions).

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

Miscellaneous proposed changes in § 423.100 in support of the above changes include updating the definition of "affected enrollee" to encompass beneficiaries affected by all negative formulary changes; and moving our current regulatory description of "other specified entities" from § 423.120(b)(5)(1) to be a standalone definition of the term in § 423.100.

In regards to notice, we also propose to move, with some revisions and streamlining, current regulations on notice of changes, and align them to our proposed approval requirements. Specifically, in § 423.120(f)(1) we would specify that only maintenance and non-maintenance negative formulary changes require 30 days' advance notice to CMS, other specified entities, and in written form to affected enrollees. We propose to retain and move to § 423.120(f)(1) an alternative option for Part D sponsors to provide a month's supply with notice at point of sale as specified. We would move and extend our existing requirements for immediate generic substitutions to include substitutions of corresponding drugs and market withdrawals, by proposing to require advance general notice of immediate negative formulary changes at § 423.120(f)(2), followed by written retrospective notice required under § 423.120(f)(3) to affected enrollees. We propose that this retrospective notice be provided to affected enrollees as soon as possible after a specific change, but by no later than the end of the month following any

month in which a change takes effect. We propose at § 423.120(f)(4) to reorganize and renumber our current requirements for the contents of the direct written notice, and provide more flexibility by no longer restricting appropriate alternative drugs to those in the same or a lower cost-sharing tier. Our proposed revision would make clear that the contents of the written notice would be largely the same regardless of the timing: whether Part D sponsors are providing notice before making a particular change (for maintenance and non-maintenance changes under § 423.120(f)(1)) or after (for negative immediate changes under § 423.120(f)(3)). Section 423.120(f)(5) would newly specify how to provide advance general notice and specific notice of changes other than negative formulary changes.

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

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

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

a. Background

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

In the January 2005 Part D final rule (70 FR 4279 through 4283), CMS codified MTM targeting criteria at § 423.153(d)(2), without further detail on the number of chronic diseases, the number of covered Part D drugs, or the annual cost threshold that would be used to identify targeted beneficiaries. In guidance provided during the Medication Therapy Management (MTM) Program User Group Discussions on May 13, 2005 and March 15, 2006, and in the HPMS Memorandum Changes to Part D Sponsors' Medication Therapy Management Program (MTMP) dated August 29, 2006, CMS initially set the annual cost threshold at $4,000 at the start of the Part D program. In the 2010 Call Letter, issued on March 30, 2009, CMS subsequently lowered the threshold to $3,000 for 2010. This approach allowed maximum flexibility for industry to develop best practices for the provision of MTM services. After gaining Part D program experience, in the final rule titled, "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," (75 FR 19772 through 19776), which appeared in the **Federal Register** on April 15, 2010, CMS revised § 423.153(d)(2) by establishing more specific targeting criteria based on an enrollee's number of

chronic diseases (with 2 being the minimum, and 3 being the maximum a sponsor may require), number of covered Part D drugs (with 2 being the minimum, and 8 being the maximum a sponsor may require), and estimated annual Part D drug costs greater than or equal to $3,000 for 2011, which is then increased by the annual percentage increase (API) specified in § 423.104(d)(5)(iv) to determine the annual cost threshold for 2012 and subsequent years. With those changes, CMS sought to promote greater consistency across the Part D program and allow for better evaluation and comparison of MTM programs going forward. With the exception of adding the requirement that Part D sponsors target all ARBs in their DMP for MTM as described previously, the MTM eligibility framework has not been updated since that time.

In the Draft CY 2012 Call Letter (See page 109, available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2012.pdf), we solicited comment on evaluating and addressing disparities in the MTM eligibility criteria. Subsequently, in January 2014, we issued a proposed rule titled, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage Program and the Medicare Prescription Drug Benefit Programs," (79 FR 1918) in which we proposed changes to broaden the targeting criteria to 2 or more chronic diseases (with at least one being a core chronic disease), 2 or more covered Part D drugs, and average annual cost associated with taking 2 generic drugs ($620 at that time). As discussed in the subsequent final rule, which appeared in the **Federal Register** on May 23, 2014 (79 FR 29865 through 29867), those proposals were not finalized, primarily due to the significant number of commenters that strongly opposed the broad expansion of MTM eligibility and concerns about the potential impact on plan administrative costs, beneficiary premiums, and the quality of existing MTM programs.[121] However, we stated that we would continue to evaluate information on MTM

[121]In the proposed rule, we estimated that approximately 55 percent of Part D enrollees would have been eligible for MTM based on the proposed criteria (79 FR 1951).

programs and monitor sponsors' compliance with the MTM requirements, with the goal of proposing revisions to the criteria in future rulemaking that would help to expand the program.

MTM eligibility rates have steadily declined over time. At the start of the Part D program, CMS expected about 25 percent of the Part D population would be eligible for MTM. By 2020, MTM eligible beneficiaries had declined to just 8 percent. In conjunction with the decreasing eligibility rate, CMS has observed near-universal convergence among Part D sponsors to the most restrictive targeting criteria currently permitted under § 423.153(d)(2). When we finalized the current regulatory requirements for targeting criteria over 12 years ago, CMS elected to give plan sponsors significant flexibility in establishing their MTM eligibility criteria. However, most plans now require 3 or more chronic diseases, 8 or more Part D drugs, and target a narrow and variable list of chronic diseases. Because plans may also limit their targeting criteria to certain diseases, drugs, or both, in addition to the low eligibility rates overall, enrollees with equivalent patient profiles (for example, same chronic diseases, same number of chronic diseases, same number of Part D drugs, and similar estimated drug costs) may or may not be eligible for MTM depending on the criteria their plan requires.[122] Under the current methodology at § 423.153(d)(2)(i)(C), the annual MTM cost threshold for 2023 will be $4,935, which also significantly limits the number of beneficiaries who are eligible to be targeted for MTM enrollment.

The high cost threshold and restrictive plan criteria have significantly reduced the MTM program size over time, and Part D enrollees with more complex drug regimens who would benefit most from MTM services are often not eligible. After an extensive review of CMS and plan-reported data, CMS has identified several issues with the current MTM targeting criteria and proposes the regulatory changes discussed in the following sections in an effort to increase MTM eligibility rates, reduce variability of MTM eligibility criteria across plans, and address

[122]Medication Therapy Management in a Chronically Ill Population: Interim Report, available at https://innovation.cms.gov/files/reports/mtm_final_report.pdf.

disparities to ensure that those who would benefit the most from MTM services have access. Taken together, the proposed changes to the MTM program targeting criteria would balance eligibility and program size while allowing us to address specific problems identified in the Part D MTM program, including marked variability and inequitable beneficiary access to MTM services.

b. Multiple Chronic Diseases

The regulation at § 423.153(d)(2)(i)(A) specifies that to be targeted for MTM, beneficiaries must have multiple chronic diseases, with 3 chronic diseases being the maximum number a Part D sponsor may require for targeted enrollment. In the current guidance (See HPMS Memorandum Correction to Contract Year 2022 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 30, 2021), CMS identifies 9 core chronic diseases, some of which are enumerated in the statute, including conditions that are highly prevalent in the Part D population, align with common targeting practices across sponsors, and are commonly treated with Part D drugs, where MTM services could most impact therapeutic clinical outcomes. The 9 core chronic diseases are: Alzheimer's disease; bone disease-arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis); chronic congestive heart failure (CHF)*; diabetes*; dyslipidemia*; end-stage renal disease (ESRD); hypertension*; mental health (such as depression, schizophrenia, bipolar disorder, or other chronic/disabling mental health conditions); and respiratory disease (such as asthma*, chronic obstructive pulmonary disease (COPD), or other chronic lung disorders).[123] While the Act specifically names congestive heart failure (CHF), we are proposing to specify only chronic CHF as a core disease. The Act also names hyperlipidemia, but we are proposing to codify dyslipidemia as a core disease to include both chronically high (hyperlipidemia) and low (hypolipidemia) lipid levels. This list of core chronic diseases aligns with longstanding MTM

[123]*denotes a disease that is enumerated in statute at section 1860D-4(c)(2)(A)(ii)(I)(aa) of the Act.

guidance identifying core chronic diseases and is also consistent with the discretion granted in the statute to identify chronic diseases.

As explained in the CMS guidance, as previously cited, sponsors may target enrollees with any chronic diseases or target beneficiaries with specific chronic diseases. Plans that do not target all chronic diseases should target at least 5 of the 9 core chronic diseases identified by CMS. Sponsors may also offer MTM services to an expanded population of enrollees who do not meet the eligibility criteria for targeted enrollment under § 423.153(d)(2).

Based on our review of 2020 plan-reported MTM program targeting criteria and Part D enrollment data, submitted at the contract level, 86 percent of Part D enrollees were in a plan that targeted the minimum of only 5 of the 9 core chronic diseases. In the same year, only 1 percent of the Part D population was enrolled in a plan that targeted all 9 core chronic diseases, a decrease from 3 percent in 2015. Those plans had an MTM enrollment rate of 15 percent versus the overall enrollment rate across Part D of 8 percent, based on analysis of contract year 2020 MTM plan-reported and validated beneficiary-level data.[124] Combined with CMS administrative claims data, we found that a significant proportion of the Part D population that we identified as having 3 or more core chronic conditions and using 8 or more drugs (approximately 9 million beneficiaries) were not eligible to be targeted for MTM (6 million). We estimate that approximately one-third of the ineligible beneficiaries (about 2 million) were not eligible due to variations in plan-specific targeting criteria (for example, plans targeting fewer than all of the core chronic diseases or targeting specific drug classes as opposed to all or most covered Part D maintenance drugs).

HIV/AIDS is not currently included in the list of core chronic diseases. Our analysis of 2020 data, including PDE data, Parts A and B claims data, validated beneficiary-level MTM data, and other available program data, revealed that Part D enrollees with HIV/AIDS have an average of 4 core chronic diseases (including HIV/AIDS), take 12 Part D covered drugs

[124]Part D reporting requirements (OMB Control No. 0938-0992).

(including 8 maintenance drugs), and incur $40,490 in Part D annual drug spend. Many of these individuals are not eligible for MTM because their plan does not target HIV/AIDS or does not target enough of their other chronic conditions. Individuals with HIV/AIDS often have complex Part D drug regimens where medication adherence is critical, very high Part D drug costs, and multiple comorbidities, and are more likely to be members of populations affected by disparities.[125,126] Although not currently identified as a core chronic disease, HIV/AIDS is more likely to be targeted by plans (about 10 percent of plans in 2021) than any other non-core chronic disease.

Based on our internal analyses and published literature, we propose to amend the regulations at § 423.153(d)(2) by adding a new paragraph (iii) to require all Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). As part of the proposed new provision at § 423.153(d)(2)(iii), we also propose to codify the 9 core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. Under this proposal, sponsors would maintain the flexibility to target beneficiaries with additional chronic diseases that are not identified as core chronic diseases, or to include all chronic diseases in their targeting criteria. Because we developed the existing regulations and guidance early in the Part D program, and without the benefit of substantial program experience, we initially permitted significant plan discretion in developing targeting criteria. We now have data showing that approximately 20 percent of enrollees who meet even the most restrictive criteria permitted (that is, have 3 or more chronic diseases, are taking 8 or more Part D drugs, and are likely to meet the cost threshold) are not eligible because almost all plans also adopt the most restrictive number of core chronic diseases to target (5 core chronic diseases). Accordingly, this proposed change aims

[125]https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnapshot-HIV.pdf https://www.cdc.gov/hiv/group/hiv-idu.html

[126]Kogut SJ. Racial disparities in medication use: imperatives for managed care pharmacy. J Manag Care Spec Pharm. 2020;26(11):1468-1474. doi:10.18553/jmcp.2020.26.11.1468.

to close this gap in access and better ensure that the beneficiaries who are most in need of MTM services are targeted for enrollment. By reducing the variability in targeting criteria across plans, we would eliminate situations where enrollees meet the requirement in § 423.153(d)(2)(i) of having 3 chronic diseases but are not targeted for MTM enrollment because their plan does not target their chronic diseases. This reduced variability would also allow CMS to more accurately estimate program size when calculating burden and assessing impact.

CMS solicits comment on whether we should consider including additional diseases in the core chronic diseases proposed at § 423.153(d)(2)(iii), including cancer to support the goals of the Cancer Moonshot.[127] We seek comment on broadly including cancer as a core chronic condition or alternatively including specific cancers that are likely to be treated with covered Part D drugs such as oral chemotherapies where MTM could be leveraged to improve medication adherence and support careful monitoring. In particular, we are interested in feedback from Part D sponsors, MTM providers, and prescribers, including oncologists, on any potential implications if CMS were to include cancer as a core chronic condition as part of the MTM eligibility criteria. We are also interested in comments on the impact of including any additional core chronic diseases on specialized MTM provider training and on MTM program size. We also solicit comments on whether MTM services furnished under a Part D MTM program are an effective mechanism for management of certain diseases (for example, those with high use of Part B drugs or frequently changing medication regimens) given the statutory goals of the MTM program – specifically, reducing the risk of adverse events, including adverse drug interactions, and ensuring that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use. We will consider the comments received in developing our policies with respect to targeting of core chronic diseases for the final rule.

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[127] https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/

c. Multiple Part D Drugs

Section 1860D-4(c)(2)(A)(ii) of the Act requires that targeted beneficiaries be taking multiple covered Part D drugs. The current regulation at § 423.153(d)(2)(i)(B) specifies that 8 Part D drugs is the maximum number a Part D plan sponsor may require for targeted MTM enrollment. Under current CMS guidance (See HPMS Memorandum CY 2020 Medication Therapy Management Program Guidance and Submission Instructions dated April 5, 2019), sponsors are permitted to include either all Part D drugs, all Part D maintenance drugs, or specific drug classes.

Based on our internal analyses and published literature, we propose to amend the regulations at § 423.153(d)(2) by adding a new paragraph (iii) to require all Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases, as provided under paragraph § 423.153(d)(2)(i)(A). As part of this provision, we also propose to codify the 9 core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. Under this proposal, sponsors would maintain the flexibility to target beneficiaries with additional chronic diseases that are not identified as core chronic diseases, or to include all chronic diseases in their targeting criteria. In 2020, only 13 percent of Part D plans (4 percent of the Part D population) included all covered Part D drugs in their criteria, while 81 percent of plans (87 percent of the Part D population) limited their criteria to chronic/maintenance drugs, and 7 percent of plans (9 percent of the Part D population) limited their criteria to specific drug classes only.

We propose to revise § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require from 8 to 5 for plan years beginning on or after January 1, 2024. Published literature demonstrates increased risk of medication errors and increased MTM effectiveness for individuals taking only a few drugs. While there is no consensus definition of polypharmacy, concurrent and/or prolonged use of 5 or more drugs has been associated with

significant increases in adverse events.[128] Decreasing the maximum number of Part D drugs a sponsor may require from 8 to 5 would serve as a more accurate proxy to help ensure that the MTM program continues to focus on individuals with more complex drug regimens and increased risk of medication therapy problems, reduce potential gaps in eligibility due to utilization disparities, and take into account Part D utilization trends. While we are proposing changes to the targeting criteria with respect to the number of Part D drugs, we note that the CMR described in § 423.153(d)(1)(vii)(B) will continue to include review of all prescription medications, over-the-counter drugs (OTCs), herbal therapies, and dietary supplements.

The statutory requirement specifying that MTM targeted beneficiaries have multiple chronic diseases and take multiple covered Part D drugs suggests that the focus of MTM should be Part D covered drugs for longer term use. Maintenance drugs are drugs that are commonly prescribed to treat a chronic disease, usually administered continuously rather than intermittently, and typically prescribed for a longer course of therapy. Beneficiaries taking maintenance medications for chronic diseases may benefit most over time from the close monitoring provided by MTM required interventions, including comprehensive medication reviews (CMRs) and routine targeted medication review assessments. Accordingly, we propose to add a new provision at § 423.153(d)(2)(iv), which would require all sponsors to include all Part D maintenance drugs in their targeting criteria beginning in 2024. Plans are currently able to include all maintenance drugs in their targeting criteria as an option in the MTM Submission Module in HPMS; however, CMS does not have guidance related to how maintenance drugs are identified for this purpose. To ensure consistency across the MTM program, we also propose that, for the purpose of identifying maintenance drugs, plans would be required to rely on information contained within a widely accepted, commercially or publicly available drug information database commonly used for this purpose, such as Medi-Span or First Databank, but

[128]M.-C. Weng, et al., The impact of number of drugs prescribed on the risk of potentially inappropriate medication among outpatient older adults with chronic diseases, QJM: An International Journal of Medicine, Volume 106, Issue 11, November 2013, Pages 1009–1015, https://doi.org/10.1093/qjmed/hct141.

would have the discretion to determine which one they use. Under this proposal, sponsors would no longer be allowed to target only specific Part D drug classes, but would be required to target all Part D maintenance drugs. However, plans would retain the option to expand their criteria by targeting all Part D drugs. CMS solicits public comment on our proposed parameters for defining maintenance drugs, including potential additional sources for making such determinations.

These proposed changes would reduce variability in MTM eligibility across plans and improve access to MTM services for Medicare Part D beneficiaries at risk of medication therapy problems. Black and Hispanic individuals tend to use fewer prescription drugs and incur lower prescription drug costs than Non-Hispanic White individuals.[129] Consequently, the Part D utilization- and cost-based MTM eligibility criteria, if set too high, may be an access barrier for those populations, as well as other populations with similar utilization patterns. Medically underserved individuals may benefit from MTM services to address potential medication therapy problems, including nonadherence. MTM services may also benefit underserved individuals through identification of un- or under-treated conditions, help with utilization of preventative therapy, or referral to needed health services. Furthermore, using 2020 data, including PDE data, Parts A and B claims data, validated beneficiary-level MTM data, and other available program data to look at the entire Part D population, we found that Part D enrollees overall have an average of 2 core chronic diseases (including the 9 core chronic diseases in the current guidance along with the proposed addition of HIV/AIDS), take 5 Part D maintenance drugs, and incur $3,931 in Part D annual drug spend (median is $617). The subset of Part D enrollees with at least one core chronic disease (including the 9 core chronic diseases in the current guidance along with the proposed addition of HIV/AIDS) have an average of 3 core chronic diseases, take 6 Part D maintenance drugs, and incur $4,595 in Part D annual drug spend (median is $899).

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[129] Wang et al. Potential Health Implications of the MTM Eligibility Criteria in the Affordable Care Act Across Racial and Ethnic Groups. J Manag Care Spec Pharm. 2015 November; 21(11): 993–1003.

d. Annual Cost Threshold

Section 1860D-4(c)(2)(A)(ii) of the Act specifies that targeted beneficiaries for MTM must be likely to incur annual costs for covered Part D drugs that exceed a threshold determined by CMS. The regulation at § 423.153(d)(2)(i)(C) codifies the current cost threshold methodology, which was set at costs for covered Part D drugs greater than or equal to $3,000 for 2011, increased by the annual percentage specified in § 423.104(d)(5)(iv) for each subsequent year beginning in 2012. The annual cost threshold for 2023 will be $4,935. The cost threshold has increased substantially since it was established in regulation, while the availability of lower cost generics and the generic utilization rates have also increased significantly since the Part D program began.[130] Together, these factors have resulted in a cost threshold that is grossly misaligned with CMS' intent and inappropriately reduces MTM eligibility among Part D enrollees who have multiple chronic conditions and are taking multiple Part D drugs. The current cost threshold is more than three times the average annual cost of 8 generic Part D drugs, which is the maximum number of Part D drugs sponsors may require for MTM targeting under the current regulations.

The cost threshold has been identified as a significant barrier to MTM access, and, in the past, interested parties have recommended that it be lowered. CMS has found that the increasing threshold has significantly reduced MTM eligibility rates over the program's lifetime. Using 2020 data, CMS identified approximately 9 million Part D beneficiaries with 3 or more core chronic conditions and using 8 or more Part D drugs, which are the most restrictive criteria CMS currently permits. Based on validated beneficiary-level plan-reported data, about one third (approximately 3 million) of those beneficiaries were eligible for MTM, and the remaining two thirds (approximately 6 million) were not. We estimate that about 65 to 70 percent (approximately 4 million) of the ineligible beneficiaries had Part D drug costs below the MTM

[130] The Part D generic dispensing rate (the total number of generic drug fills divided by the sum of generic and brand drug fills), was approximately 60 percent in 2006 and has increased steadily to a rate of 83 percent in 2019.

cost threshold based on 2020 Part D PDE data, confirming that the cost threshold substantially decreases the MTM program size.

When CMS initially codified the MTM requirements in the January 2005 Part D final rule (70 FR 4282), we noted that cost might not be the best proxy for identifying patients that could benefit most from MTM. Since that time, a robust body of published literature concludes that polypharmacy, often defined as concurrent or prolonged use of multiple drugs, increases the risk of adverse drug events. While there is no consensus definition of polypharmacy, concurrent use of 5 or more drugs is commonly cited in research studies. Although other definitions include considerations of the number of comorbid chronic disease states, drug indications, drug interactions, healthcare setting, and duration of therapy, none of these definitions include drug cost.[131] As plans continue to adopt the most restrictive eligibility criteria CMS permits with respect to the minimum number of chronic diseases and Part D drugs, lowering the cost threshold is especially important to help ensure MTM access for the targeted population contemplated in the statute. Based on published literature, comments from stakeholders, and extensive internal analysis of CMS data, we continue to believe that the cost threshold remains the biggest driver of reduced MTM eligibility rates.

Accordingly, we propose to set the MTM cost threshold for the 2024 plan year and each subsequent plan year at the average annual cost of 5 generic drugs. Based on 2020 PDE data, the annual cost of five generic drugs was approximately $1,004. Under this proposal, for 2024 and subsequent years, CMS would calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using PDE data from the plan year that ended 12 months prior to the applicable plan year, which is the PDE data currently used to determine the specialty-tier cost threshold as specified in the current provision at § 423.104(d)(2)(iv)(C). For 2024, the calculation would use PDE data from 2022 to identify the average daily cost of a generic fill, multiplied by 365 days for an annual amount. The average daily cost for a drug, would be based

[131]Mansoon, N., et al. What is polypharmacy? A systematic review of definitions. BMC Geriatrics (2017) 17:230.

on the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, and would include both plan paid amounts and enrollee cost sharing. As is currently the case, the MTM cost threshold will be published in the annual Part D Bidding Instructions memo.

While the dollar amount would continue to be calculated annually, revising the methodology to base the cost threshold on the average cost of 5 generic drugs would considerably reduce year-to-year variability. Under the current methodology, the threshold amount has increased by an average of $140 each year since it was established in 2011. In contrast, the average annual cost of a generic drug, adjusted for days' supply, decreased slightly between 2012 and 2020. The proposed change to the cost threshold would also greatly reduce the likelihood that enrollees taking primarily lower cost generic alternatives would be excluded from MTM as a result of a prohibitively high cost threshold, aligning with a pillar of the Part D program: encouraging the use of generics/lower cost drugs when medically appropriate.

We propose to amend the regulation at § 423.153(d)(2)(i)(C) to reflect this new MTM cost threshold for plans years starting in 2024 and subsequent years. Specifically, we propose to set the MTM cost threshold at the average cost of 5 generic drugs, as defined at § 423.4. We also propose to codify that CMS will set the MTM cost threshold for a plan year beginning on or after January 1, 2024, by calculating the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C).

e. Summary

The MTM eligibility criteria established in regulation early in the Part D program were identified based on a targeted program size. The changes we are proposing would reframe the criteria and the MTM program to focus on Part D drug utilization and beneficiaries with complex patient profiles and drug regimens, with less emphasis on high drug costs. Under our proposal, cost would continue to play a role in determining which beneficiaries must be targeted for MTM, but would no longer be the main driver of eligibility. The revisions proposed in this section would also better align MTM eligibility criteria with the statutory goals of reducing the risk of

adverse events, including adverse drug interactions, and optimizing therapeutic outcomes for beneficiaries with multiple chronic conditions and who take multiple Part D drugs, while maintaining a reasonable cost criterion.

In summary, we are proposing to:

- Add a new paragraph at § 423.153(d)(2)(iii) to: (1) codify the current 9 core chronic diseases in regulation and add HIV/AIDS as a core chronic disease, for a total of 10 core chronic diseases and (2) require sponsors to include all 10 core chronic diseases in their targeting criteria;
- Revise § 423.153(d)(2)(i)(B) to lower the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs;
- Add a new paragraph at § 423.153(d)(2)(iv) to require sponsors to include all Part D maintenance drugs when determining the number of drugs an enrollee is taking for purposes of MTM eligibility; and
- Revise § 423.153(d)(2)(i)(C) to change the annual cost threshold methodology ($4,935 in 2023) to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020).

We are proposing that these changes would be applicable beginning in plan year 2024. With these proposed changes, we estimate an MTM program size of approximately 23 percent of the Part D population. Burden estimates and impacts are discussed in sections IV.X. and VIII.X. of this proposed rule, respectively.

2. Define "unable to accept an offer to participate" in a comprehensive medication review (CMR)

Section 1860D-4(c) of the Act requires all Part D plan sponsors to have a Medication Therapy Management (MTM) program that is designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. This requirement was codified at § 423.153(d)(1) in the January 2005 Part D final rule (70 FR 4279). CMS subsequently finalized a requirement at § 423.153(d)(1)(vii)(B) specifying that, beginning in

2011, MTM programs must offer each MTM enrollee an annual CMR, including an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care (LTC) setting (75 FR 19772 through 19774). We included this exemption from the requirement to offer a CMR because we recognized that many LTC residents may not be able to participate in the interactive consultation due to cognitive impairment.

For 2013 and subsequent plan years, the Affordable Care Act (ACA) amended the Act by adding section 1860D-4(c)(2)(C)(i), which requires all Part D sponsors to offer all enrollees targeted for MTM an annual CMR. Consistent with the statutory change, CMS revised the regulation at § 423.153(d)(1)(vii)(B) in the April 2012 final rule (77 FR 22072) to remove the exemption for residents of LTC settings beginning in 2013. In the preamble to the final rule, we noted that the ACA provision did not provide a basis for creating an exception to the requirement to offer a CMR based on the setting of care (77 FR 22140 through 22142). However, CMS acknowledged that many LTC residents, as well as individuals in other health care settings (for example, hospice), may suffer cognitive impairments and, therefore, may not be able to participate in the CMR. Accordingly, in the same rule, we finalized a new provision at § 423.153(d)(1)(vii)(B)(2) to permit the CMR provider to perform the CMR with an enrollee's prescriber, caregiver, or other authorized individual if the enrollee is unable to accept the offer to participate.

In guidance issued annually, including our most recent HPMS guidance memorandum titled "Correction to CY 2022 MTM Program Guidance and Submission Instructions" dated April 30, 2021, CMS has consistently stated that we consider a beneficiary to be unable to accept an offer to participate in the CMR only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. In this proposed rule, we propose to codify this definition by amending the current regulation text at § 423.153(d)(1)(vii)(B)(2) to specify that in order for the CMR to be performed with an individual other than the beneficiary, the beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

Consistent with existing CMS guidance, the flexibility to perform the CMR with an individual other than the beneficiary would not apply to situations where the sponsor is unable to reach the beneficiary (such as no response by mail, no response after one or more phone attempts, or lack of phone number or address), if there is no evidence of cognitive impairment, or the beneficiary declines the CMR offer.

Cognitive status may be determined using interviews with the beneficiary or their authorized representative, caregiver, or prescriber. If the MTM provider determines a beneficiary is unable to accept the offer to participate in a CMR, and the MTM provider is unable to identify another individual who is able to participate, a CMR cannot be performed. However, sponsors are still required to provide the other required MTM services detailed in § 423.153(d)(1)(vii). Although claims data or diagnosis codes may be used to gather information about a beneficiary's medical conditions, Part D sponsors must not rely on such administrative information alone to determine whether a beneficiary is cognitively impaired and unable to accept the offer to participate in their own CMR.

We continue to recommend that when a targeted beneficiary moves to a LTC facility, Part D plan sponsors should identify the appropriate contact for each beneficiary. This contact could be the authorized representative, caregiver, or prescriber. Sponsors, or their MTM providers, could contact the admissions coordinator, Minimum Data Set (MDS) coordinator, Director of Nursing, or other appropriate facility staff person to ascertain if an authorized representative has been designated in the beneficiary's medical record or chart. Sponsors are encouraged to develop processes and procedures to contact the facility in the least burdensome manner to request assistance from the facility to identify beneficiaries who are not cognitively impaired and may be able to accept the offer to participate in their CMR, and beneficiaries who have a health care proxy. In the event that the definition of authorized representative differs by State or in settings other than LTC, we defer to State law.

The change we are proposing to the regulatory text reflects longstanding CMS guidance and is also consistent with the discussion of this policy in the preamble to the April 2012 final rule (77 FR 22140). Plan sponsors have complied with this policy for several years as evidenced by CMS data analyses using plan-reported data to identify contract-level outliers regarding CMR completion rates, the CMR recipient, and cognitive impairment status of MTM program enrollees. As such, there is no associated paperwork burden not already accounted for and approved by the Office of Management and Budget under OMB control number 0938-1154 (CMS-10396).

3. Requirement for in-person or synchronous telehealth consultation

Since 2011, the regulation at § 423.153(d)(1)(vii)(B)(*1*)(*i*) has required that CMRs provided under a Part D sponsor's MTM program include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. In the preamble to both the proposed (74 FR 54693) and final rules (75 FR 19773) in which we first adopted this requirement, CMS emphasized that the consultation must be conducted in real-time, either face-to-face or via an alternative real-time method, such as the telephone. We further specified in response to public comments that plans would have the discretion to determine the method used, including emerging technologies, as long as the CMR is conducted in real-time. In MTM guidance issued annually through Call Letters and HPMS memoranda, most recently in the April 30, 2021 HPMS memorandum titled, "Correction to CY 2022 MTM Program Guidance and Submission Instructions," CMS has specified that CMRs should be performed in real-time.

In the 12 years since we finalized the current regulation text, including during the COVID-19 public health emergency, telehealth capabilities have developed considerably and experienced significant growth. In its Best Practice Guide: Telehealth for Direct-To-Consumer Care (https://telehealth.hhs.gov/providers/direct-to-consumer/), HHS refers to synchronous telehealth as an interaction that occurs in live, real-time settings, usually via phone or video. Asynchronous telehealth, also referred to as "store-and-forward," involves communication that is

sent and received at different times (for example, a patient sends photos to their doctor that the doctor reviews later). Advancements in telehealth, such as widespread use of smart phones and secure video interactions, have confounded the concept of "person-to-person" interaction, which CMS – in the context of the current CMR requirements in § 423.153(d)(1)(vii)(B)(1)(i) – intended to refer to an in-person interaction as opposed to a telehealth consultation.

As a result of these developments, CMS has identified a need to update our regulatory text. We propose to amend the existing regulation text at § 423.153(d)(1)(vii)(B)(1)(i) to require that the CMR be performed either in person or via synchronous telehealth to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth. While the consultation must be conducted in real-time, under this proposal, plans would continue to have the discretion to determine whether the CMR can be performed in person or using the telephone, video conferencing, or another real-time method.

The change proposed in this section is consistent with our longstanding policy that the CMR be conducted in real-time as described in the original rulemaking establishing the CMR requirement and codifies existing guidance, issued annually, which plan sponsors have complied with for years. Sponsors are required to submit their MTM program parameters to CMS for review each year, and, in doing so, are required to indicate the type of interactive, person-to-person or telehealth consultation (for example, face-to-face, telephone, telehealth), and to supply a detailed description of the CMR consultation. Because this proposed change codifies existing program guidance with which plans are already compliant, there is no paperwork burden associated with it.

4. MTM Program Technical Changes

We are proposing several technical changes to the regulation text related to the Part D MTM program. At § 423.4, we propose to add a definition for "MTM program" to clarify the meaning of this term as used in Part 423. In the heading for § 423.153(d), we propose to remove

the dash and replace it with a period to be consistent with other paragraph headings in Subpart D. We propose to amend § 423.153(d) by striking "or" from the end of existing paragraph (d)(2)(i)(C)(2) to clarify that, consistent with section 1860D-4(c)(2)(A)(ii) of the Act, plan sponsors must target enrollees described in paragraph (d)(2)(i) and enrollees described in paragraph (d)(2)(ii). Throughout Part 423, Subpart D, we propose to replace "MTMP" with "MTM program" to ensure that the terminology is used consistently.

S. Standards for Electronic Prescribing (§ 423.160)

We propose updates to the standards to be used by Medicare Part D prescription drug plans for electronic prescribing (e-prescribing). This includes: 1) after a transition period, requiring the National Council for Prescription Drug Plans (NDPDP) 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 (including medication history and electronic prior authorization (ePA) transactions) using electronic media for covered Part D drugs for Part D eligible individuals; 2) 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; and 3) revising current regulatory text referring to standards for eligibility transactions.

In this proposed rule, we propose a novel approach to updating e-prescribing standards by cross-referencing Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards adopted for electronic transactions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations. A joint approach to adopting and updating electronic prescribing standards aims to mitigate potential compliance challenges for HHS and the healthcare industry that may result from independent adoption of such standards.

The NCPDP SCRIPT standards are used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans (PDPs). The Medicare Part D statute at section 1860D–4(e) of the Act and regulations at § 423.160(a) require drug plans participating in the prescription benefit to support e-prescribing, as defined at § 423.159(a), and physicians and pharmacies who transmit prescriptions and related communications electronically, to utilize the adopted standards. The proposed updated NCPDP SCRIPT standards have been requested by the industry and provide a number of updates that the industry and CMS support. Accordingly, we propose to update § 423.160 throughout for prescription, medication history, and ePA transactions utilizing the NCPDP SCRIPT standard, as well as to permit an 18-month transition period beginning July 1, 2023 where either NCPDP SCRIPT standard version 2017071 or 2022011 can be used, with exclusive use of NCPDP SCRIPT standard version 2022011 required by January 1, 2025.

The NCPDP RTPB standard enables the exchange of patient eligibility, preferred pharmacy network participation status, product coverage (including any restrictions and alternatives), and associated cost sharing so prescribers have access to this information through a RTBT application that can be utilized at the point-of-prescribing. As discussed in section III.Y.2. of this proposed rule, CMS requires at § 423.160(b)(7) 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. The NCPDP RTPB standard version 12 has since been developed and tested in real-world applications. We propose to require it as the standard for prescriber RTBT applications at § 423.160(b)(7) starting January 1, 2025.

Eligibility transactions utilize the NCPDP Telecommunication or Accredited Standards Committee X12 standard 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. Pursuant to legal authority that we discuss in this rule, we propose to update the Part D regulation at § 423.160(b)(3) by adding a new paragraph (iii) indicating that eligibility transactions must utilize the applicable standard named in the HIPAA regulation at 45 CFR 162.1202, which we propose to be required beginning July 1, 2023 in 42 CFR 423.160(b)(1)(vi). Since the HIPAA regulation 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. However, on November 9, 2022, HHS's 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," (87 FR 67634), which proposes to adopt updated versions of the retail pharmacy standards for electronic transactions at 45 CFR 462.1202, appeared in the **Federal Register**. Thus, our proposal will assure Part D requirements align with the HIPAA requirements should a newer version of the NCPDP Telecommunication (or other) standards be adopted as the HIPAA standard for these types of electronic transactions as a result of the aforementioned proposed rule and any future HHS rules.

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 adoption of transaction standards for the Part D e-prescribing program to

ensure secure ePA request and response transactions between prescribers and Part D plan sponsors for Part D-covered drugs prescribed to Part D-eligible individuals. 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 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 plan sponsors are required to support the Part D e-prescribing program transaction standards. Likewise, as specified at § 423.160(a)(2), providers and pharmacies 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 industry. CMS discussed these processes 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 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 industry standard was available at the time. 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 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 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 at § 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 in order to address stakeholder concerns about misalignment. See section III.T. of this proposed rule for additional discussion of ONC's proposal and authority. Similarly, the preamble of the May 2012 final rule 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. Adoption of NCPDP SCRIPT Standard Version 2022011 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 between 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.

NCPDP requested that CMS adopt the proposed updated NCPDP SCRIPT standard version 2022011 in a letter to CMS dated January 14, 2022.[132] The updated version provides a number of updates that the industry and CMS support. A major enhancement 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 (for which compliance actions will commence on or after January 1, 2025 as specified in § 423.160(a)(5)). Additional major enhancements include general extensibility, redesign of the Product/Drug groupings, Observation elements added to REMS transaction, ProhibitRenewalRequest added to RxChangeResponse and RxRenewalResponse, modified Structured and Codified Sig Structure format, and data element refinements and support related to dental procedure codes, RxBarCode, PatientConditions, patient gender and pronouns, TherapeuticSubstitutionIndicator, and multi-party communications and withdrawal/retracting of a previous sent message using the MessageIndicatorFlag.

Because the functionality offered in NCPDP SCRIPT standard version 2022011 offers important updates and efficiencies to the healthcare industry, we believe it would be an appropriate electronic prescribing standard for the Medicare Part D program. NCPDP SCRIPT standard version 2022011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071. This allows for a less burdensome implementation process and flexible adoption timeline for the industry since backwards compatibility permits a transition period where both versions of the NCPDP SCRIPT standards may be used simultaneously.

In addition to its use for electronic prescriptions, the NCPDP SCRIPT standard is used for medication history (§ 423.160(b)(4)) and ePA transactions (§ 423.160(b)(8)). Thus, we

[132]https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf

propose conforming amendments to require, after a transition period, NCPDP SCRIPT standard version 2022011 as the Part D electronic prescribing standard for the medication history transactions and ePA transactions in § 423.160(b)(4) and § 423.160(b)(8), respectively.

Instead of independently naming the NCPDP SCRIPT standard version 2022011 and incorporating the corresponding implementation guide by reference at § 423.160(c), we propose to amend § 423.160(b) throughout by cross referencing 45 CFR 170.205(b), where ONC proposes to adopt NCPDP SCRIPT standard version 2022011. See section III.T.5. of this proposed rule for additional discussion of this coordination effort. We propose the same approach for the amendments listed at § 423.160(b)(2) for prescription transactions, discussed in this section of this proposed rule, and conforming changes at § 423.160(b)(4) for medication history transactions and at § 423.160(b)(8) for ePA transactions.

The proposed approach would enable CMS and ONC to avoid misalignment from independent adoption of NCPDP SCRIPT standard version 2022011 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.

Since the NCPDP SCRIPT standard version 2022011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071, the industry can accommodate a transition period when either version may be used. We propose changes at §§ 423.160(b)(1)(vi), 423.160(b)(4)(iii), and 423.160(b)(8)(iii), which, taken together with ONC proposals for 45 CFR 170.205(b), would establish a transition period from July 1, 2023 until January 1, 2025, with a compliance deadline of January 1, 2025, when use of NCPDP SCRIPT standard version 2022011 will be mandatory. Given NCPDP SCRIPT standard version 2022011 is backwards compatible with NCPDP SCRIPT standard version 2017071, we are seeking to allow Part D plans to begin updating to NCPDP SCRIPT standard version 2022011 as soon as practicable. While we are proposing July 1, 2023 for the start of the transition period, we will consider

updating the proposed start date for the transition period in the final rule to align with the effective date for the final rule if it falls before July 1, 2023.

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. The transactions for prescriptions that we propose to codify at § 423.160(b)(2)(v)(A)-(Y) are:

- GetMessage;
- Status;
- Error;
- NewRxRequest;
- NewRx;
- RxChangeRequest;
- RxChangeResponse;
- RxRenewalRequest;
- Resupply;
- RxRenewalResponse;
- Verify;
- CancelRx;
- CancelRxResponse;
- RxFill;
- DrugAdministration;
- NewRxResponseDenied;
- RxTransferInitiationRequest (previously named RxTransferRequest in NCPDP SCRIPT standard version 2017071);
- RxTransfer (previously named RxTransferResponse NCPDP SCRIPT standard version 2017071);

- RxTransferConfirm;
- RxFillIndicatorChange;
- Recertification;
- REMSIinitiationRequest;
- REMSIinitiationResponse;
- REMSRequest; and
- REMSResponse.

The transactions for ePA that we propose to codify at § 423.160(b)(8)(iii)(A)-(I) are:

- PAInitiationRequest;
- PAInitiationResponse;
- PARequest;
- PAResponse;
- PAAppealRequest;
- PAAppealResponse;
- PACancelRequest;
- PACancelResponse; and
- PANotification.

The transactions specific to electronic prescribing remain the same as those required for NCPDP SCRIPT standard version 2017071 (§ 423.160(b)(2)(iv)), except where renamed as noted above. The transactions specific to ePA are also the same as those required with NCPDP SCRIPT standard version 2017071, with one additional transaction (PANotification) which was incorporated into the standard after NCPDP SCRIPT standard version 2017071. As discussed in section III.T.6. of this proposed rule, NCPDP SCRIPT standard version 2022011 is proposed for adoption at 45 CFR 170.205(b)(2), and SCRIPT version 2017071 is proposed to expire on January 1, 2025 at 45 CFR 170.205(b)(1). Consequently, use of NCPDP SCRIPT standard version 2022011 for the transactions related to electronic prescribing and ePA (proposed at §§

423.160(b)(2)(v)(A)-(Y) and 423.160(b)(8)(iii)(A)-(I), respectively) will be mandatory by January 1, 2025, if the expiration date for SCRIPT version 2017071 is adopted as proposed. We also note that the RxTransfer-related transactions take place between pharmacies (that is, dispensers) and are not applicable to prescribers. Therefore, we have proposed to acknowledge this in the proposed regulation at § 423.160(b)(2)(v) by adding language that indicates that the business functions supported by the transactions listed for the transmission of prescription-related information may be between prescribers and dispensers (as stated in § 423.160(b)(2)(iv)) or between dispensers.

Mandatory use of the NCPDP SCRIPT standard for the transactions listed means that the specified version of the NCPDP SCRIPT standard must be used to carry out the particular business function supported by the transaction. Mandatory use does not mean that all transactions must be utilized (that is, if the business function supported by the transaction is not needed, then the NCPDP SCRIPT standard transaction would not be utilized). For example, we have been informed that the "GetMessage" transaction is not widely used among prescribers. For this reason, we are reiterating guidance[133] 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) involved in completing or supporting such business functions when and if they are utilized. Our intent is that the applicable NCPDP SCRIPT standard version is used for business functions that the applicable NCPDP SCRIPT standard transactions support, which are named in regulation. We believe the pharmacy industry has implemented the standards in this manner, based on discussions with NCPDP. However, we acknowledge that the transactions currently named in regulation, and as we propose, are specific to the NCPDP SCRIPT standard. Thus, the specific transactions (based on literal interpretation) can only be used in the context of the NCPDP SCRIPT standard as a whole. We propose to add language at §§ 423.160(b)(2)(v)

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

and 423.160(b)(8)(iii) to indicate that these transactions represent the business functions for which the NCPDP SCRIPT standard transactions must be used if such business function is utilized.

In summary, we propose to amend § 423.160 by:

- Revising paragraph § 423.160(b)(1)(v) to reference applicable standards for transactions until June 30, 2023;
- Adding paragraph § 423.160(b)(1)(vi) to identify applicable standards for transactions beginning July 1, 2023;
- Adding paragraph § 423.160(b)(2)(v) to acknowledge the entities to whom certain transactions are applicable, to include distinction that the transactions listed represent business functions for which the NCPDP SCRIPT standard must be used, and to indicate that communication of prescriptions and prescription-related transactions listed at § 423.160(b)(2)(v)(A)-(Y) must comply with 45 CFR 170.205(b). This cross-reference permits a transition period when either NCPDP SCRIPT standard versions 2017071 or 2022011 may be used because, as ONC has proposed at 45 CFR 170.205(b)(1), the NCPDP SCRIPT standard version 2017071 would not expire until January 1, 2025;
- Revising paragraph § 423.160(b)(4)(ii) to indicate exclusive use of NCPDP SCRIPT standard version 2017071 for medication history transactions is required from January 1, 2020 until June 30, 2023;
- Adding paragraph § 423.160(b)(4)(iii) indicating that starting July 1, 2023, medication history transactions must comply with 45 CFR 170.205(b). This cross-reference would permit a transition period when either NCPDP SCRIPT standard versions 2017071 or 2022011 may be used to complete medication history transactions because ONC proposes at 45 CFR 170.205(b)(1) that the NCPDP SCRIPT standard version 2017071 would not expire until January 1, 2025;

- Revising paragraph § 423.160(b)(8)(ii) to indicate exclusive use of NCPDP SCRIPT standard version 2017071 for ePA transactions is required from January 1, 2022 until June 30, 2023; and

- Adding paragraph § 423.160(b)(8)(iii) indicating that starting July 1, 2023, ePA transactions listed at § 423.160(b)(8)(iii)(A)-(I) represent business functions which must comply with 45 CFR 170.205(b). This cross-reference would permit a transition period when either NCPDP SCRIPT standard versions 2017071 or 2022011 may be used for ePA transactions because ONC proposes at 45 CFR 170.205(b)(1) that the NCPDP SCRIPT standard version 2017071 would not expire until January 1, 2025.

We specifically solicit comment on the following aspects of this proposal: (1) requiring NCPDP SCRIPT version 2022011 and retiring NCPDP SCRIPT standard version 2017071, following a transition period; (2) requiring compliance with 45 CFR 170.205(b) to align Part D electronic prescribing requirements with standards adopted by ONC; and (3) whether the proposed date of January 1, 2025 to retire NCPDP SCRIPT standard version 201071 provides a sufficient transition period for industry and other interested stakeholders or if delaying this date to January 1, 2026 or later offers advantages or disadvantages.

4. Adoption of the NCPDP Real-Time Prescription Benefit (RTPB) Standard

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, an electronic real-time benefit tool (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 and clinically appropriate patient-specific real-time formulary and benefit information (including out-of-pocket cost, clinically appropriate formulary alternatives, and utilization management requirements). At that time, there were no industry-wide standards for RTBTs. NCPDP has since developed and tested an RTPB standard for use with RTBT applications. In an August 20, 2021 letter to CMS, NCPDP recommended

adoption of RTPB standard version 12.[134] The NCPDP RTPB standard version 12 enables the real-time exchange of information about patient eligibility, patient-specific formulary and benefit information, and preferred pharmacy network participation status. For a submitted drug product, the RTPB standard will indicate coverage status, coverage restrictions, and patient financial responsibility. The RTPB standard also supports providing information on alternative pharmacies and products.

The NCPDP RTPB standard version 12 standard is designed for prescriber, not beneficiary, RTBT applications; however, CMS is aware that the use of the NCPDP RTPB standard for the prescriber RTBT may facilitate beneficiary RTBTs since the data elements from the NCPDP RTPB standard would also be able to feed into a beneficiary RTBT. CMS is not prohibiting such a practice, but we emphasize that we are not proposing that the proposed standard be required for beneficiary RTBTs. 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).

As discussed in section III.T.6. of this proposed rule, ONC proposes to adopt the NCPDP RTPB standard version 12 at 45 CFR 170.205(c). We therefore propose to add paragraphs § 423.160(b)(1)(vii) and § 423.160(b)(7)(i) to indicate that as of January 1, 2025, Part D sponsors' RTBT must comply with 45 CFR 170.205(c).

We solicit comment on this proposal.

5. Standards for Eligibility Transactions

We propose to revise § 423.160(b)(3) by adding a new paragraph (iii) to indicate that eligibility transactions must comply with 45 CFR 162.1202. Both sections currently name the

[134]https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBandFandBStandardsAdoptionRequest.pdf

NCPDP Telecommunication standard Version D.0 with equivalent batch standard Version 1.2 and the Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 5010 (ASC X12N/005010x279). The eligibility standards adopted at § 423.160(b)(3)(i) and (ii) were adopted 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 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," which appeared in the November 9, 2022 **Federal Register** (87 FR 67634), proposes to update the HIPAA standards used for eligibility transactions. We therefore propose to streamline the Part D regulation by indicate that eligibility transactions must comply with the applicable HIPAA regulations, as opposed to naming standards independently, which would ensure, should the HIPAA standards be updated as a result of HHS rulemaking, 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 so that the industry and CMS would not be at risk of compliance issues.

Thus, we propose to modify § 423.160(b)(3) by adding a new paragraph (iii) to indicate that eligibility transactions should comply with 45 CFR 162.1202. We also propose to replace earlier references to § 423.160(b)(3) in paragraphs § 423.160(b)(1)(i) through (b)(1)(iv) with revised references to § 423.160(b)(3)(i) and (ii), to specify where these historical standards referred to the standards specifically named at § 423.160(b)(3)(i) and (ii). This approach would

avoid ambiguity with respect to historical expectations from prior to April 1, 2009 through the proposed effective date of July 1, 2023, which we propose in § 423.160(b)(1)(vi).

We solicit comment on this proposal.

T. Adoption of Health IT Standards (45 CFR 170.205)

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 is proposing 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.S. of this proposed rule. These proposals reflect a unified approach across the Department to adopt standards for electronic prescribing activities that have previously been adopted separately by CMS and ONC under independent authorities. This new approach is intended to increase alignment across HHS and reduce regulatory burden for stakeholders subject to program requirements that incorporate these standards.

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" (ONC 2015 Edition Final Rule), 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 framework[135] 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.[136] 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.[137]

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. Prescribers of Medicare Part D covered drugs that are prescribed for a Medicare Part D eligible individual must generally adhere to the standards set by the Part D Program for conveying prescriptions using electronic media, while participants in the Promoting Interoperability programs must use technology certified under ONC's Health IT Certification Program to complete measures included in the program, including e-prescribing. Alignment across the standards adopted for these HHS programs is critical to ensure consistent regulatory requirements for Part D plan sponsors, health care providers, and health IT developers who

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[135]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..

[136]HITAC Annual Report CY 2019 published March 2, 2020: https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf.

[137]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.

implement and utilize technology tools for electronic prescribing. In addition to adopting the same standards, ONC and CMS must also align the requirements for use of those standards within their respective programs.

In this section of this proposed rule, we briefly summarize 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.

On January 13, 2010, the Secretary issued an interim final rule "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" (2010 interim final rule) which adopted an initial set of standards, implementation specifications, and certification criteria to meet the requirement specified at section 3004(b)(1) of the PHSA (75 FR 2013). To ensure consistency with standards previously adopted by CMS under the MMA for electronic prescribing, the 2010 interim final rule adopted NCPDP SCRIPT standard version 8.1 by referencing the Part D requirement for use of the standard in § 423.160. The 2010 interim final rule also adopted the Formulary and Benefits standard version 1.0 (75 FR 2031) for the purposes of performing a drug formulary check by referencing the Part D requirement for use of the standard in § 423.160.

On July 28, 2010, ONC's final rule "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" to complete the adoption of an initial set of standards, implementation specifications, and certification criteria, appeared in the **Federal Register** (75 FR 44589). In that final rule, ONC replaced the reference to § 423.160 adopted in the 2010 interim final rule, as previously described, by adopting and incorporating by reference both NCPDP SCRIPT standard version 8.1 and NCPDP SCRIPT standard version 10.6 in 45 CFR 170.205. As stated in the final rule, ONC finalized this policy to align with the adoption and incorporation by reference of NCPDP SCRIPT standard version 10.6 by CMS in the "Medicare Program; Identification of

Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (NCPDP SCRIPT 10.6)" interim final rule, which appeared in the July 1, 2010 **Federal Register** (75 FR 38026).

Most recently, in the "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" final rule (ONC 21st Century Cures Act Final Rule), which was effective June 30, 2020, ONC adopted NCPDP SCRIPT standard version 2017071 in 45 CFR 170.205(b)(1) and incorporated it by reference in 45 CFR 170.299 (85 FR 25678). By adopting this standard, ONC aligned with 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 (2019 Part C/D final rule), which appeared in the April 16, 2018 **Federal Register**, in which CMS adopted and incorporated NCPDP SCRIPT standard version 2017071 in § 423.160(b)(2)(iv) for use beginning in January 2020 (83 FR 16440).

While CMS and ONC have worked closely together to ensure consistent adoption of standards through regulatory actions, as previously described, we recognize that the current practice of different HHS components conducting parallel adoption of the same standards may result in additional regulatory burden and confusion for stakeholders. As a result of different HHS components maintaining and updating separate regulatory provisions in different areas of the Code of Federal Regulations for health IT standards that impact the same stakeholders, impacted stakeholders must monitor changes to standards in multiple regulatory vehicles. In addition, ONC and CMS must identify separate regulatory vehicles and pursue separate rulemaking processes in which to adopt the same standard. Due to other constraints around regulatory cycles in each agency, proposed and final actions to adopt the same standard may occur on different timelines. For instance, due to discrepancies between regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules (respectively, the ONC 21st Century Cures Act final rule and the 2019 Part C/D final rule) led to a period where

ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program.[138] Stakeholders affected by these updates expressed repeated concerns during this period regarding when updates to respective standards would be finalized and how these regulatory contingencies would affect program requirements referencing these standards.

Given past concerns, ONC and CMS are seeking to pursue a new approach to alignment of standards in this proposed rule. Under this approach, HHS would adopt the standards specified (the NCPDP SCRIPT standard version 2022011 and the NCPDP Real-Time Prescription Benefit standard version 12) under the Secretary's authority to adopt health IT standards in the PHSA. If finalized, these proposals would result in the adoption and incorporation by reference to the proposed standards in a single Code of Federal Regulations location at 45 CFR 170.205. Programs across HHS could then cross-reference the adopted standards. As more than one version of the NCPDP SCRIPT standard would be specified in 45 CFR 170.205(b) if our proposal is finalized, we have also identified an expiration date for the current version of the standard to clearly specify when versions of the NCPDP SCRIPT standard in 45 CFR 170.205(b) would be available for use by HHS programs.

We note that these proposals pertain only to the adoption and incorporation by reference of the proposed standards, and when these standards are available for use by HHS. CMS and ONC would continue to set other program requirements independently for programs such as the ONC Health IT Certification Program and the Part D Program, which may require use of these standards. For instance, program requirements may continue to include provisions such as additional amendments or guidance related to use of standards specific to each program. However, we believe that the approach reflected in these proposals for adoption of standards in a single CFR location for HHS use will help to address the concerns around alignment, as

[138]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

previously described. We are requesting comment on this approach to adopting standards in a single location for HHS use.

6. 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) and (c), 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 2022011.
- NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12

a. Electronic Prescribing.

As discussed previously, 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 2022011 includes important enhancements, such as additions 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.[139]

[139]See https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf

We propose to remove NCPDP SCRIPT standard version 10.6 from 45 CFR 170.205(b)(2) and to adopt NCPDP SCRIPT standard version 2022011[140] in 45 CFR 170.205(b)(2). We note that NCPDP SCRIPT standard version 10.6 is no longer required for use in either the Part D Program or the ONC Health IT Certification Program, and we believe it is appropriate to remove this standard from the Code of Federal Regulations. We also propose to incorporate NCPDP SCRIPT standard version 2022011 by reference in 45 CFR 170.299.

Regarding the 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, 2025. If these proposals are finalized, this would mean that both the 2017071 and 2022011 versions of the NCPDP SCRIPT standard would be available for HHS use from the effective date of a final rule until January 1, 2025. This "transition period" is consistent with previous policy in both the ONC Health IT Certification Program and the Part D program with respect to versions of e-prescribing standards which allow for concurrent usage. On and after January 1, 2025, only the 2022011 version of the NCPDP SCRIPT standard would be available for HHS use where a standard in 45 CFR 170.205(b) is required.

We request comment on the appropriateness of this proposed expiration date for NCPDP SCRIPT standard version 2017071, and whether we should consider, as an alternative, finalizing a transition period of an additional year, up to January 1, 2026, or a longer period. We are interested in whether commenters believe an extended transition period, during which use of both standards would be allowed for programs requiring use of a standard in 45 CFR 170.205(b), would be appropriate. We welcome any information commenters can provide about the time needed for stakeholders to implement the updated version of the standard for different uses.

While we are not proposing changes to the "electronic prescribing" certification criterion in the ONC Health IT Certification Program (45 CFR 170.315(b)(3)) in this proposed rule, ONC

[140]See http://www.ncpdp.org/Standards/Standards-Info.

will consider any updates to this criterion in future rulemaking to align with the updated NCPDP SCRIPT standard and with the Part D program, should this proposal be finalized, consistent with past practice.

b. Real Time Prescription Benefit

We propose to adopt the NCPDP Real-Time Prescription Benefit standard version 12 to meet the requirements of Division CC, Title I, Subtitle B, Section 119 of the Consolidated Appropriations Act, 2021 (CAA), Pub. L. 116–260. The CAA required sponsors of Medicare prescription drug plans and Medicare Advantage Organizations to implement a real-time benefit tool that meets technical standards named by the Secretary, in consultation with ONC. The NCPDP Real-Time Prescription Benefit standard version 12[141] 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.

In section III.S. of this proposed rule, CMS is proposing to require Part D plan sponsors to comply with this standard when implementing the real-time benefit tool or tools required in § 423.160(b)(7). 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 12, should our proposal be 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

[141] See http://www.ncpdp.org/Standards/Standards-Info

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.[142] 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 2020[143] and discussed the NCPDP Real-Time Prescription Benefit standard as an important tool for addressing administrative transactions around prescribing.

We are proposing to adopt the NCPDP Real-Time Prescription Benefit standard version 12[144] in 45 CFR 170.205(c)(1) and to incorporate this standard by reference in 45 CFR 170.299. As noted in section III.S.4. of this proposed rule, CMS proposes at § 423.160(b)(7)(i) to require this standard for use by Part D plan sponsors to fulfill the requirements for real-time benefit tools at § 423.160(b)(7). 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 solicit comment on these proposals.

c. 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.[145] 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

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[142]See https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf

[143]See https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf

[144]See http://www.ncpdp.org/Standards/Standards-Info.

[145]See https://www.healthit.gov/isa.

consensus among industry stakeholders 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 2022011 and the NCPDP Real-Time Prescription Benefit standard version 12 are currently identified under the "Pharmacy Interoperability" domain.[146] We encourage interested parties to review the ISA to better understand key applications for the implementation specifications proposed for adoption in this proposed rule.

7. ONC Health IT Certification Program

As previously noted, we are not proposing new or revised certification criteria based on the proposed adoption of standards within this rulemaking. Regarding the Real-Time Prescription Benefit Standard, Section 119 of the CAA does not require ONC to adopt certification criteria for RTBT at the same time as the standard, but instead allows that the criteria be established after the standard has been 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. We believe this will not only support alignment across HHS, but will allow for continued input from interested parties on how this standard should be incorporated into specific certification criteria for certified health IT functionality prior to any such proposals in future rulemaking. 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

[146]See https://www.healthit.gov/isa/section/pharmacyinteroperability

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 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.

U. 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.

- National Council for Prescription Drug Programs (NCPDP), SCRIPT Standard Implementation Guide, Version 2022011, January 2022 (Approval Date for ANSI: December 2, 2021)

URL: http://www.ncpdp.org/Standards/Standards-Info.

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

Summary: NCPDP 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 12, October 2021 (Approval Date for ANSI: September 27, 2021)

URL: http://www.ncpdp.org/Standards/Standards-Info.

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.

V. Limitation on PDP Contracts Held by Subsidiaries of the Same Parent (§ 423.272)

1. Overview and Summary

We are proposing to limit the number of PDP contracts under which a Part D sponsor or its parent organization (as defined in § 423.4), directly or through subsidiaries, can offer individual market PBPs in a PDP region to one contract per region. Individual market PBPs are plans that are marketed to all Medicare beneficiaries in a region, unlike employer group waiver plans, which are only open to retirees whose employers contract with them to provide Part D benefits. This requirement would promote longstanding CMS policy to encourage meaningful competition among and a level playing field for Part D sponsors in the Part D program. The policy to promote meaningful competition has been implemented through our crosswalk policy

(discussed in section IV.AD. of this proposed rule), the limit of three per region on the number of PDP plan benefit packages (PBP) that a sponsor can offer (codified effective January 1, 2022 at current § 423.265(b)(2)), the requirement that PDP PBPs offered by a sponsor be "substantially different" (codified effective January 1, 2011 at § 423.272(b)(3)), and the prohibition on approval of applications that would result in a sponsor or its parent holding more than one PDP contract per region (codified effective July 22, 2014 at § 423.503(a)(3)).

2. Discussion

Since the beginning of the Part D program, CMS has promoted meaningful competition among Part D sponsors and meaningful choice among plans for Part D beneficiaries. CMS has pursued multiple avenues to promote these goals. CMS attempts to ensure that PDP sponsors only offer the number and type of PBPs necessary to provide beneficiaries meaningfully different plan options. Effective January 1, 2022, we codified at § 423.265(b) our longstanding policy limiting the number of PBPs a PDP sponsor may offer to no more than three in a service area. These offerings may not include more than one PBP offering basic prescription drug coverage, as defined at § 423.100, and no more than two enhanced alternative plans, as defined at § 423.104(f)(1). The enhanced plan offerings must be "substantially different" from the basic prescription drug coverage pursuant to § 423.272(b)(3). All three PBPs are usually offered under the same contract, although if a sponsor or its parent holds multiple contracts, the sponsor may only operate three PBPs across all the contracts in the region. CMS allows Part D sponsors, or the parent organizations of Part D sponsors, a two-year transition period to meet these requirements after they have acquired another Part D sponsor pursuant to § 423.272(b)(3)(ii). Finally, under § 423.503(a)(3), CMS does not approve an application to qualify as a PDP sponsor that would result in the applicant's parent organization, directly or through subsidiaries, holding more than one PDP sponsor contract offering individual market plans in a PDP region.

Consistent with these requirements, CMS has traditionally encouraged PDP sponsors and their parent organizations that acquire new PDP contracts by, for example, merging with or

acquiring other PDP sponsors to consolidate their PDP contracts so that they only offer individual market PBPs under one PDP contract per PDP region. Individual market PBPs are plans that are marketed to all Medicare beneficiaries in a region, unlike employer group waiver plans, which are only open to retirees whose employers contract with them to provide Part D benefits. Such contract consolidations are accomplished through contract consolidation crosswalks, described in section IV.AD. of this proposed rule, which allow sponsors to transfer enrollment from a non-renewing PDP to the surviving PDP.

CMS advises that plans take not more than two full benefit years to accomplish a consolidation. CMS uses its negotiation authority under section 1860D-11(d)(2)(B) of the Act, the three-plan limit, and the substantial difference requirement to encourage consolidations. Both the three-plan limit and the substantial difference requirements are applied at the parent organization level – that is, a parent organization with subsidiaries that hold multiple contracts in a PDP region cannot, after the two-year transition period following acquisition, offer more than three PDP PBPs in that region. PDP sponsors usually consolidate their PDPs in response to our encouragement and to accommodate the three-plan limit and substantial difference requirements, but some have delayed consolidation or declined to consolidate altogether. In proposing to require consolidations, CMS intends not only to promote meaningful choice and competition, but to ensure a level playing field for all affected PDP sponsors.

At § 423.272(b), we propose to add a new paragraph (5) to codify limits on the number of PDP contracts held by subsidiaries of the same parent organization in a PDP region. We propose to adopt this requirement pursuant to our authority to add additional contract terms and conditions, not inconsistent with Part C, as necessary and appropriate (see section 1860D-12(b)(3)(D) of the Act). We propose to add a new paragraph (5)(i) to provide that CMS would no longer approve bids that would result in a PDP sponsor or a PDP sponsor's parent organization, directly or through its subsidiaries, offering individual market PBPs under more than one PDP contract in a PDP region. This proposed requirement would not apply to EGWP PBPs. For

instance, if Parent Organization 1 had two subsidiaries, Sponsor 1 and Sponsor 2, that each had a PDP contract in Region 3 for at least the past two years, CMS would not approve the bids from both Sponsor 1 and Sponsor 2 unless one of the contracts was non-renewed or its service area reduced so it no longer served Region 3. This requirement would align bid review and approval criteria with our current prohibition at § 423.503(a)(3) on approving applications that would result in multiple PDPs held by the same sponsor or parent organization in a region.

This proposal promotes meaningful competition among Part D sponsors by preventing sponsors that are controlled and operated by the same parent organization from offering competing PDP contracts in a region. Two subsidiaries of the same parent organizations offering plans in the same PDP region are not truly competitors, as decisions concerning their operations are ultimately controlled by a single entity or parent organization. PDP sponsors under common parent organizations usually share leadership and operational staff, use the same pharmacy benefit manager, and use the same systems and procedures to administer the Part D benefit across different contracts. Because of § 423.503(a)(3), the only way a parent organization could have two PDP sponsor contracts in a region is if they applied for them before we adopted § 423.503(a)(3) in 2014 or if they purchase an existing PDP sponsor. CMS does not believe that it is fair to continue to allow these exceptions to our general policy limiting the number of contracts that a parent organization may operate in a region.

CMS is also concerned that Part D sponsors and parent organizations offering multiple PDPs in a region may do so to segment risk or manipulate Part D Star Ratings. Informal communications with organizations seeking multiple contracts in a region have indicated that some of these organizations wish to segregate low-income beneficiaries into their own contract and/or confine the experience of a low performing plan to a single contract. Allowing organizations to isolate low income, or otherwise high risk or high cost, individuals into a single contract subverts Part D nondiscrimination requirements at section 1860D-11(e)(2)(D)(i) of the Act. Allowing segregation of low performing plans in a different contract from higher

performing plans offered by a subsidiary of the same parent organization also undermines the integrity of CMS's Star Ratings. CMS assigns star ratings at the contract level. Ratings are meant to reflect all aspects of the PDP operations controlled by a contracting entity. This purpose is undermined when a parent organization is allowed to effectively administer two or more PDP contracts in a region in a way that would allow them to inflate their Star Ratings under one of the contracts by confining poor-performing plans to another contract. Such manipulation of the Star Ratings could mislead beneficiaries about the performance of the organization responsible for administering a plan.

CMS recognizes that consolidating contracts held by subsidiaries of the same parent organization can be complex and requires careful planning, particularly if one or more of these contracts was recently acquired through the purchase of or merger with another PDP sponsor. Consistent with CMS's current practice, CMS is therefore proposing at new paragraphs (5)(ii) and (iii) to allow sponsors or parent organizations that acquire new PDP contracts or that operate more than one contract in a PDP region as of January 1, 2024 a transition period of two bid cycles to reduce the number of PDP contracts offering individual market PBPs to one per region. This proposed requirement would not apply to EGWP PBPs, so that subsidiaries of a parent organization could continue to operate multiple PDP contracts in a region so long as all but one of those contracts only operated EGWP PBPs in that region.

Consolidating PDP contracts results in the beneficiaries from one contract being transferred, or "crosswalked," into a PBP in another contract held by a subsidiary of the same parent organization. We are proposing to codify this process at section IV.AD. of this proposed rule. Consolidations can involve substantial disruption to operations and affected enrollees' experience. Particularly where a newly acquired PDP contract is served by a different pharmacy benefit manager, sponsors must plan carefully to update systems and transfer information in a way that minimizes disruptions for beneficiaries. Benefits can also vary significantly between PBPs offered under different PDP contracts immediately following an acquisition. Based on its

experience in the program, CMS has found that a transition period of two bid cycles is sufficient for plans to minimize disruptions by planning for transitions and, where appropriate, gradually adjusting the benefits offered by PBPs under different contracts each year so that benefit structures between two contracts are more closely aligned before beneficiaries are crosswalked to a different contract.

Consistent with current practice when encouraging consolidations and assessing substantial difference under § 423.272(b)(3), CMS would only apply the proposed limit on PDP contracts after the sponsor or its parent has submitted bids under multiple contracts for two contract years. For example, if a parent organization currently operates Contract 1 in a region and acquires Contract 2 in the same region on September 1, 2024, the organization would be permitted to operate multiple contracts for the remainder of 2024 and for 2025, as well as for 2026 and 2027. The parent organization would not have had the opportunity to adjust the 2025 bid in light of the acquisition because it did not acquire the contract until after the 2025 bid deadline. CMS would therefore allow them to submit bids for 2026 and 2027 in 2025 and 2026, respectively, in order to plan for an orderly transition.

CMS acknowledges that a few Part D sponsors and parent organizations have operated multiple PDP contracts offering individual market PBPs in a region for many years. For the reasons already discussed, CMS does not believe that this is consistent with our policy promoting meaningful competition and beneficiary choices. Nor do we believe that allowing parent organizations whose contracts predate the 2014 restriction on approval of applications that would result in multiple PDP contracts to continue to operate multiple contracts in region is fair to other parent organizations. CMS also believes that continuing to allow these sponsors to operate multiple contracts in a region is unfair to organizations that may be required to reduce the number of contracts offered in a region following an acquisition pursuant to the proposed provisions at § 423.272(b)(5)(i) and (ii). CMS therefore proposes to require these parent organizations to reduce the number of PDPs offered in a region to one PDP per parent, per

region, after a transition period of two bid cycles as described previously. For example, if this proposed rule is finalized prior to the 2024 bid submission deadline of June 5, 2023, a parent organization holding two or more PDP contracts at that time (directly or through subsidiaries) would be allowed to submit 2024 and 2025 bids for multiple contracts in 2023 and 2024, but would be required to submit 2026 bids in 2025 that only included one PDP per region.

CMS solicits comments on the length of the transition period proposed at paragraph (b)(5)(iii). In particular, CMS solicits comments on whether the transition periods for new acquisitions and organizations offering multiple PDP contracts on January 1, 2024 should be the different to account for the fact that organizations offering multiple PDP contracts on January 1, 2024 do not face the same transition difficulties as organizations that acquire new PDP contracts.

In summary, we are proposing to:

- Add § 423.272(b)(5) to limit the number of PDP contracts held by subsidiaries of the same parent organization to one PDP contract per region;
- At proposed § 423.272(b)(5)(ii) & (iii), provide a two-year transition period for parent organizations that do not currently meet the requirement or that violate the requirement following a future acquisition to comply with the requirement.

We solicit comment on these proposals.

W. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§ 401.305(a)(2))

Section 6402(a) of the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively known as the Affordable Care Act) established section 1128J(d) of the Act. Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, and to notify the Secretary, State, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(4)(B)

of the Act defines the term "overpayment" as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. Section 1128J(d)(4)(C) of the Act defines, the term "person" for purposes of Medicare Part A and Part B to include providers and suppliers as those terms are defined in the Act. Section 1128J(d)(4)(C) of the Act also defines the term "person" for purposes of Medicare Part C and Part D to include a Medicare Advantage organization ("MAO") (as defined in section 1859(a)(1) of the Act) and a Part D sponsor (as defined in section 1860D-41(a)(13) of the Act).

Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of the False Claims Act, 31 U.S.C. 3729.

Section 1128J(d)(4)(A) of the Act provides that the terms "knowing" and "knowingly" have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). The False Claims Act (31 U.S.C. 3729(b)(1)(A)) defines the terms "knowing" and "knowingly" to include information about which a person "has actual knowledge," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information."

1. Regulations Promulgated Under Section 1128J(d) of the Act

The agency has published two final rules under section 1128J(d) of the Act. On May 23, 2014, CMS published a final rule titled "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (79 FR 29844) (hereinafter referred to as the final "Parts C & D Overpayment Rule"), which provided, among other things, that an MAO or Part D sponsor has identified an overpayment when the MAO or Part D sponsor has determined, or should have determined

through the exercise of reasonable diligence, that the MAO or Part D sponsor has received an overpayment.

On February 12, 2016, we published a final rule titled "Medicare Program; Reporting and Returning of Overpayments, in Medicare Parts A and B" (81 FR 7654) (hereinafter referred to as the final "Parts A & B Overpayment Rule"), which provided, among other things, that a provider or supplier has identified an overpayment when the provider or supplier has determined, or should have determined through the exercise of reasonable diligence, that the provider or supplier has received an overpayment and quantified the amount of the overpayment.

2. Relevant Litigation

In *UnitedHealthcare Insurance Co. v. Azar*, a group of MAOs challenged the final Parts C & D Overpayment Rule, and the District Court held, in relevant part, that by requiring MAOs to use "reasonable diligence" in searching for and identifying overpayments, the final rule impermissibly created False Claims Act liability for mere negligence. *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140). The District Court noted that "(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a-7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly' … a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' " *Id.* at 190. We now propose to amend the final Parts C & D Overpayment Rule at §§ 422.326(c) and 423.360(c), as well as the final Parts A & B Overpayment Rule at § 401.305(a)(2), to remove the reference to "reasonable diligence" and replace it with language at section 1128J(d)(4)(A) that gives the terms "knowing" and "knowingly" the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). *See UnitedHealthcare*, 330 F. Supp. 3d at 191 (finding

that this language would be consistent with a 2000 agency rule, the FCA, and the Affordable Care Act's reference to the FCA).

3. Provisions of Proposed Regulations

a. Medicare Part A and Part B - Amending the Standard for When an Overpayment Is Identified (§ 401.305(a)(2))

This section of the proposed rule would amend § 401.305(a)(2) to change the standard for an "identified overpayment." Consistent with the proposed Medicare Part C and Part D provisions under this Overpayment Rule, we propose to remove the existing standard and adopt, by reference, the False Claims Act definition of "knowing" and "knowingly." Under the proposed rule, a provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

b. Medicare Advantage Program and Part D - Amending the Standard for When an Overpayment Is Identified (§§ 422.326(c) and 423.360(c))

This section of the proposed rule would amend §§ 422.326(c) and 423.360(c) to change the standard for an "identified overpayment" to align with the statutory obligation provided by Congress in section 1128J(d)(4)(A) of the Act, which provides that the terms "knowing" and "knowingly" have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). We propose to remove the existing standard and adopt, by reference, the False Claims Act definition of "knowing" and "knowingly." Under the proposed rule, an MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

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

A. Amending the Definition of Severe or Disabling Chronic Condition; Defining C-SNPs and Plan Types; and Codifying List of Chronic Conditions (§ 422.2)

A specialized MA plan for special needs individuals, generally known as a special needs plan or SNP, is an MA plan specifically designed to provide targeted care and limit enrollment to special needs individuals. CMS defines Specialized MA Plans for Special Needs Individuals at § 422.2 as an MA coordinated care plan (CCP) that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that provides Part D benefits under part 423 to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population. As provided in section 1859(b)(6) of the Act and the definition in § 422.2, a special needs individual could be any one of the following: an institutionalized or institutionalized-equivalent individual; a dual eligible individual; or an individual with a severe or disabling chronic condition and who would benefit from enrollment in a specialized MA plan. Chronic Condition Special Needs Plans (C-SNPs) are SNPs that restrict enrollment to special needs individuals with specific severe or disabling chronic conditions, defined at § 422.2.

The Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123) amended section 1859 of the Act to revise the definition of "severe or disabling chronic condition" for purposes of identifying individuals eligible to enroll in C-SNPs beginning January 1, 2022; add care management requirements for special needs individuals who have a severe or disabling chronic condition; direct the Secretary to convene a panel of clinical advisors to establish and update a list of severe or disabling chronic conditions that meet certain criteria; mandate the inclusion of several current C-SNP chronic conditions onto the list; and direct that the panel take into account

the availability of benefits in the Medicare Advantage Value-Based Insurance Design model. Section 1859(f)(9) of the Act, as added by the BBA, instructs the Secretary to convene the panel of clinical advisors not later than December 31, 2020 and every 5 years thereafter, to establish and update a list of conditions that meet the statutory criteria to be a severe or disabling chronic condition and conditions that meet the statutory criteria for certain other conditions that require prescription drugs, providers, and models of care that are unique to the specific populations covered by MA special needs plans. We are proposing to codify the BBA of 2018's amendment of the definition of severe or disabling chronic condition; define C-SNP; update and codify the recommended list of chronic conditions by a panel of clinical advisors as specified by the BBA; and codify existing subregulatory guidance permitting the inclusion of certain chronic condition combinations for the purposes of offering single standalone C-SNP plan benefit packages (PBPs).

1. Amending the Definition of Severe or Disabling Chronic Condition

Section 231 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended sections 1851(a)(2)(A) and 1859(b) of the Act to authorize the creation of specialized MA plans for special needs individuals, including specialized MA plans that exclusively enroll individuals with severe or disabling chronic conditions. The MMA did not define severe and disabling chronic conditions but noted that the Secretary may determine specific requirements that special needs individuals would need to meet in order to enroll in a chronic condition plan. In the proposed rule titled, "Medicare Program; Establishment of the Medicare Advantage Program" (69 FR 46865), which appeared in the August 3, 2004 issue of the **Federal Register** (hereinafter, the August 2004 MA proposed rule), CMS did not propose a definition of "severe or disabling chronic condition"; however, we asked for comments on whether CMS should set standards for the designation of an individual with severe or disabling chronic conditions and what criteria should be used. In the ensuing final rule titled Medicare Program: Establishment of the Medicare Advantage Program (70 FR 4588), which appeared in

Federal Register on the January 28, 2005 (hereinafter the January 2005 MA final rule), we declined to establish a detailed definition of severe and disabling chronic because of concerns that a definition might limit plan flexibility. The January 2005 MA final rule stated that CMS would review and evaluate proposals for specialized MA plans that serve beneficiaries who may qualify for enrollment in SNPs covering severe or disabling chronic disease categories, and that among the criteria to be considered would be the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against "sicker" members of the target population (70 FR 4596). CMS then developed a process that allowed MA organizations to identify qualifying chronic conditions.

Section 164(e) of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) added a new clause to section 1859(b)(6)(B)(iii) of the Act to clarify the definition of the special needs individuals eligible for C-SNPs. Beginning on January 1, 2010, the third type of special needs individual (in addition to the categories for individuals who were institutionalized or dually eligible for Medicare and Medicaid) was defined as an individual who has one or more co-morbid and medically complex chronic condition(s) that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care. CMS continued to use the term "special needs individual who has a severe or disabling chronic condition" for this group. Based on the MIPPA amendments to the Act, CMS adopted the definition of severe or disabling chronic condition at § 422.2 in the final rule with comment period titled 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 1493, hereafter, the January 2009 final rule (FR)). (The January 2009 FC discussed and finalized a number of provisions related to eligibility for and performance requirements for C-SNPs and SNPs generally.)

Section 164(e) of MIPPA also directed the Secretary to convene a panel of clinical advisors to determine the chronic conditions that meet the definition severe or disabling chronic conditions used in the amendment to the definition at section 1859(b)(6)(B)(iii) of the Act. CMS subsequently convened the panel in October 2008 and implemented the fifteen SNP-specific chronic conditions recommended by the panel that met the definition of severe or disabling and needed specialized care management. The list was later incorporated into Chapter 16b of the Medicare Managed Care Manual (MMCM).

In 2018, the BBA of 2018 amended section 1859(b)(6)(B)(iii) of the Act by adding a new definition of special needs individuals to apply beginning January 1, 2022. Under the new definition of special needs individual, an eligible individual must, on or after January 1, 2022, "have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed under [section 1859(f)(9)(A) of the Act]." Subsection (f)(9)(A) directs the Secretary to convene a panel of clinical advisors every 5 years to review and revise a list of chronic conditions that meet two sets of criteria:

- The amended definition of a severe or disabling chronic condition in subsection (b)(6)(B)(iii); and
- Conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a specialized MA plan for special needs individuals and either (1) as a result of enrollment in a C-SNP, the enrollee with the condition would have a reasonable expectation of meeting a certain standard regarding health status, outcomes and costs compared to other coverage options, or (2) the condition has a low prevalence in the general population of Medicare beneficiaries or a disproportionally high per-beneficiary cost.

We are proposing now to amend the definition of severe or disabling chronic condition at § 422.2 to match the definition at section 1859(b)(6)(B)(iii)(II) of the Act and to include the specific conditions identified by the panel convened under section 1859(f)(9)(A) of the Act.

Currently, CMS provides guidance on severe or disabling chronic conditions that meet the current regulatory definition of the term in Chapter 16b of the Medicare Managed Care Manual (MMCM), which includes a list of SNP-specific chronic conditions in section 20.1.2. That list of conditions was drawn from a panel of clinical advisors established under section 164(e)(2) of the MIPPA of 2008. Starting in 2010, CMS adopted subregulatory guidance whereby a C-SNP could only offer a plan benefit package (PBP) that covered one of the fifteen SNP-specific chronic conditions identified in the guidance. Several of the chronic condition categories include a list of sub conditions that provide further information regarding the types of diseases that qualify under the chronic condition categories. Examples of such conditions include autoimmune disorders, cardiovascular disorders, severe hematologic disorders, chronic lung disorders, chronic disabling mental health conditions, and chronic disabling neurologic disorders. A C-SNP that targets several sub-categorical disorders must enroll an eligible beneficiary who has one or more of these sub-categorical disorders; the C-SNP is not permitted to exclude an eligible beneficiary having the covered condition or a covered sub-categorical condition. For example, a C-SNP that enrolls special needs individuals with a chronic and disabling mental health condition must enroll special needs individuals with one or more of the following sub-categorical conditions: bipolar disorders, major depressive disorder, paranoid disorder, schizophrenia, or schizoaffective disorder. Currently, C-SNPs may only cover one of the fifteen qualifying chronic conditions in a single PBP, unless the C-SNP receives approval from CMS to focus on a group of severe or disabling chronic conditions. Generally, CMS believes that structuring a C-SNP to target multiple commonly co-morbid conditions that are not clinically linked in their treatment would result in a general market product rather than an MA plan that is sufficiently tailored for special needs individuals. Therefore, CMS will approve

targeting of multiple severe or disabling chronic conditions by a C-SNP only for: (1) one of the CMS-developed group of commonly co-morbid and clinically linked conditions listed in section 20.1.3.1 of Chapter 16b where the special needs individuals may have one or more of the conditions in the grouping or (2) a MAO-customized group of multiple co-morbid and clinically linked conditions where the special needs individuals served by the C-SNP have all of the specified conditions.

In meeting its obligation under section 1859(f)(9)(A) of the Act to convene a panel of clinical advisors not later than December 31, 2020, to establish the list of conditions that meet the statutory criteria, CMS was committed to engaging the public—industry, advocates, beneficiaries, and medical professional societies—in the discussion about appropriate SNP-specific chronic conditions. Panel members were tasked with assessing the statutory criteria for reviewing the appropriateness of potential conditions as required by section 1859(f)(9)(A) of the Act. The criteria are:

- The condition meets the definition of a severe or disabling chronic condition under section 1859(b)(6)(B)(iii)(II) of the Act on or after January 1, 2022; and
- Conditions that require prescription drugs, providers, and models of care that are unique to the special needs individuals with several or disabling chronic conditions as defined in subsection (b)(6)(B)(iii)(II) of section 1859 of the Act as of that date and:

++ As a result of access to, and enrollment in, such a specialized MA plan for special needs individuals, individuals with such condition would have a reasonable expectation of slowing or halting the progression of the disease, improving health outcomes and decreasing overall costs for individuals diagnosed with such condition compared to available options of care other than through such a specialized MA plan for special needs individuals; or

++ Have a low prevalence in the general population of beneficiaries under this title or a disproportionally high per-beneficiary cost under title XVIII of the Act.

In addition, sections 1859(f)(9)(B) and (C) of the Act require that:

- The list of severe or disabling chronic conditions used for C-SNPs include: HIV/AIDS, end stage renal disease (ESRD), and chronic and disabling mental illness.

- The panel consider the availability of varied benefits, cost-sharing, and supplemental benefits under the Medicare Advantage Value-Based Insurance Design (VBID) model being tested by the Center for Medicare and Medicaid Innovation (CMMI).

On August 8, 2019, CMS announced a Request for Information (RFI) related to the review of C-SNP specific chronic conditions as mandated by the BBA of 2018 to solicit comments from the public to assist the panel of advisors convened by CMS under section 1859(f)(9)(A) of the Act.[147] The 2019 SNP Chronic Condition Panel met for three sessions between September 9 and September 23, 2019. CMS provided panelists with a summary of comments received in response to the RFI. The panelists reviewed and discussed the written public comments from 14 stakeholders representing the industry, advocacy groups, medical societies, and beneficiaries. The panelists also examined the chronic conditions already covered by existing C-SNPs. They employed their collective national and international experience with chronic condition research and clinical practice to weigh inclusion of chronic conditions on the list. As in 2008, the panelists also considered the condition's prevalence in the Medicare population, a factor that would potentially affect the capacity of an MA organization to attract eligible enrollees and be viable in a given service area as well as being identified in section 1959(f)(9)(A)(ii)(II) of the Act as a criterion to be considered. The panelists were sensitive to the reality that C-SNPs require sufficient disease prevalence and access to a specialized provider network within a marketable service area to manage risk under a capitated payment system (even with risk-adjustment of those capitated payments), and effectively and efficiently serve the targeted special needs beneficiaries. The panelists also reflected on the need for beneficiaries, health care practitioners, and the health care industry to recognize the SNP-specific chronic

[147]The full RFI can be found here: https://www.cms.gov/Medicare/Health-Plans/SpecialNeedsPlans/Downloads/RFI-Chronic-Condition-SNP-Panel.pdf.

conditions and consider them appropriate for a specialized service delivery system in order to stimulate participation. While the Panel did consider a condition's prevalence in the Medicare population as required by section 1859(f)(9)(A) of the Act, it was not charged with and did not make any additional judgments based on business considerations (that is, the potential profitability of the selected chronic conditions) as CMS expects interested MA organizations to reach their own conclusions about product offerings and markets in which they wish to operate.

Upon review and deliberation, the Panel identified 22 chronic conditions as meeting the statutory criteria. The conditions identified are:

1. Chronic alcohol use disorder and other substance use disorders;
2. Autoimmune disorders:
    - Polyarteritis nodosa,
    - Polymyalgia rheumatica,
    - Polymyositis,
    - Dermatomyositis
    - Rheumatoid arthritis,
    - Systemic lupus erythematosus,
    - Psoriatic arthritis, and
    - Scleroderma;
3. Cancer;
4. Cardiovascular disorders:
    - Cardiac arrhythmias,
    - Coronary artery disease,
    - Peripheral vascular disease, and
    - Valvular heart disease;
5. Chronic heart failure;
6. Dementia;

7. Diabetes mellitus;
8. Overweight, Obesity, and Metabolic Syndrome;
9. Chronic gastrointestinal disease:
    - Chronic liver disease,
    - Non-alcoholic fatty liver disease (NAFLD),
    - Hepatitis B,
    - Hepatitis C,
    - Pancreatitis,
    - Irritable bowel syndrome, and
    - Inflammatory bowel disease;
10. Chronic kidney disease (CKD):
    - CKD requiring dialysis/End-stage renal disease (ESRD), and
    - CKD not requiring dialysis;
11. Severe hematologic disorders:
    - Aplastic anemia,
    - Hemophilia,
    - Immune thrombocytopenic purpura,
    - Myelodysplastic syndrome,
    - Sickle-cell disease (excluding sickle-cell trait), and
    - Chronic venous thromboembolic disorder;
12. HIV/AIDS;
13. Chronic lung disorders:
    - Asthma,
    - Chronic bronchitis,
    - Cystic Fibrosis,
    - Emphysema,

- Pulmonary fibrosis,
- Pulmonary hypertension, and
- Chronic Obstructive Pulmonary Disease (COPD);

14. Chronic and disabling mental health conditions:
    - Bipolar disorders,
    - Major depressive disorders,
    - Paranoid disorder,
    - Schizophrenia,
    - Schizoaffective disorder,
    - Post-traumatic stress disorder (PTSD),
    - Eating Disorders, and
    - Anxiety disorders;
15. Neurologic disorders:
    - Amyotrophic lateral sclerosis (ALS),
    - Epilepsy,
    - Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia),
    - Huntington's disease,
    - Multiple sclerosis,
    - Parkinson's disease,
    - Polyneuropathy,
    - Fibromyalgia,
    - Chronic fatigue syndrome,
    - Spinal cord injuries,
    - Spinal stenosis, and
    - Stroke-related neurologic deficit;
16. Stroke;

17. Post-organ transplantation care;

18. Immunodeficiency and Immunosuppressive disorders;

19. Conditions that may cause cognitive impairment:

- Alzheimer's disease,
- Intellectual and developmental disabilities,
- Traumatic brain injuries,
- Disabling mental illness associated with cognitive impairment, and
- Mild cognitive impairment;

20. Conditions that may cause similar functional challenges and require similar services:

- Spinal cord injuries,
- Paralysis,
- Limb loss,
- Stroke, and
- Arthritis;

21. Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell;

22. Conditions that require continued therapy services in order for individuals to maintain or retain functioning.

The Panel recommended a number of changes to the list of chronic conditions that are currently used by CMS to approve C-SNPs. In this proposed rule, we are proposing to codify the list of chronic conditions created by the panel as part of the definition of severe and disabling chronic condition at § 422.2. This proposal takes into account the changes recommended by the panel, as discussed in this section of this proposed rule. These changes include:

- Removed the term "limited." The panel chose this revision so that unlisted chronic conditions will not disqualify the enrollee from plan eligibility even if the unlisted or another listed condition is not the targeted condition that qualifies the beneficiary for a specific C-SNP. In other words, the beneficiary could have other conditions beyond the index condition (which is

required to be present) and still be permitted to enroll in a specific C-SNP. For example, a beneficiary with heart failure could also have psoriasis or epilepsy and not be excluded from the Chronic Heart Failure C-SNP. Because our proposal does not exclude a beneficiary from being a special needs individual or eligibility for an applicable C-SNP if the beneficiary has conditions in addition to a severe or disabling chronic condition, we are not proposing to use the word "including" in the proposed definition; our proposal is to codify the list of specific conditions (and subconditions) that have been identified as meeting the statutory criteria and avoid ambiguity regarding related but unlisted conditions;

- Renamed "Chronic alcohol and other drug dependence" to "Chronic alcohol use disorder and other substance use disorders;"
- Added dermatomyositis, psoriatic arthritis, and scleroderma to the Autoimmune disorders chronic condition category;
- The panel recommended changing title of "Cancer, excluding pre-cancer conditions or in-situ status" to "Cancer; "however; they did not recommend altering the current limitations to the chronic condition category, only a clerical change to the title;
- Added valvular heart disease to the Cardiovascular disorders chronic condition category;
- Added new chronic condition category, "Overweight, Obesity, and Metabolic Syndrome;"
- Added new chronic condition category, "Chronic gastrointestinal disease" with the following conditions: chronic liver disease, non-alcoholic fatty liver disease (NAFLD), hepatitis B, hepatitis C, pancreatitis, irritable bowel syndrome, and inflammatory bowel disease;
- Renamed the "End Stage Renal Disease (ESRD) requiring dialysis" condition category to "Chronic kidney disease (CKD)" with the following conditions: CKD requiring dialysis/end-stage renal disease (ESRD), and CKD not requiring dialysis;

- Added Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD) to the Chronic lung disorders chronic condition category;
- Added post-traumatic stress disorder (PTSD), eating disorders, and anxiety disorders to the Chronic and disabling mental health conditions category;
- Added fibromyalgia, chronic fatigue syndrome, and spinal cord injuries to the Neurologic disorders conditions category;
- Added post-organ transplantation care and immunodeficiency and immunosuppressive disorders as new chronic condition categories;
- Created new chronic condition category "Conditions that may cause cognitive impairment," including the following sub-conditions: Alzheimer's disease, intellectual disabilities, developmental disabilities, traumatic brain injuries, disabling mental illness associated with cognitive impairment, and mild cognitive impairment;
- Created new chronic condition category "Conditions that may cause similar functional challenges and require similar services," including the following sub-conditions: spinal cord injuries, paralysis, limb loss, stroke, arthritis, and chronic conditions that impair vision, hearing (deafness), taste, touch, and smell; and
- Created new chronic condition category "Conditions that require continued therapy services in order for individuals to maintain or retain functioning."

As previously demonstrated in the last three bullets, the panel recommended the creation of several new chronic condition categories that differ from how the current list of severe or disabling chronic conditions uses categories as a single condition or set of related diseases. By including these new categories, we are proposing that C-SNPs will be permitted to create benefit packages and care coordination services to address the needs of beneficiaries who share the same functional needs even if their specific disease or chronic condition may differ. For example, using the condition categories "Conditions associated with cognitive impairment;" "Conditions associated with similar functional challenges and require similar services;" "Chronic conditions

that impair vision, hearing (deafness), taste, touch, and smell;" and "Conditions that require continued therapy services in order for individuals to maintain or retain functioning;" MA organizations would have the opportunity to propose C-SNPs that seek to ameliorate specific disease outcomes such as impaired vision without having to target one specific chronic condition. In another example, MA organizations would be permitted to create specific care coordination services and benefit packages to address the functional challenges facing beneficiaries with spinal cord injuries and those suffering paralysis from stroke. The challenge for SNPs would be to address the needs not of enrollees who share the same disease or chronic condition, but those diagnosed with different diseases and chronic conditions that share similar impacts on health and functionality. The proposed categories in this paragraph will apply the same statutory and regulatory considerations per the parameters of a severe and disabling chronic condition and as noted in Title XVIII of the Act and part 422. That is, by proposing to list these three categories that are focused on impacts on health and functionality rather than underlying disease or condition, we are not proposing to eliminate the need for the effect on the enrollee to meet the statutory criteria in section 1859(f)(9) of the Act. We believe this new approach to creating a C-SNP is in line with types of services and benefits required of current C-SNPs in operation, and beneficiaries facing similar challenges would benefit from coordination of care among multiple providers for services found in a variety of settings appropriate for the enrollee's health challenges.

Under our proposal, this new definition of severe or disabling chronic condition will be applicable for plan years that begin on or after January 1, 2025. We believe the additional delay will allow plans and CMS to put in the place the necessary operational steps to permit transition between the current list of chronic conditions and the list in this proposal. If adopted in the final rule, several current chronic conditions would transition to new chronic condition categories, such as End Stage Renal Disease (ESRD) and End Stage Liver Disease. As of June 2022, there are 17 ESRD plans with a total enrollment of 4,529 members. There are no C-SNPs that restrict

enrollment to End Stage Liver Disease for CY 2022. However, if our proposal is finalized, MA organizations seeking to establish a plan covering End Stage Liver Disease would be able to do so under the proposed new category of Chronic Gastrointestinal Disease. Although this proposal would make changes to the list of conditions used by MA organizations to determine C-SNP plan offerings, we believe the impact of those changes will be minimal. In addition, we are proposing the delay implementing the new chronic condition list in order to give CMS time to collect data and information related to the structuring of the proposed CKD C-SNP plan bids. Per section 1853(a)(1)(H) of the Act, the capitation rates paid to MA plans for enrollees with ESRD are set separately from the capitation rates and bidding benchmarks applicable for other enrollees, which may complicate the transition to using this specific severe or disabling chronic condition category. Current ESRD C-SNPs plan bids are based on a distinct bidding methodology. CMS will provide additional bid pricing information to MAOs if this proposal is finalized. We solicit comment on the proposed updates to this definition. Specifically, we are soliciting comment on our proposal to limit the regulatory definition of severe or disabling chronic condition to the list the conditions on the list established by the panel. Also, we are seeking comment on the proposed list of chronic conditions recommended by the 2019 panel of clinical advisors. We would like to call particular attention to proposed condition numbers 19 through 22. Under these proposed conditions, the C-SNP would focus on specific and clinically appropriate therapeutic approaches that address multiple chronic disease types causing similar health outcomes and functional limitations. We are seeking feedback on the potential clinical accomplishments that may be addressed through this type of plan design. We are also seeking comment on challenges that might exist both from a clinical and business standpoint. For example, we would be interested to know whether and the extent to which MA organizations require further guidance from CMS to identify chronic conditions or diseases that would fit into condition numbers 19 through 22.

2. Chronic Condition Special Needs Plan Definition, Scope and Eligibility (§§ 422.2, 422.4, and 422.52)

A C-SNP must have specific attributes and meet certain standards that go beyond the provision of basic benefits (as defined in § 422.100(c)) and care coordination that is required of all coordinated care plans; such additional standards include the enrollment limitations and care management requirements set forth in section 1859(f) of the Act and codified in the regulations at §§ 422.52(a) and (b), 422.101(f), and § 422.152(g). While C-SNPs must generally meet requirements that are specified to all SNPs, we believe it is important to codify a definition of C-SNP that reflects how they are limited to serving special needs individuals who have a severe or disabling chronic condition, as defined in § 422.2 (and which we are also proposing to revise). Adopting a definition of C-SNP in § 422.2 would be consistent with how we have previously adopted definitions for the term dual eligible special needs plan (D-SNP) and specific types of D-SNPs. We believe adopting a specific definition will help to clarify how C-SNP specific requirements and policies are distinguishable from requirements and policies for D-SNPs and I-SNPs as well as different from general MA coordinated care plans. Since the intent of the proposed definition is to provide clarification for MA organizations and providers regarding the meaning and scope of C-SNPs, we believe this codification will have little to no impact on MA enrollees nor accrue operational or other costs to MA organizations. Our proposal generally reflects current policy and practice, with a few modifications as discussed where applicable.

As part of current C-SNP subregulatory guidance and during the MA plan application process, MAOs may apply to offer a C-SNP that targets any one of the following:

- A single CMS-approved chronic condition (selected from the list in section 20.1.2 of Chapter 16b);
- A CMS-approved group of commonly co-morbid and clinically-linked conditions (described in section 20.1.3.1 of Chapter 16b); or

- An MA organization-customized group of multiple chronic conditions (described in section 20.1.3.2 of Chapter 16b).

CMS recognizes that there is value for C-SNPs to use groupings of severe or disabling chronic conditions in identifying their focus and limiting enrollment, and our proposals reflect how the MA organizations that offer C-SNPs must choose a single chronic condition from the definition of severe or disabling chronic condition or choose from a list of permitted multiple chronic conditions found in in the new subparagraphs (A) and (B) under § 422.4(a)(1)(iv).

First, we are proposing, as part of the definition of C-SNP at § 422.2 and in the description of special needs plans at § 422.4(a)(1)(iv), to codify current guidance regarding the ability of MA organizations to offer a C-SNP that focuses on single or multiple chronic conditions. The proposed definition of chronic condition special needs plan (C-SNP) provides that C-SNPs are SNPs that restrict enrollment to MA special needs eligible individuals who have a severe or disabling chronic condition as defined in § 422.2 under this section. In other words, the chronic conditions on which a C-SNP may focus are limited to those conditions listed in the definition of severe or disabling chronic condition. When a C-SNP focuses on one chronic condition, enrollees must have that severe or disabling chronic condition in order to enroll in the C-SNP. In addition to single chronic condition category PBPs, CMS currently permits MA organizations to apply to offer a C-SNP that includes specific combinations of CMS-approved group of commonly co-morbid and clinically linked conditions, as described in section 20.1.3.1 of Chapter 16b of the MMCM. We are proposing to codify how a C-SNP may focus on multiple chronic conditions in two ways. The proposed definition of C-SNP provides that the restricted enrollment to individuals with severe or disabling chronic conditions includes restricting enrollment based on the multiple commonly co-morbid and clinically-liked conditions groupings specified in § 422.4(a)(1)(iv) of this chapter.

Currently, CMS has identified five combinations of commonly co-existing chronic conditions that may be the focus of a C-SNP based on our data analysis and recognized national guidelines. The current set of combinations include:

- Diabetes mellitus and chronic heart failure;
- Chronic heart failure and cardiovascular disorders;
- Diabetes mellitus and cardiovascular disorders;
- Diabetes mellitus, chronic heart failure, and cardiovascular disorders; and
- Stroke and cardiovascular disorders.

As of March 2022, MA organizations offered 178 C-SNPs covering more than one chronic condition. A majority of these plans (151) represent a grouping of just three commonly co-morbid and clinically-linked conditions: cardiovascular disease, congestive heart failure (CHF), and diabetes mellitus. Another 21 plans represented a combination of cardiovascular disease and CHF. C-SNPs have tended to focus on combinations of these three specific conditions since this policy was implemented. Considering the established clinical connection between these conditions and the interest among plans and beneficiaries, we propose to maintain the current list. We are proposing to codify this current list of combinations of chronic conditions that may be used by a C-SNP at § 422.4(a)(1)(iv)(A)(*1*) through (*5*).

A C-SNP may not be structured around multiple commonly co-morbid conditions that are not clinically linked in their treatment because such an arrangement results in a general market product rather than one that is tailored for a particular population. As part of its review, the 2019 clinical advisor panel convened in accordance with section 1859(f)(9)(A) of the Act recommended the continuation of the current Chapter 16b linked conditions plus three additional groups. The panel considered a number of relevant factors, including all statutory criteria required under the Act, when determining the appropriateness of additional pairings, including clinical considerations and the potential of these conditions to be successfully managed by a

specialized provider network. The panel recommended the following additional groupings conditions were as follows:

- Anxiety associated with COPD.
- CKD and post-renal organ transplantation.
- Substance Use Disorder (SUD) and Chronic and disabling mental health conditions.

In addition to our proposal to codify the current approved set of commonly co-morbid and clinically-linked conditions, we propose to add the three recommended pairings as permissible groupings of severe or disabling chronic conditions that may be used by C-SNPs at new § 422.4(a)(1)(iv)(B)(*6*) through (*8*). Under this proposal, a C-SNP may focus on one of the commonly co-morbid and clinically-linked conditions specified in these eight specific combinations of co-morbid condition groupings upon CMS approval. We are also proposing to add a new paragraph (a)(1)(iv)(A) at § 422.4 to clarify that enrollees need only have one of the qualifying conditions for enrollment listed in the approved groupings in proposed paragraph (a)(1)(iv)(B). This is consistent with current CMS operational practices regarding the current set of approved C-SNP groups. We are seeking comment on our proposal to codify the current list of five commonly co-morbid and clinically-linked conditions. We are also seeking comment on the applicability of the proposed set of three new chronic condition pairs based on the chronic condition panel's recommendations. Second, we are also proposing to add at a new paragraph (g) at § 422.52 that SNPs may enroll eligible beneficiaries into a C-SNP consisting of commonly co-morbid and clinically-linked conditions if the beneficiary has only one of the qualifying conditions for enrollment.

Lastly, CMS is not proposing to codify a C-SNP plan application option that is currently available under subregulatory guidance in section 20.1.3.2 of Chapter 16b of the MMCM. In effect, this will remove this approach as an option for C-SNPs beginning 2024. Under the current guidance, we permit MA organizations seeking to sponsor a C-SNP to apply for an MA organization-customized group of multiple chronic conditions. If a C-SNP uses such a

customized group of conditions, enrollment in that C-SNP is limited to special needs individuals who have all of the severe or disabling conditions in the group. CMS has reviewed only a few SNP plan application proposals since the initial implementation of the C-SNP program and has not granted any applications either due to the lack of clinical connection between the proposed conditions or because the MA organization failed to meet other conditions of the application process. No C-SNPs of this type have been approved nor will be operational in CY 2023. We are proposing to remove this option from the C-SNP application process beginning in CY 2024. Given the historical lack of interest from MA organizations, beneficiaries, or patient advocacy groups, we believe there will be minimal impact on stakeholders associated with the elimination of this current flexibility. In addition, with the addition of three new groupings and the ability to establish a C-SNP that is based on functional limitations that we are proposing with paragraphs (20) through (21) of the proposed definition of severe or disabling chronic condition, we believe that there is adequate flexibility for MA organizations to develop C-SNPs that meet the needs of the Medicare population.

In conclusion, we are proposing to define C-SNPs at § 422.2 as SNPs that restrict enrollment to MA eligible individuals who have a severe or disabling chronic condition as defined under § 422.2. We are proposing to amend § 422.4(a)(1)(iv) to limit C-SNPs that focus on multiple chronic conditions to the list of CMS-approved group of commonly co-morbid and clinically linked conditions. And we are proposing to amend § 422.52 to clarify that enrollees need only have one of the qualifying conditions for enrollment when a C-SNP focuses on multiple conditions in one of the groupings specified in proposed § 422.4(a)(1)(iv)(B). This will provide greater clarity for MA organizations seeking to establish combination plans and for Medicare beneficiaries exploring potential MA plan options. We are seeking comment on these proposals.

Many of the changes we are proposing in connection with C-SNPs, including the revision of the definition of severe and disabling chronic condition and the new definition of C-SNP,

would unify and streamline existing requirements, which should reduce burden and are therefore not expected to have impact. The proposal regarding the definitions of severe or disabling chronic condition and C-SNP and the amendments to §§ 422.4(a)(1)(iv) and 422.52 would be applicable beginning with plan year 2024. Together, these proposals would implement the new list of chronic conditions recommended by the panel of clinical advisors established by section 1859(f)(9)(A) of the Act. Our proposed update to the list would create new chronic condition categories, relabel several existing categories, and include several new sub-conditions under a number of chronic conditions. It is unclear how many MA organizations would create new C-SNPs based on the proposed new list of severe or disabling chronic conditions that meet the criteria in section 1859 of the Act. Historically, MA organizations have generally focused plan and benefit efforts around a few specific chronic conditions. As reflected on Table D-A 1, C-SNPs based on just three conditions make up 63 percent of all C-SNPs created since 2007: Cardiovascular Disorders, Chronic Heart Failure, and Diabetes Mellitus.[148] Given this historical pattern, we expect that MA organizations may be slow or hesitant to create new C-SNP plan type options around the new set of chronic conditions.

We anticipate that changes from current plan and enrollment practices would most likely be seen in connection with chronic condition categories like ESRD, where the proposal would somewhat revise enrollment qualifications. Based on the proposal to use the condition category "Chronic kidney disease (CKD)" and to include ESRD as part of that condition category, we expect that current ESRD C-SNPs will be permitted to enroll, in addition to those with ESRD, beneficiaries with CKD Stages 1–4 once this proposal is finalized. As of July 2022, CMS contracts with 17 C-SNPs for ESRD. CMS estimates that just under 23 percent of Medicare beneficiaries qualify for one of the stages of CKD; however, this figure includes beneficiaries

[148]Table D-A 1 was created using data from CMS' SNP Comprehensive Report, found here: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data. Data was collected by sampling reports from May 2007 through January 2022. Data from reports was then coded and analyzed to create a distribution of C-SNP plan types.

who may already qualify for an ESRD C-SNP in their area.[149] However, we have no clear evidence to suggest how this will impact enrollment for current ESRD plans potentially impacted by this proposal or new C-SNPs that would be created because of it.

Because MA organizations would be able to choose to create and submit a C-SNP under one of the new chronic condition categories starting in CY 2024 (with the exception CKD as proposed in section IV.A.1. of this proposed rule), we do not see this as a new burden. The burden associated with the MA application process is covered under PRA CMS-10237/OMB 0938-0935, while the burden associated with complying with the SNP MOC process is covered under PRA CMS-10565/OMB 0938-1296. The proposals here, if finalized, would add no additional burden for MA organizations sponsoring a C-SNP now or in the future. The proposed policy would allow MA organizations to select new C-SNP plan type options, but it would not compel them to do so. However, we would monitor all C-SNP type applications for CY 2025 and future years to inform future implementation strategies and impact on the program.

TABLE D-A 1. DISTRIBUTION OF C-SNPS BY CHRONIC CONDITION 2007 – 2022

Chronic Condition Category	Frequency	Percent
Cardiovascular Disorders, Chronic Heart Failure, and Diabetes	730	28
Diabetes	539	21
Chronic lung disorders	265	10
Multiple conditions, 4+ (2007-2010)	192	7
Chronic Heart Failure and Diabetes	164	6
Cardiovascular Disorders and Chronic Heart Failure	152	6
ESRD	144	6
Unknown and Plans < 11 members	132	5
Dementia	52	2
HIV/AIDS	52	2
Chronic and disabling mental health conditions	43	2
Chronic lung disorders; Diabetes	27	1
Diabetes and Hypertension	20	1
Chronic Heart Failure	19	1
Pulmonary Disease and Diabetes	18	1
Hypercholesterolemia	12	< 1
Dyslipidemia	11	< 1
Cardiovascular Disorders	9	< 1
Obesity	3	< 1
Chronic lung disorders; ESRD; Diabetes	3	< 1

[149]This 2018 estimate is based on the CMS Office of Enterprise Data and Analytics analysis of chronic conditions identified using ICD-10 codes. Additional information can be found here: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.

Chronic Condition Category	Frequency	Percent
Cardiovascular Disorders and Diabetes	2	< 1
CKD/Chronic Renal Failure and ESRD	2	< 1
Hypertension	2	< 1
Diabetes, Cardiovascular Disease, and Stroke	2	< 1
Hypertension, Diabetes, and Dyslipidemia	1	< 1
congestive heart failure; ischemic stroke; coronary artery disease	1	< 1
Congestive heart failure and Chronic obstructive pulmonary disease	1	< 1
Chronic Kidney disease; ESRD; post-transplant; Kidney Transplant; Post-Transplant	1	< 1
Chronic alcohol use disorder and other substance use disorders	1	< 1

B. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2)

Institutional Special Needs Plans (I-SNPs) are MA special needs plans (SNPs) that restrict enrollment to MA-eligible individuals who are institutionalized or institutionalized-equivalent as those terms are defined in § 422.2. Institutionalized is defined, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), as an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings: skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare); nursing facility (NF) as defined in section 1919 of the Act (Medicaid); intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act; psychiatric hospital or unit as defined in section 1861(f) of the Act; rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act; long-term care hospital as defined in section 1886(d)(1)(B) of the Act; hospital which has an agreement under section 1883 of the Act (a swing-bed hospital); and last, subject to CMS approval, a facility that is not listed as part of the definition of "Institutionalized" at § 422.2 but meets both of the following: furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and whose residents have similar needs and healthcare status as residents of one or more facilities listed in the definition of "Institutionalized" at § 422.2. We define, at § 422.2, the term "institutionalized-equivalent," for the purpose of identifying a special needs individual, as an MA eligible individual who is living in the community, but requires an institutional level of

care; in addition, the definition of the term "institutionalized equivalent" includes specific limitations on how an assessment is made that an individual meets the definition.

Per the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), I-SNPs, along with C-SNPs and D-SNPs, are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859(b)(6)(B) and (f)(1) of the Act, I-SNPs restrict enrollment to MA eligible individuals who meet the definitions of "institutionalized" or "institutionalized-equivalent" in § 422.2, which are based on section 1859(b)(6)(B)(i) and (f)(2)(A) of the Act. As of February 2022, there are 87 I-SNP MA contracts with 186 plans serving 96,792 enrollees.[150] CMS currently permits MA organizations to submit SNP applications that are restricted to institutionalized individuals only or institutionalized-equivalent individuals only, as defined in § 422.2 respectively, or to submit an application for a combination SNP that covers beneficiaries who qualify for either institutionalized or institutionalized-equivalent status, but are enrolled under the same plan.

We propose to add four definitions at § 422.2: a definition of I-SNPs and three additional definitions for each of the current I-SNP types that correspond to CMS' current MA application process. In addition, we propose to codify, as part of the definitions for I-SNPs that enroll special needs individuals who are institutionalized, current policies that address the need for the I-SNP to contract with the institutions where such special needs individuals reside. We believe that adding these four definitions will help clarify the specific standards that are applicable to I-SNPs, as distinguished from other MA plans and from other MA SNPs. This proposal includes tying the definitions of institutionalized and institutionalized-equivalent in § 422.2 and the list of eligible institutions set forth in that definition, to our proposed definition of I-SNP. This approach is consistent with how CMS has adopted regulatory definitions for D-SNPs, FIDE SNPs, and HIDE SNPs in § 422.2. The proposed definitions clarify that MA organizations may offer SNPs that

[150]See "SNP Comprehensive Report 2022 02," found here: https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldataspecial-needs/snp-comprehensive-report-2022-02

are: exclusive to beneficiaries meeting the definition of institutionalized under § 422.2; are exclusive to beneficiaries meeting the definition of institutionalized-equivalent under § 422.2; or are exclusive to beneficiaries who meet either of those definitions. Our proposed language linking I-SNP enrollment to the definitions noted here matches current subregulatory guidance and practice used by CMS during the MA application process for I-SNPs.

Lastly, we are proposing to amend § 422.101(f)(2) to add a requirement that the models of care for I-SNPs ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in § 422.2) contain requirements allowing I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized. This proposed new paragraph (f)(2)(vi) would codify longstanding subregulatory guidance in section 20.3 of Chapter 16b of the MMCM that is designed to provide I-SNPs enrollees protections regarding access to care coordination and communication between providers and I-SNP staff. Under our proposal, I-SNP clinical and care coordination staff may be employed by the MA organization offering the I-SNP or under contract with the I-SNP to furnish healthcare, clinical or care coordination services. CMS has received feedback in the past that institutional providers sometimes fail to share relevant information regarding an I-SNP enrollee's health status or need for care or services with the I-SNP staff. We intend that codifying this requirement for I-SNP MOCs to ensure that the contracts between the I-SNP and these institutions where I-SNP enrollees reside include provisions allowing access for I-SNP staff will protect beneficiaries. Our proposal would leave the details of how access to I-SNP enrollees would be assured for I-SNP staff but we intend the term "access" to be interpreted broadly to encompass information sharing, admission to physical facilities to see enrollees, and other issues. We are seeking comment on whether the regulation text needs to more specifically address information sharing or other related issues. We believe that codifying this policy would improve transparency for stakeholders, improve care coordination and ensure the continuity of care for vulnerable beneficiaries. In the years since it was issued in 2016, we have used the I-SNP guidance from

section 20.3 of Chapter 16b to administer policies central to plan compliance and application review. In that time, I-SNP enrollment has grown from 54,643 enrollees under 37 contracts and 79 plans to 96,792 enrollees being served by 87 I-SNP MA contracts with 186 plans.[151] As of 2021, MedPAC shows that 72 percent of Medicare beneficiaries have access to at least one I-SNP plan, up from 52 percent in 2017.[152] As MedPAC noted in its March 2013 report, I–SNPs perform better than other SNPs and other MA plans on the majority of available quality measures for SNPs. MedPAC also noted in the same report that I–SNPs had much lower than expected hospital readmission rates and scored just as well as D-SNPs and C-SNPs on other measures.[153] From an administrative standpoint, CMS has found I-SNPs to be comparable to other SNPs when it comes to meeting compliance standards.

Section 1859(f) of the Act includes additional requirements for all types of specialized MA plans for special needs individuals and requirements specific to I-SNPs. Per the current definition of specialized MA plan for special needs individuals in § 422.2, MA SNPs must all cover Part D benefits under part 423 for their enrollees. In addition, the definition of MA SNPs provides that these MA plans have been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population. The proposed definition of the term "institutional special needs plan (I-SNPs)" uses the term "specialized MA plan for special needs individuals" and therefore incorporates the requirements and limitations on SNPs that are included in that definition in § 422.2.

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[151]See "SNP Comprehensive Report 2016 01," found here: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data-Items/SNP-Comprehensive-Report-2016-01; and "SNP Comprehensive Report 2022 02," found here: https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldataspecial-needs/snp-comprehensive-report-2022-02.

[152]See Chapter 12: The Medicare Advantage program: Status report (March 2021), found here: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch12_sec.pdf.

[153]The full report, "Chapter 14: Medicare Advantage special needs plans" (March 2013), can be found here: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-14-medicare-advantage-special-needs-plans-march-2013-report-.pdf.

Accordingly, we are proposing to define I-SNPs as SNPs that restrict enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent in this section. We are also proposing to include in our definition of I-SNP that there are the following types: I-SNP Institutionalized, I-SNP Equivalent, and I-SNP Hybrid. We believe this definition is consistent with our current guidance and operational practices involving I-SNPs and Medicare beneficiaries enrolled in those plans such that this proposal represents a continuation of I-SNP policies.

We are also proposing to define three I-SNP types that are currently used by CMS to operationalize MA applications and Medicare beneficiary enrollment into I-SNPs. The proposed definitions address both enrollment limitations used by these different types of I-SNPs and certain performance and contracting requirements that are specific to each type. Each new definition would be added to § 422.2.

Our first proposed definition is an I-SNP type that enrolls only Medicare beneficiaries who meet the definition of institutionalized in § 422.2. We proposing to call these I-SNPs "Facility-based Institutional Special Needs plans" or FI-SNPs. In addition to the enrollment criteria noted in this paragraph, the proposed definition provides that FI-SNPs must own or have a contractual arrangement with at least one institution specified in the definition of institutionalized in § 422.2 for each county within the plan's service area and with each institutionalized facility serving enrollees in their plan. The latter two requirements represent codifications of longstanding subregulatory guidance in section 20.3 of Chapter 16b of the MMCM.

We are proposing a definition for a second I-SNP type called "Institutional-equivalent Special Needs Plan" or IE-SNP. IE-SNPs are an I-SNP type that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent in § 422.2. Those special needs individuals are living in the community but require an institutional level of care, which is determined using assessment tools that meet requirement specified in the definition of

the term institutionalized-equivalent. The determination that a Medicare beneficiary requires an institutional level of care (LOC) must be made using a State assessment tool from the State in which the individual resides and the LOC assessment must be conducted by an impartial party with the requisite knowledge and experience to accurately identify whether the beneficiary meets the institutional LOC criteria. CMS has interpreted the standard that the assessment be done by an impartial entity as requiring that the entity be other than the I-SNP and that the I-SNP cannot own or control the entity. CMS currently uses the IE-SNP designation for operational purposes during the MA application review and approval process.

We are proposing a definition for a third I-SNP type called "Hybrid Institutional Special Needs Plan." HI-SNPs are I-SNP type that restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent. For enrollees that meet the definition of institutionalized, the HI-SNP must own or contract with at least one institution, as determined under the definition of institutionalized in this section, for each county within the plan's county-based service area; and must own or have a contractual arrangement with each institutionalized facility serving enrollees. In other words, we are proposing that HI-SNPs meet the standards specified in the definitions of FI-SNPs and HE-SNPs since these hybrids serve both type of special needs individuals. CMS currently uses the HI-SNP designation for operational purposes during the MA application review process.

CMS's current guidance for I-SNPs in section 20.3.4 of Chapter 16b of the MMCM addresses a number of requirements that the contract between the I-SNP and the LTC facility must include in order for an I-SNP to meet CMS compliance in addition to the requirement, proposed to be added to § 422.101(f)(2)(vi), that the I-SNP model of care ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in § 422.2) contain requirements allowing I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized. Some of that guidance addressing an I-SNP's relationship

with long-term care institutions is proposed to be included in the definitions for specific types of I-SNPs. We are not proposing to codify the remainder of the requirements listed in section 20.3.4 of Chapter 16b because they would duplicate requirements in other current MA regulations under part 422. Specifically, we believe the following standards described in section 20.3 are addressed or required by current regulations:

• Section 20.3.4 states that facilities in a chain organization must be contracted to adhere to the I-SNP MOC. Currently, requirements for compliance with and implementation of the I-SNP's required model of care (MOC) by the LTC facilities and other providers that contract with the I-SNP to furnish services to the I-SNP's enrollees are addressed by §§ 422.101(f)(2), 422.202 and 422.504. Currently, all SNPs are required under § 422.4(a)(1)(iv) to submit their model of care (MOC) to CMS for National Commission on Quality Assurance (NCQA) evaluation and approval. All SNPs (including I-SNPs) are required by § 422.101(f)(2) to have appropriate employed, contracted, or non-contracted staff trained on the SNP plan MOC to coordinate and/or deliver all services and benefits; and in addition, SNPs must develop and implement model of care requirements to coordinate the delivery of care to their enrollees across healthcare settings, providers, and services to assure continuity of care. Per § 422.202, MA organizations are required to provide information about the rules of participation in the organization's network of providers and to have a mechanism for consulting with and communicating practice guidelines and utilization management guidelines to contracted providers. Finally, § 422.504(i) provides that MA organizations must include certain provisions and beneficiary protections in their contracts with first tier, downstream and related entities (which includes contracted providers), including compliance with Medicare laws and the MA organization's contractual obligations with CMS. Thus, we believe codifying this aspect of the existing guidance would be duplicative. We solicit comment from providers whether an additional regulation specific to this issue is necessary to further clarify the obligations of I-SNPs.

● Section 20.3.3 provides that an I-SNP must document that it is prepared to implement the approved MOC when an enrollee changes residence or LTC facility that furnishes services to the I-SNP's enrollees. If an I-SNP enrollee changes applicable facility status, the I-SNP must document that it is prepared to implement the approved MOC at the enrollee's new residence or in another I-SNP contracted LTC setting that provides an institutional level of care. Again, we believe a regulation that is specific to this issue would be duplicative of existing regulations. All SNPs, including I-SNPs, are required under § 422.101(f)(2)(ii) to have contracted staff trained on the MOC. In addition, per § 422.101(f)(1), SNPs must develop and implement individualized plans of care for enrollees and use interdisciplinary teams to manage and furnish care; we believe that in order to meet those obligations, an I-SNP would necessarily have to involve and coordinate services with the long-term care facility (LTCF) where an enrollee receives services.

● Section 20.3.4 of Chapter 16b also addresses how:

++ The I-SNP must provide protocols to all LTCFs for serving the I-SNP's enrollees in accordance with the approved I-SNP MOC, and the contract with each LTCF must reference these protocols.

++ The I-SNP must clearly specify in its contract with the LTCF provider the services to be provided to I-SNP enrollees by the LTCF and its staff, in accordance with the protocols and payment for the services provided by each LTCF. The I-SNP must include in its contract with the LTCF provider a training plan to ensure that LTC facility staff understands their responsibilities in accordance with the approved I-SNP MOC, protocols, and contract. If the training plan is a separate document, then the contract should reference it.

Like the other issues previously discussed, these actions are required in order for an I-SNP to meet their obligations to coordinate and implement the approved MOCs and to maintain effective oversight over first tier, downstream and related entities involved in the furnishing of covered benefits to enrollees under §§ 422.101(f) and 422.504. We believe additional

regulations that are specific to how §§ 422.101(f) and 422.504 work together in this context would be unnecessary and duplicative.

- Section 20.3.4 provides that I-SNPs must develop procedures for LTCFs to maintain a list of credentialed I-SNP clinical staff in accordance with the LTC facility's responsibilities under Medicare conditions of participation. Per § 422.204(b)(2), MAOs must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements in meeting the initial credentialing and recredentialing requirements. In addition, per § 422.204(b)(3), the I-SNP can only contract with a LTCF (which is a provider of services as that term is defined in section 1861(u) of the Act) for furnishing Part A and B benefits when the facility has a Medicare participation agreement, which would include the obligations to comply with conditions of participation in 42 CFR part 483. We believe that an additional regulation that specifies that I-SNPs must include in their contracts with LTCFs that the LCTFs comply with their Medicare conditions of participation would be unnecessarily duplicative.

- Section 20.3.4 of Chapter 16b provides that I-SNPs must ensure that the contract between the I-SNP and the LTCF where enrollees of the I-SNP reside must specify the start and end date of the contract; the guidance also states that the contract should include the full CMS contract cycle, which begins on January 1 and ends on December 31. The I-SNP may also contract with additional LTC facilities throughout the CMS contract cycle. To the extent that this guidance goes beyond requirements in § 422.504(i), we do not believe that it is necessary to adopt a regulation to require these specific contract terms for I-SNPs and their contracted LTCFs. The proposed definitions for the I-SNPs that serve beneficiaries that are institutionalized would require those MA plans to have contracts with the LTCFs where enrollees reside and with LTCFs in the service area; in order to meet these requirements during the full term of the I-SNP's contract with CMS, those contracts would necessarily have to cover the full January

through December time frame. We do not believe that a more detailed regulation governing the terms of contracts between I-SNPs and LTCFs on this point is necessary.

- Finally, section 20.3.4 of Chapter 16b provides that the contract between the I-SNP and the LTCF include a termination clause that clearly states any grounds for early termination of the contract and a clear plan for transitioning the enrollees to another facility where the I-SNP can furnish covered benefits should the I-SNP's contract with the LTC facility terminate. In addition, a transition plan would only be necessary if the beneficiary elects to continue enrollment with the I-SNP rather than elect enrollment in a different MA plan or Original Medicare. Further, we note that a beneficiary who remains in the terminated facility or who transfers to another non-contracted facility would lose eligibility for enrollment in their current I-SNP. Section 422.504(i) requires MA organizations to include in their contracts with first tier, downstream and related entities provisions that address termination and scope of the activities to be performed by the contracted entity; this regulation applies to contracts between the MA plan and providers. In addition, SNPs are required to implement the MOC under § 422.101(f) with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees and to have individualized plans of care for each enrollee; ensuring the continued delivery of services during a period of transition would necessarily have to be addressed in implementation of the MOC and plans of care. Therefore, we are not proposing an additional regulation to codify this aspect of our current guidance.

The changes that we are proposing carry no burden. We are proposing definitions of I-SNP and I-SNP types under § 422.2 to clarify existing policies that are specific to I-SNPs and not general policies impacting D-SNPs or C-SNPs. This proposal is also a codification of several specific longstanding subregulatory guidance in Chapter 16b of the MMCM. We believe there is no burden associated with either pieces of our proposal, as the creation of a definition will not engender operational or policy changes impacting MA organizations sponsoring I-SNPs nor impact enrollees; likewise, we do not expect any burden associated with the continuation of

existing guidance that was incorporated and implemented with the release of the 2016 update of Chapter 16b of the MMCM.

We are seeking comment on the proposed codification of chapter 16b subregulatory guidance and the proposed new definition of I-SNP. In particular, we are seeking feedback on I-SNP operationalization of the current subregulatory guidance. We also seek feedback from commenters who have other suggestions for improving the care furnished to the special needs individuals enrolled in I-SNPs, many of whom are dually eligible for Medicare and Medicaid, based on parallels or lessons learned from other State or Federal programs administering services to long-term care residents or beneficiaries requiring a nursing home level of care.

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

This proposed revision would move the current definition of a network-based plan from § 422.114(a)(3)(ii) to the definitions section in § 422.2. This proposed change has no implications for other provisions in part 422 in which the definition or description of network plans play a role, for example, the network adequacy provisions at § 422.116 and the plan contract crosswalk provisions at § 422.530. Currently, § 422.116(a)(1)(i) references the current definition of network-based plan at § 422.114(a)(3)(ii) in its specification of network adequacy requirements for the various plan types. We propose to make, however, a conforming change to § 422.116(a)(1)(i) consistent with our proposal to move the definition of network-based plan; this conforming change is to reference § 422.2. The regulation at § 422.530(a)(5) specifically addresses the types of plans to which it applies and when CMS considers a crosswalk to be to a plan of a different type, so we do not believe any amendment to § 422.530 is necessary in connection with moving the definition of network based plan to § 422.2.

Private-fee-for-service (PFFS) plans were established by the Balanced Budget Act of 1997 and were originally not required to have networks. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) revised the PFFS requirements to require that beginning contract year 2011 any PFFS plan operating in the same service area as two or more

network-based plans also have a network. For purposes of this requirement, section 1852(d)(5)(C) of the Act and § 422.114(a)(3)(ii) define network-based plans as a coordinated care plan (as described in section 1851(a)(2)(A) of the Act and § 422.4(a)(1)(ii)), a network-based MSA plan, and a section 1876 reasonable cost plan. The statutory and regulatory definitions both specifically exclude an MA regional plan that meets access requirements substantially through means other than written contracts, per § 422.112(a)(1)(ii).

When codifying this requirement in the final rule that appeared in the **Federal Register** September 18, 2008 titled "Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs", (73 FR 54226), we included the definition of network-based plan in the section of the regulations for PFFS plans, as the definition was integral to the new requirement for PFFS plans. (73 FR 54230, 54249) A network-based plan, however, has meaning in contexts other than in addressing these specific requirements for MA PFFS plans and, in order to ensure that the definition is more readily accessible for those seeking requirements related to network-based plans, we are proposing to move it to the definitions section at § 422.2. The PFFS section at § 422.114(a)(3)(ii) would continue to include language specifying the network requirement, but the proposed conforming change to this section would refer to the definitions in § 422.2 instead of including the definition in § 422.114(a)(3)(ii).

D. Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

Section 231 of the Medicare Modernization Act of 2003 (MMA) amended section 1851(a)(2)(A)(ii) of the Act to establish specialized MA plans for special needs individuals. Special needs plans (SNPs), defined at section 1859(b)(6)(A) of the Act, are plans with limited enrollment, specifically designed to provide targeted care to institutionalized individuals, dual eligible individuals, or individuals with severe or disabling chronic conditions, collectively known as a "special needs individual" as defined at section 1859(b)(6)(B) of the Act. Only those individuals who qualify as special needs may enroll, and remain enrolled, in a SNP. In the January 2005 MA final rule, we established regulations at § 422.52 that provided that to be

eligible to enroll in a SNP, an individual must meet the definition of a special needs individual, meet the eligibility requirements for that specific SNP, and be eligible to elect an MA plan. Sections 1859(b)(6)(B) and 1894(c)(4) of the Act, and CMS's implementing regulation at § 422.52(d), allow individuals who lose special needs status, if, for example, they were to no longer have the level of Medicaid eligibility or other qualifying condition necessary to be eligible for the plan, to have a period of deemed continued eligibility if they are reasonably expected to regain special needs status within, at most, the succeeding 6-month period. The period of deemed eligibility must be at least 30 days but may not be longer than 6 months. In implementing regulations, we also established loss of special needs status (and of deemed continued eligibility if applicable) as a basis for required disenrollment at § 422.74(b)(2)(iv).

The January 2005 MA final rule served as the basis for our current sub-regulatory guidance in Chapter 2 of the Medicare Managed Care Manual, Section 50.2.5, which specifically provides that plans send certain notices prior to and following the effective date of involuntary disenrollment based on loss of special needs status. These policies are intended to ensure that beneficiaries are given adequate notice prior to being disenrolled from a SNP and provided an opportunity to prove that they are eligible to remain enrolled in the plan, if applicable. Providing these members at least 30 days advance notice of disenrollment, along with information about deemed continued eligibility and eligibility for an SEP to elect other coverage, gives beneficiaries ample time to prove they are still eligible for their SNP or to evaluate other coverage options.

To provide stability and assurance about the requirements for MA organizations in these situations as well as transparency to stakeholders, we are proposing to codify current policy for MA plan notices prior to a member's disenrollment for loss of special needs status, as well as a final disenrollment notice. We intend that stakeholders will be able to rely on these regulations, and that these regulations would only be changed through a subsequent rulemaking, establishing the procedures that an MA organization must follow in the event that a SNP enrollee loses

special needs status and is disenrolled from the SNP on that basis. Specifically, we are proposing to revise § 422.74(d) by redesignating paragraph (d)(8) as paragraph (9) and adding new paragraph (8), to state that the plan would be required to provide the enrollee a minimum of 30 days advance notice of disenrollment, regardless of the date of the loss of special needs status. As proposed in new paragraphs (8)(i) and (ii), an advance notice would be provided to the enrollee within 10 calendar days of learning of the loss of special needs status, affording the enrollee an opportunity to prove that he or she is still eligible to remain in the plan. The advance notice would also include the disenrollment effective date, a description of SEP eligibility, as described in § 422.62(b)(11), and, if applicable, information regarding the period of deemed continued eligibility, the duration of the period of deemed continued eligibility, and the consequences of not regaining special needs status within the period of deemed continued eligibility. Additionally, as proposed in new paragraph (8)(iii), the plan would be required to provide the enrollee a final notice of involuntary disenrollment within 3 business days following the disenrollment effective date, which is either the last day of the period of deemed continued eligibility, if applicable or a minimum of 30 days after providing the advance notice of disenrollment, and must be sent before submission of the disenrollment to CMS. Lastly, we propose in new paragraph (8)(iv), that the final involuntary disenrollment notice must include an explanation of the individual's right to file a grievance under the MA organization's grievance procedures, which are required by § 422.564.

We are codifying longstanding guidance with these changes. Based on infrequent questions or complaints from MA organizations and enrollees on these notices, we believe that these notice requirements have been previously implemented and are currently being followed by plans. We do not believe the proposed changes to the regulatory text will adversely impact MA organizations or individuals enrolled in MA special needs plans who lose special needs status, other than the appropriate disenrollment from the plan due to the individual’s loss of eligibility

for the plan. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

E. Involuntary Disenrollment for Individuals Enrolled in a MA Medical Savings Account (MSA) Plan (§ 422.74)

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1851(a)(2) of the Act establishing private health plan options available through Part C of the Medicare program known originally as "Medicare + Choice" and later as "Medicare Advantage (MA)." Under this program, eligible individuals may elect to receive Medicare benefits through enrollment in one of an array of private health plan choices beyond the original Medicare program. As enacted, section 1851(a)(2)(B) of the Act established the authority for an MA organization to offer a MA medical savings account (MSA) option which is, a combination of a high-deductible MA plan, as defined in section 1859(b)(3) of the Act, with a contribution into a Medical Savings Account (MSA).

In the interim final rule titled Medicare Program; Establishment of the Medicare+Choice Program," published in the **Federal Register** June 26, 1998 (63 FR 34968), we established the conditions for MA organizations to enroll individuals in a MA MSA plan. The restrictions on enrollment in MA MSA plans were set forth under section 1851(b)(2) and (b)(3) of the Act and in implementing regulations at § 422.56. Specifically, consistent with section 1851(b)(2) of the Act, § 422.56(b) provides that an individual who is enrolled in a Federal Employee Health Benefits Program (FEHB) plan, or is eligible for health care benefits through the Veterans Administration (VA) or the Department of Defense (DoD), may not enroll in a MA MSA plan. In addition, § 422.56(c) incorporates the statutory prohibition under section 1851(b)(3) of the Act on enrollment in MA MSA plans by individuals who are eligible for Medicare cost-sharing under Medicaid State plans. Additional restrictions were set forth under section 1852(a)(3)(B) of the Act and in implementing regulations at § 422.56(d) based on supplemental benefits under an MA MSA plan.

The January 2005 MA final rule implemented section 233 of the Medicare Modernization Act, which lifted the time and enrollment limits on MSA plans imposed by the BBA of 1997. However, section 233 of the MMA did not alter the prohibitions in sections 1851(b)(2) and (b)(3) of the Act on enrollment into an MA MSA plan for individuals covered under other health programs, and likewise the January 2005 MA final rule did not alter the implementing regulations regarding these policies at § 422.56.

The current regulations do not specify whether the eligibility criteria described in § 422.56, which preclude an individual with certain health care coverage from electing an MA MSA plan, are applicable to individuals who gain or become eligible for other coverage *while enrolled in* an MSA plan. In other words, the current regulations do not specify that an individual who ceases to satisfy the eligibility criteria described in § 422.56 while already enrolled in an MA MSA plan must be involuntarily disenrolled from the MSA, regardless of the time of year. CMS has historically understood the eligibility criteria for an individual to be enrolled in an MSA plan in § 422.56, coupled with the statutory prohibitions on enrolling in an MA MSA by individuals with Medicaid or coverage under other health benefits, to mean that an enrollee in an MSA plan is not able to remain a member of the MSA plan and must be disenrolled by the plan when the individual ceases to meet the statutory and regulatory criteria for eligibility. We also note that this policy is consistent with our general approach in section 50.2, Chapter 2 of the Medicare Managed Care Manual, in which an enrollee becomes ineligible due to a status change, such as the loss of entitlement to Medicare Part A or Part B or the inability to regain special needs status during the period of deemed continued eligibility and outlined in § 422.74.

To address more clearly the consequences of the general loss of eligibility in an MSA plan, we are proposing to amend § 422.74 to add new paragraph (b)(2)(vi) to include the requirement that an MA MSA enrollee must be disenrolled, prospectively, due to the loss of eligibility. If an MA MSA enrollee does not provide assurances that he or she will reside in the

United States for at least 183 days during the year the election is effective, is eligible for or begins receiving health benefits through Medicaid, FEHBP, DoD, or the VA or obtains other health coverage that covers all or part of the annual Medicare MSA deductible, that enrollee must be involuntarily disenrolled by the MSA plan effective the first day of the calendar month after the month in which notice by the MA organization is issued that the individual no longer meets the MA MSA's eligibility criteria, as proposed in § 422.74(d)(10). We are also proposing to revise § 422.74(c) to require MA MSA plans to provide a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual before the disenrollment transaction is submitted to CMS.

Should an individual's coverage under an MA MSA plan end before the end of a calendar year, CMS recovers from the plan the amount of the lump-sum deposit attributable to the remaining months of that year. This requirement is codified at § 422.314(c). In addition, the disenrolled beneficiary will owe a prorated portion of the current year's deposit amount back to the MA MSA plan. Plans will be able to reconcile and identify MSA deposit amounts for the Current Payment Month (CPM) at the beneficiary-level from the monthly generated MSA Deposit-Recovery Data file. We are proposing at § 422.74(e)(1) that involuntarily disenrolled individuals will be defaulted to enrollment in Original Medicare, which will now pay claims incurred by the former MSA enrollees. Conversely, the former MSA enrollee also has the option to elect to join another MA plan during a valid enrollment period.

F. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (§ 422.101)

Congress first authorized special needs plans (SNPs) to exclusively or disproportionately serve individuals with special needs through passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the MMA) (Pub. L. 108-173). The law authorized CMS to contract with Medicare Advantage (MA) coordinated care plans that are specifically designed to provide targeted care to individuals with special needs. Originally SNPs were statutorily authorized for a limited period, but after several

extensions of that authority, section 50311(a) of the BBA of 2018 permanently authorized SNPs. Under section 1859(f)(1) of the Act, SNPs are able to restrict enrollment to Medicare beneficiaries who are: (1) Institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long-term care facility, and institutionalized equivalent individuals who reside in the community but need an institutional level of care when certain conditions are met; (2) individuals entitled to medical assistance under a State plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of July 2022, 492 SNP contracts with1,198 SNP plans had at least 11 members. These figures included 307 Dual Eligible SNP contracts (D-SNPs) with 729 D-SNP plans with at least 11 members, 87 Institutional SNP contracts (I-SNPs) with 186 I-SNP plans with at least 11 members, and 98 Chronic or Disabling Condition SNP contracts (C-SNPs) with 283 C-SNP plans with at least 11 members. SNPs as of June 2022 serve 4,897,054 MA enrollees, with D-SNPs enrolling 4,385,315, C-SNPs with 409,931, and I-SNPs with 100,808 members.

Section 164 of the Medicare Improvements for Patients and Providers Act (hereinafter referred to as MIPPA) (Pub. L. 110-275) added care management requirements for all SNPs effective January 1, 2010, which are in section 1859(f)(5)(A) of the Act. As a result, all SNPs are required to implement care management requirements which have two explicit components: an evidence-based model of care (MOC) and a series of care management services. For more discussion of the history of SNPs, please see Chapter 16b of the Medicare Managed Care Manual (MMCM).

This proposed rule would codify certain subregulatory guidance from Chapters 5 and 16b of the MMCM about current SNP MOC scoring protocols; annual C-SNP MOC submissions as required by the BBA of 2018; and processes for amending SNP MOCs after National Committee for Quality Assurance (NCQA) approval.

1. Codification of Model of Care (MOC) Scoring Requirements for Special Needs Plans (SNPs) (§ 422.101)

Section 3205 of the Patient Protection and Affordable Care Act of 2010 (hereinafter referred to as the Affordable Care Act) (Pub. L. 111-148) amended section 1859(f) of the Act to require that, starting in 2012, all SNPs be approved by NCQA based on standards developed by the Secretary. As provided under §§ 422.4(a)(iv), 422.101(f), and 422.152(g), the NCQA approval process is based on evaluation and approval of the SNP MOC. 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 **Federal Register** on January 12, 2021 (hereinafter referred to as the January 2021 final rule), we adopted several regulatory amendments to implement requirements for the SNP MOC that were enacted as part of the BBA of 2018 and our extension of some C-SNP-specific standards to all SNP MOCs.

All SNPs must submit their MOCs to CMS for NCQA evaluation. An MA organization sponsoring multiple SNPs must develop a separate MOC to meet the needs of the targeted population for each SNP type it offers. MA organizations that wish to offer a SNP must submit an application (under part 422, subpart K) to demonstrate that they meet SNP specific requirements, including the requirement in § 422.101(f) that MA organizations offering a SNP implement an evidence-based MOC to be evaluated by the NCQA; the requirement in § 422.107 that D-SNPs have a contract with the State Medicaid agencies in the states in which they operate; and the requirement in § 422.152(g) that SNPs conduct quality improvement programs. SNP applicants follow the same process in accordance with the same timeline as applicants seeking to contract with CMS to offer other MA plans. Most recently, in the January 2021 final rule, CMS revised and amended § 422.101(f) to improve plan implementation of enrollee care management

practices and to strengthen the review process by establishing a minimum benchmark score of 50 percent for each element of a plan's MOC (§ 422.101(f)(3)(iii)).

Since the beginning of the MOC approval process, CMS has developed and issued guidance on the MOC to improve plan performance and beneficiary care. CMS provided guidance and instructions in the CY 2010 Final Call Letter issued March 30, 2009, in a section titled, "Model of Care Reporting for New Applicants and Existing SNPs," in order to more clearly establish and clarify delivery of care standards for SNPs.[154] In May, 2008, CMS proposed that SNPs have networks with clinical expertise specific to the special needs population of the plan; use performance measures to evaluate models of care; and be able to coordinate and deliver care targeted to people with frailty or disability, and those near the end of life based on appropriate protocols. (73 FR 28555, 28559) Section 164 of the MIPPA subsequently added care management requirements for all SNPs in an amendment to section 1859(f)(5) of the Act, outlining new requirements for an evidence-based model of care that include—(1) an appropriate network of providers and specialists to meet the specialized needs of the SNP target population; (2) a comprehensive initial health risk assessment (HRA) and annual reassessments; (3) an individualized plan of care containing goals and measurable outcomes; and (4) an interdisciplinary team to manage care. The MIPPA amendments to section 1859(f)(5) of the Act laid a statutory foundation for much of our regulatory standards for the model of care. In the September 2008 interim final rule with comment (73 FR 54226, 54228) and the January 2009 final rule (74 FR 1493, 1498), we finalized standards for the required model of care at § 422.101(f).

MOCs are a vital quality improvement tool and integral component for ensuring that the unique needs of each beneficiary enrolled in a SNP are identified and addressed. As we noted in the May 2008 proposed rule, CMS deliberately structured its guidance toward the conceptual

[154]The full 2010 Call Letter can be found here: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2010finalcallletter_03.30.09_59.pdf.

framework of a MOC without being prescriptive about the specific staff structure, provider network, clinical protocols, performance improvement, and communication systems. We expected SNPs to develop a MOC structure that allowed plans to develop care plans that addressed differing needs among members of the plan. For example, a C-SNP targeting diabetes mellitus may enroll a member with diabetic complications who is near the end of life and might require assisted living or institutional services for which the SNP would develop different goals, expanded specialty services and facilities in their provider network, different performance measures, and additional protocols that would inappropriate for enrollees in the C-SNP who have less severe health complications.

In addition to the requirements in § 422.107(f) for the MOC, CMS has issued guidance over the years, for both NCQA's use in reviewing and approving MOCs and SNPs' use in developing and implementing their MOCs. We believe that, in practice, MOCs are consistent with the existing guidance. The MOC is organized to promote clarity and enhance the focus on care coordination, care transition, care needs and activities. It is a vital quality improvement tool and integral component for ensuring that the unique needs of each enrollee are identified by the SNP and addressed through the plan's care management practices. The NCQA review and approval process is based on scoring each of the clinical and non-clinical elements of the MOC. Each element is comprised of a set of required subcomponents, or factors, such as an identification and comprehensive description of the SNP-specific population. These subcomponents are reviewed and scored by NCQA and contribute to the overall score for that element. A full list of elements and factors is in Chapter 5 of the MMCM. CMS also includes the list of elements as part of attachment A (or the MOC Matrix) of the "Initial and Renewal Model of Care Submissions and Off-cycle Submission of Model of Care Changes" PRA package (CMS-10565).[155] This MOC Matrix is released for public comment prior to the expiration of the

[155]The full MOC PRA package can be found here: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10565.

PRA package. We are proposing here to codify the SNP MOC scoring protocols by amending § 422.101(f)(3)(iii) to include the current subregulatory scoring protocols. This proposal, and these scoring protocols, align with the minimum benchmark for each element of the SNP MOC of a plan that is currently reflected at § 422.101(f)(3)(iii), as added by the January 2021 final rule. Our adoption of these scoring standards is authorized by section 1859(f)(7) of the Act for NCQA review and approval to be based on standards established by the Secretary and our authority in section 1856(b) of the Act to establish standards to carry out the MA program.

First, we are proposing to amend § 422.101(f)(3)(iii) to add the minimum overall score requirement for approval of a SNP's MOC, using the term aggregate minimum benchmark; we are proposing to use the same minimum standard for the aggregate minimum benchmark as is currently used by NCQA in reviewing and approving MOCs. Currently, SNP MOCs are approved for 1, 2, or 3-year periods. Each element of the SNP's submitted MOC is reviewed and scored. As provided in § 422.101(f)(3)(iii), the minimum benchmark for each element is 50 percent. The MOC is scored by NCQA based on the review of four elements: Description of the SNP Population; Care Coordination; SNP Provider Network; and MOC Quality Measurement & Performance Improvement. Each of these four elements has a number of sub-elements and factors to address the necessary scope and detail of the MOCs. Currently, each of the four SNP model of care elements is valued at 16 points. The aggregate total of all possible points across all elements equals 64, which is then converted to percentage scores based on the number of total points received. CMS provides additional information regarding MOC scoring criteria in Section 20.2.2 of Chapter 5 of the MMCM. In addition to the current element-level minimum benchmark regulatory requirement at § 422.101(f)(3)(iii), SNPs are also required to meet a minimum benchmark score for the aggregate total – otherwise known as the aggregate minimum benchmark. Currently, the aggregate minimum benchmark is 70 percent of the total 64 points. We are proposing to codify this current practice by amending § 422.101(f)(3)(iii) to add that, in addition to the current requirement that all SNPs must meet a minimum benchmark

score of 50 percent on each element, each SNP's MOC must meet an aggregate minimum benchmark of 70 percent. As reflected in the proposed revision to paragraph (f)(3)(iii), a SNP's model of care will only be approved if each element of the model of care meets the minimum benchmark and the entire model of care meets the aggregate minimum benchmark.

Second, we are proposing regulation text to address the period of approval for the MOCs that meet the aggregate minimum benchmark. We are proposing to codify at § 422.107(f)(3)(iii)(A) the requirement, from section 1859(f)(5)(B) of the Act, that C-SNP MOCs are annually reviewed and evaluated. Beginning in 2020, under the MOC review process, C-SNPs are only eligible to receive a MOC approval for 1-year and therefore are subject to annual review and approval processes. Specifically, we are proposing at paragraph (f)(3)(iii)(A) to codify that an MOC for a C-SNP that receives a passing score is approved for 1 year. We do not propose to apply the requirement for annual review and approval to the MOCs of all D-SNPs and I-SNPs. Instead, we are proposing, at new paragraph (f)(3)(iii)(B), to codify different approval permits for the MOCs of I-SNPs and D-SNPs that is based on the final score of the MOC on the aggregate minimum benchmark. We are proposing that: (1) an MOC for an I-SNP or D-SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years; (2) an MOC for an I-SNP or D-SNP that receives a score of 75 percent to 84 percent is approved for 2 years; and (3) an MOC for an I-SNP or D-SNP that receives a score of 70 percent to 74 percent is approved for 1 year. This proposed scoring process matches the current process NCQA uses to score initial and annual MOCs. We believe it is prudent to maintain the current scoring process as it has worked well to incentivize improvements in MOCs and strikes a balance with respect to the burden associated with reviews and approvals for all stakeholders by allowing higher scoring MOCs remain in place longer.

Third, we are proposing a new paragraph (f)(3)(iii)(C) to provide an opportunity for a SNP to cure deficiencies in its MOC if the MOC fails to meet the minimum element benchmark or the aggregate minimum benchmark when reviewed and scored by NCQA. Currently, the

review and evaluation process includes a second opportunity to submit an initial or renewal MOC, known as "the cure process." Regardless of the final score by NCQA of an MOC resubmitted using the cure process (provided the MOC has the minimum scores to be approved), SNPs that need to use the cure process to reach a passing aggregate minimum and/or minimum element benchmark score will receive only a 1-year approval under this proposal. This policy provides added incentive for SNPs to develop and submit comprehensive and carefully considered MOCs for initial NCQA approval and rewards those SNPs that have demonstrated ability to develop quality MOCs without requiring additional time. We are proposing that the opportunity to cure deficiencies in the MOC is only available once per scoring cycle for each MOC. Under this proposal, a MA organization that fails to meet either the minimum element benchmark for any MOC element or the aggregate minimum benchmark for the entire MOC after having an opportunity to cure deficiencies will not have its MOC approved. MOCs that do not receive NCQA approval after the cure review will not have a third opportunity for review. As a result, the SNP(s) that use that MOC would need to be nonrenewed by the MA organization or terminated by CMS for failure to meet a necessary qualification for SNPs.

We reiterate that this proposal would maintain the current scoring criteria and review process. We believe this proposal creates no additional burden to SNPs, as current MOCs are evaluated based on this criterion already. We welcome comment on the codification of existing MOC scoring requirements for SNPs. These new regulations would be applicable for MOCs reviewed for contract year 2024 and we will continue our current practice pending a final rule.

2. Amending SNP MOCs after NCQA Approval

CMS is proposing to codify current policies and procedures for an MA organizations to amend its MOCs after NCQA approval. CMS has labeled this the "off-cycle MOC submission process." CMS has acknowledged in the past that in order to more effectively address the specific needs of its enrollees, a SNP may need to modify its processes and strategies for providing care during the course of its approved MOC timeframe; CMS announced a process for

SNPs to submit MOC changes for review in the CY 2016 Final Call Letter.[156] Currently, a D-SNP or I-SNP that decides to make substantive revisions to their existing approved MOC may submit a summary of their off-cycle MOC changes, along with the red-lined MOC, in the Model of Care module in HPMS for NCQA review and approval. Substantive revisions are those that have a significant impact on care management approaches, enrollee benefits, and/or SNP operations. MOC changes are at the discretion of the applicable MA organization offering the SNP and it is the responsibility of the MA organization to notify CMS of substantive changes and electronically submit their summary of changes to their MOC in HPMS. Beginning with CY 2020, C-SNPs are required to submit MOCs annually, and thus, their MOCs receive approvals for a period of one-year. Upon implementation the annual review and approval of C-SNP MOCs, C-SNPs were not permitted to submit a revised MOC through an off-cycle submission.

At the time of the CY 2016 Final Call Letter, based on our previous experience with the small number of SNPs seeking to amend their MOCs, we expected that mid-cycle amendments to MOCs would be relatively rare and CMS did not anticipate that the off-cycle process would result in a higher incidence of such MOC changes. We believed that only relatively unusual circumstances would require SNPs to make changes to their MOCs that are so significant that notification to CMS and review of the changes to the MOC would be warranted. However, CMS and NCQA have seen the number of off-cycle MOC submissions steadily rise over the past four years and plans have expressed frustration and confusion over what plan changes merit or require submission to NCQA for an off-cycle approval. This proposed rule is intended to address stakeholder feedback regarding the off-cycle review process and to mitigate the SNP community's concerns regarding continued plan burden in this area.

In general, CMS intends the MOC review and approval process to include an MA organization's submission of a MOC only in the following scenarios: the MA organization seeks

[156]See https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2016.pdf.

to offer a new SNP; the MA organization's SNP's MOC approval period ends; or CMS deems revision and resubmission of the MOC necessary to ensure compliance with the applicable standards and requirements, such as a change in applicable law or when CMS discovers a violation. For the last scenario, an off-cycle MOC submission may be necessary if during an audit, it appears that the MOC (including in practice as the SNP applied the MOC) is not meeting applicable standards, then CMS may ask the SNP to correct and resubmit the MOC. Other examples include regulatory changes or when a State Medicaid agency requires changes to the MOC of a D-SNP to meet State-specific requirements. In order to ensure a stable care management process and to ensure appropriate oversight by CMS of SNPs and their operation, SNPs may not implement any changes to a MOC until NCQA has approved the changes. Based on our experience, additional situations may justify the submission of a revised MOC for review and approval. This proposal would establish when an MA organization may submit updates and corrections to its approved MOC.

First, we are proposing to codify the off-cycle process at § 422.101(f)(3)(iv). We propose that MA organizations offering SNPs that need to revise their MOC mid-cycle during their MOC approval period may submit the revised MOC for review by NCQA at specific times. CMS has historically restricted the period that SNPs can submit an off-cycle submission from June 1st to November 30th of any contract year, which is meant to allow for the efficient and prudent administration of the annual initial and review MOC process—with the exception of C-SNPs who are prohibited from submitting off-cycle submissions because of the requirement that plans submit their MOC annually. However, CMS has also allowed SNPs to submit off-cycle MOCs outside of this window when CMS deems it necessary to ensure the SNP or its MOC was meeting statutory or regulatory requirements, guarantee the safety of enrollees, or meet State Medicaid requirements. We propose to maintain this process and codify it at § 422.101(f)(3)(iv)(A). We propose that SNPs may submit updates and corrections to their NCQA-approved MOC between June 1st and November 30th of each calendar year or when

CMS deems it necessary to ensure compliance with applicable standards and requirements. We intend the phrase "applicable standards and requirements" to encompass the situations described here in the preamble or similar situations where a potential or existing violation needs to be addressed. To ensure consistent application of this standard and demonstrate our intent that these be limited situations where a revision is truly necessary, the proposed regulation text is clear that CMS will make this determination and provide directions to the MA organization. If an MA organization believes that this standard in which revision is necessary to ensure compliance by the SNP and its MOC, we anticipate that the MA organization will contact CMS for guidance and approval to submit a revision.

Since the beginning of the off-cycle submission process, CMS has attempted to provide guidance clarifying which MOC changes require submission to CMS and how SNPs should submit their MOC changes to CMS. We have said in the past that SNPs that make significant changes to their MOCs must submit (in HPMS) a summary of the pertinent modifications to the approved MOC and a redlined version of the approved MOC with the revisions highlighted. Given the level of questions we have received over the years regarding what constitutes a significant change, we are proposing to codify a list of reasons for when a SNP must use an off-cycle submission of a revised MOC for review and approval. Proposed § 422.101(f)(3)(iv)(B) provides that an MA organization must submit updates or corrections to a SNP's MOC to reflect the following:

- Changes in policies or procedures pertinent to:

++ The health risk assessment (HRA) process;

++ Revising processes to develop and update the Individualized Care Plan (ICP);

++ The integrated care team process;

++ Risk stratification methodology; or

++ Care transition protocols;

- Target population changes that warrant modifications to care management approaches or changes in benefits. For example, we intend this to include situations like adding Diabetes to a Cardiovascular Disease and Congestive Heart Failure C-SNP;
- Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations. For example, changes in Medicaid services covered by a HIDE SNP or FIDE SNP through its companion Medicaid managed care plan or changes in Medicaid policy (such as benefits or eligibility) that require changes to an ICP for coordinating Medicare and supplemental benefits with the new Medicaid policy;
- Changes in level of authority or oversight for conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel);
- Changes to quality metrics used to measure performance.

The proposed regulation text does not include immaterial examples of the type and scope of MOC policy changes that may be made by an MA organization to the SNP's approved MOC without any review or approval by CMS or NCQA. Changes that do not need to be submitted through HPMS include:

- Changes in legal entity, parent organization, and oversight (novation/mergers, changes to corporate structure);
- Changes to delegated providers and agreements;
- Changes in administrative staff, types/level of staff that do not affect the level of authority or oversight for personnel conducting care coordination activities;
- Updates on demographic data about the target population;
- Updates to quality improvement metric results and technical quality measure specification updates;
- Additions/deletions of specific named providers;
- Grammatical and/or non-substantive language changes; and

- For D-SNPs, minor changes to Medicaid benefits.

Under this proposal, we are adding a requirement to a new subparagraph D under § 422.101(f)(3)(iv) that SNPs may not implement any changes to a MOC until NCQA has approved the changes. In addition, NCQA will continue to review the summary of changes and a redlined copy of the revised MOC submitted in HPMS to verify that the revisions are consistent with the previously detailed list of applicable submissions and in line with acceptable, high-quality standards, as included in the original, approved MOC. The revised MOCs will not be rescored. Further, the MOC's original approval period (that is, 1-year or multi-year) will not be modified as a result of NCQA's approval of the changes. We propose to codify this policy at § 422.101(f)(3)(iv)(E), which provides that the successful revision of the MOC under proposed (f)(3)(iv) does not change the MOC's original period of approval by NCQA. Therefore, changes made to MOC cannot be used to improve a low score. We anticipate that the current procedures and documentation processes will continue; such procedures and operational practices do not need to be in regulation text. CMS may change procedures as necessary (for example, use of HPMS as the system for submission, the mechanism for providing notice to MA organizations of the review of the MOC initially or any revisions, etc.). We intend that the current procedures will continue for NCQA reviewers to designate the summary as "Acceptable" or "Non-Acceptable," and enter the findings in the HPMS character text box. Similarly, we will continue the current process in which a system-generated email is sent to the designated SNP Application Contact and the MA Quality Contact, as well as to the individual who submitted the revised MOC summary. Lastly, we are proposing under § 422.101(f)(3)(iv)(F) to codify existing operational practices with respect to off-cycle submissions by C-SNPs. Currently, C-SNPs are prohibited from submitting off-cycle MOC submissions, as all C-SNPs submit MOCs annually as required under section 1859(f)(5)(B)(iv) of the Act. We are proposing to codify that C-SNPs are prohibited from submitting an off-cycle MOC submission except when CMS requires an off-

cycle submission to ensure compliance with the applicable regulations. C-SNPs must wait until the annual MOC submission period to make changes to their MOC.

SNPs have one opportunity to correct ("cure") deficiencies, as noted in our proposed rule § 422.101(f)(3)(iii)(C) to confirm that the revised MOC is consistent with the standards outlined in the original MOC. If NCQA determines that revisions to an initial or renewal MOC, as delineated in the MOC summary, do not reflect the quality standards as demonstrated by the original MOC and its associated score/approval period, the SNP will be notified via email with a "Non-Acceptable" determination and a list of all deficiencies. If the summary and redlined version is not acceptable after the second review, the SNP must continue implementing its approved MOC without any revisions for the remainder of its MOC approval period. The proposed MOC off-cycle cure process at § 422.101(f)(3)(iv) differs from the review and scoring process being codified § 422.101(f)(3)(iii). The review process employed under § 422.101(f)(3)(iii) provides a one-time cure process. Likewise, the cure process proposed (and under current operational use by NCQA) would allow D-SNPs and I-SNPs to resubmit a single revised off-cycle submission or cure until the end of the Off-cycle submission period to an Off-cycle MOC that was deemed unacceptable during the off-cycle review process. We are proposing to codify this policy of a single cure opportunity during the off-cycle time period under a new paragraph at § 422.101(f)(3)(iv)(G)

We have also found that SNPs have sought to modify an initial or renewal MOC shortly after NCQA approval and before the MOC has gone into effect. We have generally rejected these submissions because the MOC has yet to go into effect. We will continue to prohibit an off-cycle submission until the approved MOC has gone into effect. For example, if NCQA approved a SNP's MOC on April 1, 2022, the plan would be prohibited from submitting an off-cycle submission until the effective date of the MOC, which would be January 1, 2023.

In order clarify this process, we are proposing to codify this guidance at § 422.101(f)(3)(iv)(C). We propose that NCQA will only review off-cycle submissions after the

start of the effective date of the current MOC unless it is deemed necessary to ensure compliance with the applicable regulations or State Medicaid agency requirements for D-SNPs. Finally, we reiterate that we still believe that off-cycle submissions to substantively revise an MOC should be a rare occurrence rather than an eventuality. We believe that these proposed processes and procedures will make certain that CMS and NCQA are apprised of up-to–date information regarding the MOC; strengthen our ability to adequately monitor the approved MOCs; and guarantee that SNPs continue to provide high quality care to enrollees. We seek comment on the codification of the current off-cycle MOC submission process.

The proposed regulations described here reflect and would codify current policy and procedures. While this proposed rule as a whole is generally intended to be applicable beginning with contract year 2024, we intend to continue our current policy as reflected here. We also believe the following proposed changes carry no burden. This proposal is a codification of previously issued subregulatory guidance in Chapter 5 and other CMS transmittals to impacted MA organizations. More importantly, the current proposed codification is already captured under the PRA package "Initial and Renewal Model of Care Submissions, and Off-cycle Submission of Summaries of Model of Care Changes (CMS-10565, OMB 0938-1296). As part of the PRA approval package, CMS reviews public comments directed towards the initial and renewal MOC process, MOC trainings, and the off-cycle MOC submission system. Again, the burden effort associated with this proposed rule covering the latter items is captured in the currently approved MOC PRA.

Based on our experience monitoring SNPs and engaging in the process for review and approval of MOCs, we believe plans are following the our current subregulatory guidance and therefore no further burden is imposed by codifying these standards.

G. Clinical Trial-Related Provisions (§§ 422.101 and 422.109)

MA plans must cover Medicare Part A and Part B benefits, excluding hospice, kidney acquisitions for transplant, and certain changes in benefits due to a National Coverage

Determination (NCD) or a legislative change. We are proposing to adopt regulations regarding MA coverage of clinical trials covered by Medicare to ensure clarity on these coverage rules for MA plans. These coverage rules implement section 1852 of the Act and are within our rulemaking authority for the MA program. These proposals generally codify guidance currently specified in section 10.7 of Chapter 4 of the Medicare Managed Care Manual for clinical trials covered under National Coverage Determination (NCD) 310.1; A and B investigational device trials (A-B IDE); and National Coverage Determinations with coverage with evidence development (NCD-CED).

1. Clinical Trials Under National Coverage Determination 310.1

Clinical trials may include some items and services that would not be covered by Medicare, absent the trial. For clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD) (NCD manual, Pub. 100-03, Part 4, section 310), longstanding CMS policy has been that traditional Medicare (that is, the Medicare FFS program) covers the routine costs of qualifying clinical trials for all Medicare enrollees who volunteer to participate in the approved trial, including those enrolled in MA plans. CMS has discussed this policy in several Advance Notices and Rate Announcements, including the advance notices of methodological changes in Part C payments issued for 2004, 2007, 2008, 2009, 2011, 2017, and 2019, and in the announcements of capitation rates and payment policies for Part C in 2009, 2011, 2012, and 2017. NCD 310.1 is the current statement of the Medicare coverage of routine costs associated with clinical trial participation. As specified in the NCD, routine costs associated with a clinical trial include:

- Items or services that are typically provided by Medicare absent a clinical trial (for example, conventional care);
- Items or services required solely for the provision of the investigational item or service (for example, administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

Although MA plans must follow all NCDs, section 1852(a)(5) of the Act, which CMS has implemented in § 422.109(b), provides that if an NCD or new legislative benefit introduced in the middle of a plan year is considered a significant cost as determined by the Office of the Actuary, MA plans are not responsible for coverage until the cost to provide the new benefit is calculated into the plan's payment rate. CMS has previously determined, as discussed in the CY 2019 Advance Notice,[157] that the multiple clinical trials covered under NCD 310.1 trigger the significant cost threshold. Therefore, traditional Medicare has covered the Medicare-covered routine costs of clinical trials that are covered under NCD 310.1 for MA enrollees. To ensure continued clarity and transparency for this longstanding policy, discussed in section 10.7.1 of Chapter 4 of the Medicare Managed Care Manual, we are proposing to codify this policy by adding new § 422.109(e). In § 422.109(e)(1), we propose to codify that traditional Medicare is responsible for coverage of routine costs of qualifying clinical trials for MA enrollees for clinical trials covered under the Clinical Trials National Coverage Determination 310.1 and all reasonable and necessary items and services used to diagnose and treat complications from participating in clinical trials.

Deductibles and MA responsibility for differences in cost-sharing

Traditional Medicare pays for all routine costs of clinical trials for MA enrollees and, as explained in the CY 2011 Rate Announcement,[158] MA enrollees do not pay the traditional Medicare Part A and B deductibles when the traditional Medicare pays the Medicare-covered

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[157]The Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter discusses the clinical trial coverage policy for the MA program on pages 23-23 and is available at this link: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf.

[158]The Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter addresses this in a response to a comment on page 20-21 and is available at the following link: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2011.pdf.

costs associated with the clinical trial.[159] In § 422.109(e)(2), we propose to codify this policy that MA enrollees participating in clinical trials are not subject to Part A and B deductibles.

MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services. We propose to codify this requirement for MA plans to pay the difference between traditional Medicare and plan's cost sharing in § 422.109(e)(3). We also propose in § 422.109(e)(4) to codify that the enrollee's in-network cost-sharing portion must be included in the plan's maximum out-of-pocket (MOOP) calculation. As the clinical trial costs within the scope of NCD 310.1 are covered by Part A and/or Part B, these are basic benefits within the scope of the MOOP requirements in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) but for clarity we are proposing to codify at § 422.109(e)(4) the requirement that the enrollee's in-network cost-sharing must be included in the plan's MOOP calculation. In requiring MA organizations to provide in-network cost sharing for clinical trial services, CMS is requiring that MA plan members have coverage for clinical trial services that is consistent with coverage they have for all other Medicare Part A and Part B services. In paragraph (e)(5), consistent with our guidance in section 10.7.1 of Chapter 4 of the Medicare Managed Care Manual, we would specify that MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial under NCD 310.1. This protection is necessary in order to ensure that MA enrollees have access to and coverage of clinical trials within the scope of NCD 310.1 to the same extent as Medicare beneficiaries enrolled in the traditional Medicare program. While MA plans are responsible for covering any differences in cost-sharing between traditional Medicare and MA plan in-network costs for services in the same category, traditional Medicare, through the MACs, is responsible

[159]In addition, the See page 31 of the MA Payment Guide for Out of Network Payments, page 31, addresses this topic. The guide is available at the following link: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf.

for all other costs included in clinical trials within the scope of NCD 310.1. Finally, in accordance with § 422.109(c)(2), CMS requires MA organizations to provide coverage for: 1) services to diagnose conditions covered by clinical trial services; 2) most services furnished as follow-up care to clinical trial services; and 3) services already covered by the MA organization. Because § 422.109(c) adequately addresses how MA organizations are required to cover certain benefits and costs even when the traditional Medicare program pays for changes in benefits as a result of an NCD or legislative change, we do not believe that additional regulation text is necessary to apply those rules in the context of NCD 310.1.

2. A-B Investigational Device Exemption Trials

The regulation at § 405.211 specifies Medicare coverage of Category A and B investigational device exemption (IDE) studies. Providers of device trials must submit approval for the devices from the FDA, as part of their application to CMS for approval of a trial. Once a trial has been approved by CMS, it is listed on the CMS website. In addition to including assessment of devices, IDE trials differ from clinical trials under NCD 310.1, as they are not covered as a result of an NCD nor are they subject to a significant cost assessment. As a result, MA organizations are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered under traditional Medicare. This is part of the MA organization's obligation to cover the items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B for their enrollees under section 1852 of the Act.

MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. An MA plan is also responsible for coverage of CMS-approved Category B devices. While CMS will cover routine care items and services, it will not approve coverage of Category A devices themselves because they are considered experimental and excluded from coverage under § 405.211(a). As with other benefits for which it

is responsible for coverage, an MA plan may apply utilization management, including prior authorization, consistent with § 422.4(a)(1)(ii).

Section 10.7.2 of Chapter 4 of the Medicare Managed Care Manual addresses this policy. In order to clarify this scope of required coverage for MA plans and avoid any inadvertent confusion between the coverage requirements associated with clinical trials under NCD 310.1, we propose to add § 422.109(f) to specify MA plan coverage of the routine items and services, including the Category B IDE device and related items and services in the context of a Category A and B IDE studies, that are covered by Medicare under §§ 405.211(a) and (b).

3. National Coverage Determinations with Coverage with Evidence Development

Section 1852(a)(1) of the Act requires MA plans to cover all Medicare Part A and Part B benefits, subject to limited exclusions. One of those exclusions relates to new NCDs that result in significant cost increases, making it clear that benefits covered under an NCD are included in what MA plans must cover. In addition, § 422.101(b)(1) explicitly requires MA plans to cover NCDs. (See section III. E. of this document, Utilization Management Requirements, for more information on CMS' proposal to address MA plan coverage obligations.) NCDs generally provide guidance about coverage of new benefits, update an existing benefit or, in some cases, specify that a procedure or service is not covered. As with other Part A and B benefits (aside from hospice and the cost of kidney acquisition for transplant), MA plans must cover NCDs. This is true for NCDs that also have a trial or registry component that is required as part of the coverage, which is explained in section 10.7.3 of Chapter 4 of the Medicare Managed Care Manual. This is referred to as "coverage with evidence development" (CED), as authorized under the statute at 1862(a)(1)(E). CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of CMS approved clinical studies or with the collection of additional clinical data (for example, registry). A list of NCD-CEDs

with the coverage protocol for each is available at:

https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development

We are merely reiterating here that MA plans must cover NCDs with CED and are not proposing a change in policy. We solicit comment whether additional regulations are needed to address NCDs with CED; we believe that § 422.101(b) is sufficient that these NCDs are within the scope of the traditional Medicare benefits that MA plans must cover and that additional regulations are unnecessary. MA plans may apply utilization management, including prior authorization, to the Medicare benefits covered under these NCDs, consistent with § 422.4(a)(1)(ii) of the MA program regulations.

Significant Cost

In cases of a new NCD or legislative change in benefits, CMS determines, consistent with § 422.109(b), whether the benefit or service is a significant cost to MA plans. CMS is including this discussion here to make clear that significant cost requirements apply to all new NCDs, that is, that the significant cost assessment includes NCDs with CED. The thresholds for significant cost are specified in §§ 422.109(a)(1) and (a)(2). The assessment generally applies to each NCD or legislative change in benefits that occurs after the rate announcement for a contract year such that the change in costs was not incorporated into the capitation rates for the contract year. Costs are estimated for a particular NCD or legislative change in benefits so the thresholds specified in §§ 422.109(a)(1) and (a)(2) apply to each NCD or legislative change in benefits rather than to the aggregate number of such changes over the course of a contract year.

H. Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§ 422.60 and 423.32)

Sections 1851(c)(1) and 1860D-1(b)(1) of the Act establish the enrollment, disenrollment, termination, and change in coverage processes for MA and PDP plans. In the June 1998 interim final rule, we established the M+C (now MA) enrollment process (63 FR 34968). These requirements are codified in regulation at § 422.60. In the January 2005 Part D final rule, we established the PDP enrollment process (70 FR 4193). These requirements are codified in regulation at § 423.32.

Section 1851(g)(3)(B)(i) of the Act provides that MA plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums on a timely basis; likewise, section 1860D-1(b)(1)(B)(v) of the Act directs the Secretary to use rules similar to (and coordinated with) the rules for an Medicare Advantage plan established under section 1851(g) of the Act. CMS has previously codified this process of optional disenrollment from an MA plan or PDP for failure to pay monthly premiums at §§ 422.74(d) and 423.44(d), as well as requirements for mandatory disenrollment for individuals who fail to pay the Part D Income Related Monthly Adjustment Amount (Part D-IRMAA), where applicable, at § 423.44(e). In addition, CMS has previously codified the ability for MAOs and PDP sponsors to reinstate for good cause an individual who is disenrolled for failure to pay plan premiums (at §§ 422.74(d)(1)(v) and 423.44(d)(1)(vi)) or the Part D-IRMAA (at § 423.44(e)(3)).

However, an individual's enrollment can also be reinstated if their enrollment in another plan is subsequently canceled within timeframes established by CMS. We established at § 422.66(b)(1) that an individual is disenrolled from their MA plan when they elect a different MA plan; likewise, at § 423.36(a), an individual is disenrolled from their PDP plan when they enroll in a different PDP plan. Sub-regulatory guidance requires MA and PDP plans to provide notification of enrollment reinstatement based on a beneficiary's cancellation of a new enrollment in a different plan. This guidance is currently outlined in the Part C and Part D sub-

regulatory guidance found in section 60.3.2 of Chapter 2 of the Medicare Managed Care Manual and section 60.2.2 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, respectively.

To provide transparency and stability for stakeholders, we are proposing at new §§ 422.60(h) and 423.32(h) to require that MA and PDP plans must notify an individual when the individual's enrollment is reinstated due to the individual's cancellation of enrollment in a different plan. A reinstatement is generally not allowed if the individual intentionally initiated a disenrollment and did not cancel the disenrollment prior to the disenrollment effective date. However, when a beneficiary is automatically disenrolled from their plan because of enrollment in a new plan but then cancels the request to enroll in the new plan within established timeframes, the associated automatic disenrollment from the previous plan becomes invalid. Therefore, the beneficiary's enrollment in the previous plan needs to be reinstated and CMS systems will attempt to automatically reinstate enrollment in the previous plan. Consistent with notification requirements in similar enrollment scenarios, we propose that the organization from which the individual was disenrolled send the member notification of the enrollment reinstatement within 10 days of receipt of Daily Transaction Reply Report (DTRR) confirmation of the individual's reinstatement. The reinstatement notice would include confirmation of the individual's enrollment in the previous plan with no break in coverage, plan-specific information as needed, and plan contact information.

These proposed changes represent the codification of longstanding guidance. Based on infrequent complaints and questions from plans and beneficiaries related to current requirements, we conclude that the requirements have been previously implemented and are currently being followed by plans. There is also no impact to the Medicare Trust Fund.

I. Part D Plan Failure to Submit Disenrollment Timely (§ 423.36)

Section 1860D-1(b) of the Act establishes the disenrollment process for Part D eligible individuals in prescription drug plans. This section of the Act grants the Secretary the authority to establish a process for the enrollment, disenrollment, termination, and change of enrollment of

Part D eligible individuals in prescription drug plans. In 2005, the implementing regulations at 70 FR 4525 established the voluntary disenrollment process for Part D prescription drug plans. These requirements are codified in regulation at § 423.36 and require the Part D sponsor to "submit a disenrollment notice to CMS within timeframes CMS specifies."

As previously noted, section 1860D-1(b)(1)(B) of the Act directs the Secretary to adopt enrollment rules "similar to (and coordinated with)" the rules established under Part C. In 1998 implementing regulations for Part C, CMS provided that if a "Medicare + Choice" (M+C) organization, later known as an MA organization, fails to submit the correct and complete notice of disenrollment, the M+C organization must reimburse the Health Care Finance Administration (the predecessor to CMS), for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely (63 FR 35071). This requirement was codified at § 422.66(b)(4) and has remained in place for MA organizations. Current Part D regulations do not impose requirements for Part D sponsors that fail to submit the transaction notice to CMS timely. However, longstanding CMS policy has provided that the PDP sponsor must submit disenrollment transactions to CMS in a timely manner, as described in section 50.4.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. When a valid request for disenrollment has not been communicated to CMS successfully within the required timeframes, a retroactive disenrollment can be submitted to CMS. If the retroactive disenrollment request is approved, the PDP sponsor must return any premium paid by the member for any month for which CMS processed a retroactive disenrollment, and CMS will retrieve any capitation payment for the retroactive period for an approved request for retroactive disenrollment, as described in section 60.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. To provide transparency and consistency for stakeholders, and align the Part D regulation with the requirements for MA organizations, we propose to codify CMS's longstanding sub-regulatory guidance by amending § 423.36 to add a new paragraph (f) to reflect that if the Part D sponsor fails to submit a disenrollment notice to CMS timely as required by

§ 423.36(b)(1), such that the Part D sponsor receives additional capitation payments from CMS, the Part D sponsor must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

This proposal is a codification of longstanding Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. As these policies have been previously implemented and are currently being followed by plans, we conclude that there is no additional paperwork burden. All information impacts related to our collection of disenrollment requests have already been accounted for under OMB control number 0938-0964 (CMS-10141).

J. Codify Existing Policy "Incomplete Disenrollment Requests" (§§ 422.66 and 423.36)

Section 1851(c)(2)(B) of the Act provides that an individual who elects an MA plan and then chooses to terminate such election can do so by submitting a request to the MA organization. In addition, section 1860D-1(b)(1)(B)(ii) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall use rules similar to (and coordinated with) the rules for an Medicare Advantage (MA) – formerly M+C – plan established under section 1851(c) of the Act.

The June 1998 final regulation established the process for individuals to voluntarily disenroll from an MA plan. This process is codified at § 422.66(b). Specifically, at § 422.66(b)(2) we provide that a disenrollment request is considered to have been made on the date the disenrollment request is received by the MA organization. Once received, the MA organization is required to send the disenrollment notice to CMS and a copy to the enrollee which informed the enrollee of any lock-in requirements of the plan that apply until the effective date of disenrollment. This process is codified at § 422.66(b)(3), including the requirement that the MA plan must file and retain the disenrollment request as specified in CMS instructions.

In 2005, CMS issued implementing regulations establishing disenrollment procedures for Part D plans, whereby an individual elects to voluntarily disenroll from the Part D plan, and also

established the requirements imposed upon the Part D sponsor as a result of that disenrollment request (63 FR 35071). These requirements were codified at § 423.36.

However, §§ 422.66(b) and 423.36 do not address what plans should do in the event that they receive incomplete disenrollment requests. CMS has historically provided the procedural steps for plans to address incomplete disenrollment requests, in section 50.4.2, Chapter 2 of the Medicare Managed Care Manual and section 50.4.2, Chapter 3 of the Medicare Prescription Drug Benefit Manual, including providing that when the disenrollment request is incomplete, plans must document its efforts to obtain information to complete the request; and if any additional information needed to make the disenrollment request "complete" is not received within prescribed timeframes, the plan must deny the disenrollment request .

To provide transparency and stability for stakeholders about the MA and Part D programs and about the requirements applicable to requests for voluntary disenrollment from MA and Part D plans, we are proposing to codify CMS's longstanding policies in this area at new paragraphs § 422.66(b)(6) and 423.36(d) that a disenrollment request is considered to be incomplete if the required but missing information is not received by the MA plan or Part D sponsor within the specified timeframes in proposed §§ 422.66(b)(3)(v)(C) and 423.36(b)(4)(iii), as described in this rule. We are also proposing at new paragraphs §§ 422.66(b)(3)(v) and 423.36(b)(4) that if the disenrollment request is incomplete, the plan must document its efforts to obtain information to complete the election. Plans would be required to notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request. For incomplete disenrollment requests received by plan sponsors during the annual election period (AEP), we are proposing information to complete the request must be received by December 7, or within 21 calendar days of the plan sponsor's request for additional information, whichever is later. For all other election periods, we are proposing that required information must be received by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later. Finally, we are proposing that if any additional

information needed to make the disenrollment request complete is not received within these timeframes, the disenrollment request must be denied.

We are codifying longstanding guidance with these changes. All information impacts related to the procedural steps plans must take to address incomplete disenrollment requests have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D. Based on infrequent questions from MA organizations and Part D plan sponsors as these requirements have been previously implemented and are currently being followed by plans, we conclude that these updates do not add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

K. Reinstatement of Enrollment for Good Cause (§§ 417.460, 422.74 and 423.44)

As previously noted, sections 1851(g)(3)(B)(i) and 1860D-1(b)(1)(B)(v) of the Act provide that MA and Part D plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums on a timely basis. In addition, section 1860D–13(a)(7) of the Act mandates that individuals with higher incomes pay an additional premium, the Part D IRMAA, for the months in which they are enrolled in Part D coverage.

Consistent with these sections of the Act, the MA and Part D subpart B regulations set forth our requirements with respect to involuntary disenrollment procedures under §§ 422.74 and 423.44, respectively. Pursuant to §§ 422.74(d)(1)(i) and 423.44(d)(1), an MA or Part D plan that chooses to disenroll beneficiaries for failure to pay premiums must be able to demonstrate to CMS that it made a reasonable effort to collect the unpaid amounts by notifying the beneficiary of the delinquency, providing the beneficiary a period of no less than two months in which to resolve the delinquency, and advising the beneficiary of the termination of coverage if the amounts owed are not paid by the end of the grace period. Further, as outlined in § 423.44(e), CMS involuntarily disenrolls individuals from their Part D coverage for failure to pay Part D-IRMAA following an initial grace period of 3 months.

Current regulations at § 417.460(c) specify that an HMO or competitive medical plan (cost plan) may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. While there is not a grace period parallel to the grace period required by the MA and Part D regulations, the requirements for cost plans are otherwise similar. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount and send the enrollee written notice of the disenrollment prior to transmitting the disenrollment to CMS.

The final rule, titled "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes" which appeared in the **Federal Register** on April 15, 2011 (76 FR 21431) amended both the Parts C and D regulations at §§ 422.74(d)(1)(v), 423.44(d)(1), and 423.44(e)(3) regarding involuntary disenrollment for non-payment of premiums or Part D-IRMAA to allow for reinstatement of the beneficiary's enrollment into the plan for good cause. The good cause provision established that CMS can reinstate enrollment of a disenrolled individual's coverage in certain circumstances where the non-payment of premiums was due to a circumstance that the individual could not reasonably foresee and could not control, such as an extended period of hospitalization. In the final rule titled "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes" which appeared in the **Federal Register** on April 12, 2012 (77 FR 22071), we extended the policy of reinstatement for good cause to include beneficiaries enrolled in cost plans in § 417.460(c)(3), thus aligning the cost plan reinstatement provision with the MA and Part D plan provisions. In the final rule titled "Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" which appeared in the **Federal Register** on February 12, 2015 (80 FR 7911), we amended § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi) to permit an entity acting on behalf of CMS, such as an MA organization, Part D sponsor, or entity offering a cost plan, to

effectuate reinstatements for beneficiaries disenrolled for nonpayment of plan premium when good cause criteria are met.

To provide transparency to stakeholders, we are proposing to codify our current policy for MA organizations, Part D sponsors, or entities offering cost plans, as set out in sub-regulatory guidance in section 60.3.4 of Chapter 2, Medicare Managed Care Manual, section 60.2.4 of Chapter 3, Medicare Prescription Drug Benefit Manual and section 60.6.3 of Chapter 17-D, Medicare Managed Care Manual, that reinstatement for good cause, pursuant to §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi), will occur only when the individual requests reinstatement within 60 calendar days of the disenrollment effective date and that an individual may make only one reinstatement request for good cause in this 60-day period. Specifically, CMS is proposing to amend §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi) to provide that the disenrolled individual must request reinstatement within 60 calendar days of the disenrollment effective date and has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment. These proposed changes represent the codification of longstanding guidance. Based on infrequent questions or complaints from plan sponsors and beneficiaries, and a lack of reported instances of noncompliance regarding the 60-day timeframe, as these requirements have been previously implemented and are currently being followed by plan sponsors, we conclude that the proposed changes to the regulatory text will not adversely impact plan sponsors or individuals disenrolled for nonpayment of plan premium who choose to request reinstatement for good cause, nor would the proposed changes have any impact to the Medicare Trust Funds or result in a paperwork burden.

L. Required Notices for Involuntary Disenrollment for Disruptive Behavior (§§ 417.460, 422.74 and 423.44)

Section 1851(g)(3)(B)(ii) of the Act authorizes an MA organization to disenroll individuals that engage in disruptive behavior. Section 1860D–1(b)(1)(B)(v) of the Act

generally directs us to establish rules related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851(g) of the Act. Section 1876 of the Act sets forth the rules for Medicare cost plan contracts with HMOs and competitive medical plans (CMPs). In implementing regulations which appeared in the **Federal Register** on September 1, 1995 (60 FR 45678), we established at § 417.460(e) the basis for HMOs and CMPs to disenroll individuals for disruptive, unruly, abusive, or uncooperative behavior. In implementing regulations which appeared in the **Federal Register** on June 26, 1998 (63 FR 35071), we established at § 422.74 the conditions for MA organizations (referred to M+C organizations at the time) to disenroll individuals for disruptive behavior. Additionally, the regulations established the requirement for a final notice to the beneficiary of the submission of the disenrollment, which applies to disruptive behavior disenrollments, at § 422.74(c). The optional basis for disenrollment for disruptive behavior was established at § 422.74(b)(1)(ii). The general standards defining disruptiveness were established in § 422.74(d)(2).

In January 2005, we published a final rule that revised the definition for disruptive behavior at § 422.74(d)(2) (70 FR 4718), with the purpose of creating an objective definition that did not use the previously subjective terms such as “unruly” or “abrasive.” The current, objective definition from the January 2005 MA final rule both defines disruptive behavior and establishes the required process for an MA plan to request disenrollment of a disruptive individual. In January 2005 we also published the Part D implementing regulation (70 FR 4525), where we established the conditions for a PDP sponsor to disenroll an individual for disruptive behavior. We established the basis for optional disenrollment for disruptive behavior at § 423.44(b)(1)(ii). We also established the definition of disruptive behavior and disenrollment process as it exists currently at § 423.44(d)(2). In the January 2005 Part D final rule, we also established the requirement for a final notice of the submission of the disenrollment transaction, which applies to disruptive behavior disenrollments, at § 423.44(c).

Under CMS's current MA and Part D regulations, disruptive behavior is defined as behavior by the plan enrollee that substantially impairs the plan's ability to arrange for or provide services for the individual or other plan members (§§ 417.460(e)(1); 422.74(d)(2)(i); 423.44(d)(2)(i)). The process for disenrolling an enrollee for disruptive behavior requires approval by CMS before the disenrollment may be submitted (§§ 417.460(e)(5); 422.74(d)(2)(v); 423.44(d)(2)(v)). MA organizations, Part D sponsors, and cost plans must make serious efforts to resolve the problem considering any extenuating circumstances; for MA organizations, cost plans, and Part D sponsors this includes providing reasonable accommodations for those beneficiaries with mental or cognitive conditions (§§ 417.460(e)(2) and (3); 422.74(d)(2)(iii); 423.44(d)(2)(iii)). MA organizations, Part D sponsors, and cost plans must also document the beneficiary's behavior and the plan's own efforts to resolve the issue, and this record must be submitted to CMS before disenrollment can be approved (§§ 417.460(e)(4) and (5); 422.74(d)(2)(iv) and (v); 423.44(d)(2)(iv) and (v)). The current definition of disruptive behavior in §§ 417.460(e)(1), 422.74(d)(2), and 423.44(d)(2) served as the basis for CMS's current sub-regulatory guidance found in Chapter 2, section 50.3.2, of the Medicare Managed Care Manual and Chapter 3, section 50.3.2, of the Medicare Prescription Drug Benefit Manual and Chapter 17D, section 50.3.3, of the Medicare Managed Care Manual. In guidance, we outline member notices that an MA organization, Part D sponsor, and cost plans must send before requesting permission from CMS to involuntarily disenroll the member.

To provide transparency to stakeholders and stability as to the operation of the program, we are proposing to codify current policy for MA, Part D, and cost plan notices during the disenrollment for disruptive behavior process. These notices provide the beneficiary with a warning of the potential consequences of continued disruptive behavior. In a new proposed paragraph, a § 422.74(d)(2)(vii), we propose to codify existing policy currently set out in sub-regulatory guidance regarding MA plan notices prior to a member disenrollment for disruptive behavior. To request approval of a disenrollment for disruptive behavior, an MA organization

would be required to provide two notices: (1) an advance notice, informing the plan member that continued disruptive behavior could lead to involuntary disenrollment; and (2) a notice of the plan's intent to request CMS permission to disenroll the member, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 422.74(c). We are also proposing to revise the existing requirement at § 422.74(d)(2)(iii) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (d)(2)(vii). Additionally, as proposed in additions to § 422.74(d)(2)(iv), the plan would be required to submit dated copies of these required notices to CMS along with the other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

At new paragraph § 423.44(d)(2)(viii), we propose to codify existing policy currently set out in subregulatory guidance regarding PDP sponsor notices prior to a member disenrollment for disruptive behavior. To request approval of a disenrollment for disruptive behavior, a PDP sponsor would be required to provide two notices: (1) an advance notice, informing the plan member that continued disruptive behavior could lead to involuntary disenrollment; (2) a notice of intent to request CMS permission to disenroll the member, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 423.44(c). We are also proposing to revise the existing requirement at § 423.44(d)(2)(iii) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (2)(d)(viii). Additionally, as proposed in additions to § 423.44(d)(2)(iv), the plan would be required to submit dated copies of these required notices to CMS along with the other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

At § 417.460(e)(7) we propose to codify existing policy guidance currently set out in subregulatory guidance regarding cost plan notices prior to an enrollee disenrollment for cause (disruptive behavior). Current guidance is found in Chapter 17D of the Medicare Managed Care Manual, section 50.3.3. To request approval of a disenrollment for disruptive behavior, an HMO or CMP would be required to provide two notices: (1) an advance notice, informing the enrollee that continued disruptive behavior could lead to involuntary disenrollment; (2) a notice of intent to request CMS permission to disenroll the enrollee, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 417.460(e)(6). We are also proposing to revise the existing requirement at § 417.460(e)(2) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (e)(7). Additionally we are proposing in § 417.460(e)(2) that, as part of its efforts to resolve the problem presented by the enrollee, a HMO or CMP must provide reasonable accommodations for individuals with mental or cognitive conditions, including mental illness and developmental disabilities, similar to the existing requirement in the MA and Part D regulations at §§ 422.74(d)(2)(iii); 423.44(d)(2)(iii)). As proposed in § 417.460(e)(4), cost plans would be required to submit dated copies of these required notices to CMS along with other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

We are codifying longstanding guidance with these changes. All information impacts related to the involuntary disenrollment by the plan for disruptive behavior have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D. Based on infrequent questions from MA organizations, Part D, and cost plan sponsors on these notices, as these notice requirements have been previously implemented and are currently being followed by plans, we conclude that these updates do not

add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

M. Codification of the Part D Optional Disenrollment for Fraud and Abuse Policy (§ 423.44)

As noted previously, section 1851(g)(3)(B)(ii) of the Act provides that an MA organization may disenroll individuals that engage in disruptive behavior. In 1998, the Part C implementing regulations at 63 FR 35075 separately referred to a different kind of "disruption" or "failure to cooperate", namely, fraud or abuse on the part of the individual on the enrollment form, or by misuse of the individual's enrollment card. This basis for termination, that is, if the individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card, which was also based on section 1851(g)(3)(B)(ii) of the Act, was codified as a separate paragraph at § 422.74(b)(1)(iii) (63 FR 35075). Regulations also provided a process for disenrollment on this basis, whereby, an M+C organization may disenroll an individual that knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the M+C plan, or intentionally permits others to use his or her enrollment card to obtain services under the M+C plan, as long as a notice of disenrollment is provided as outlined in Federal law. The M+C organization was also required to report the disenrollment to Medicare. This process for disenrollment based on fraud or abuse on the part of the individual was codified at § 422.74(d)(3) (63 FR 35075). Fraud and abuse by the enrollee are treated in the same manner as other forms of disruptive behavior, with the individual being disenrolled into the original Medicare program.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) enacted the Medicare Advantage program, which replaced the M+C program established under title XVIII of the Act, and amended title XVIII of the Act to add a new part D (Voluntary Prescription Drug Benefit Program). Section 1860D-1(b)(1)(B)(v) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall

use rules similar to (and coordinated with) the rules for an MA-PD plan established under section 1851(g) of the Act. In 2005, CMS finalized implementing regulations, at §§ 423.44 (b)(1)(ii) and (d)(2), providing that PDP sponsors may disenroll an individual who engages in disruptive behavior and defining the process for disenrollment on this basis (70 FR 4530). However, CMS's 2005 implementing regulations did not include provisions allowing PDP sponsors the ability to disenroll individuals on the basis of fraud or abuse on the part of the individual on the enrollment form, or by misuse of the individual's enrollment card, equivalent to the MA regulations at §§ 422.74(b)(1)(iii) and (d)(3).

Although CMS has adopted and implemented this same basis for optional disenrollment from a Part D plan in sub-regulatory guidance, we are now proposing to codify the policy for optional disenrollment from a Part D plan based on an individual providing fraudulent information on his or her election form or permitting abuse of his or her enrollment card. Our intent is to codify the current policy, as reflected in section 50.3.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. These proposed regulations would also align the rules for Part D plans with the current rules for MA plans for optional disenrollment for an individual who commits fraud or permits abuse of their enrollment card, as provided in the MA regulations at § 422.74. Codifying our existing policy will provide transparency and stability for stakeholders about the Part D program.

We are proposing to add a new § 423.44(b)(1)(iii) to codify that if an individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in new paragraph (d)(9) of this section, the Part D plan has the option to involuntarily disenroll the individual. Further, we are proposing to add a new § 423.44(d)(9) to establish the process for optional disenrollment for an individual who commits fraud or permits abuse of their enrollment card. We are proposing to add a new § 423.44(d)(9)(i) to establish a basis for disenrollment for an individual who commits fraud or permits abuse of their enrollment card as provided in §§ 423.44(d)(9)(i)(A) and 423.44(d)(9)(i)(B). We are proposing to establish

in § 423.44(d)(9)(i)(A) that a Part D plan may disenroll an individual who knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the Part D plan. We are proposing to establish in § 423.44(d)(9)(i)(B) that a Part D plan may disenroll an individual who intentionally permits others to use his or her enrollment card to obtain drugs under the Part D plan.

We are further proposing to add a new § 423.44(d)(9)(ii) to establish that a Part D plan who opts to disenroll an individual who commits fraud or permits abuse of their enrollment card must provide the individual a written notice of the disenrollment that meets the notice requirements set forth in § 423.44(c) of this section. We are also proposing to add a new § 423.44(d)(9)(iii) to establish that a Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

With regard to our Part D optional involuntary disenrollment for fraud and abuse policy, the following change will be submitted to OMB for review under control number OMB 0938-0964 (CMS-10141). We estimate that it will take a Part D plan three hours to capture and retain the required documentation for each occurrence of disenrollment for fraud and abuse. In part, **t**he burden associated with this requirement is the time and effort necessary for a Part D plan to document and retain the documentation that meets the requirements set forth in this section. Based on actual experience, since 2012, there have only been five disenrollments for fraud and abuse. Three of those disenrollments were from MA/MAPD plans, one was from the Limited Income Newly Eligible Transition (LI NET) plan, and one was from a standalone Part D plan. Thus, the burden to Part D plans is negligible and per 5 CFR 1320.3(c) not subject to PRA because it involves less than 10 entities per year. Nonetheless, we will still add this information to the information collection currently approved under OMB control number 0938-0964. In addition, based on this data, we do not expect any future impact to the Medicare Trust Fund.

We are further proposing in § 423.44(d)(9)(ii) that the Part D plan must provide a written notice of disenrollment to the member to advise them of the plan's intent to disenroll, as required

under § 423.44(c) of this subpart. Lastly, we are proposing in § 423.44(d)(9)(iii) that the Part D plan must report to CMS any disenrollment based on fraud or abuse by the member. All information impacts related to providing a written notice to the member and notifying CMS of the disenrollment have already been accounted for under OMB control numbers 0938–0964 (CMS–10141).

N. SPAP or Other Payer Exception for Disenrollment for Failure to Pay (§ 423.44)

Section 1851(g)(3)(B)(i) of the Act allows MA plans to disenroll members who fail to pay premiums on a timely basis. Section 1860D-1(b)(1)(B)(v) of the Act directs us to adopt Part D disenrollment rules similar to the MA provisions in section 1851(g) of the Act. Additionally, section 1860D-1(b)(3)(A)(iii) of the Act states that disenrollment in a plan for failure to pay premiums will be considered a voluntary disenrollment action. In Part D implementing regulations (70 FR 4525), we established the basis for an optional involuntary disenrollment for failure to pay premiums as well as the disenrollment process. The basis for disenrollment for failure to pay premiums was established at § 423.44(b)(1)(i). The disenrollment process for failure to pay premiums was established at § 423.44(d)(1). In 2009, we added an exception to this disenrollment provision which prohibited plans from disenrolling individuals who are in premium withhold status (74 FR 1543). The premium withhold status exception was established at § 423.44(d)(1)(iv) and later renumbered to paragraph (v) in 2010 when we added the grace period requirement at § 423.44(d)(1)(iii) (75 FR 19816).

Section 1860D-23 of the Act directed the Secretary to establish coordination rules between State Pharmaceutical Assistance Programs (SPAPs) and Part D plan sponsors regarding the payment of premiums for Part D eligible individuals. SPAPs, and other third-party payer assistance programs, have the option to cover Part D premiums for individuals. Implementing regulation (70 FR 4525) established the requirement that Part D plan sponsors must permit SPAPs, and other entities, to coordinate benefits with the plan, including paying for premiums, at § 423.464(a).

To protect beneficiaries who have SPAPs, or other payers, cover their premiums, we propose to codify current policy that excepts certain prescription drug plan (PDP) members from being disenrolled for failure to pay plan premiums, at § 423.44(d)(1)(v). This policy is currently set out in sub-regulatory guidance, specifically section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, that Part D plan sponsors have previously implemented and are currently following. We propose, at revised § 423.44(d)(1)(v), a disenrollment exception if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer. Sponsors would not be able to initiate the disenrollment process or disenroll members who qualify for this exception.

In addition, we are taking this opportunity to propose a technical correction to revise an erroneous cross reference in § 423.44(d)(1). Instead of referring to paragraph (d)(1)(iv), the language should refer to paragraph (d)(1)(v).

We are codifying longstanding guidance with these changes. All information impacts related to the involuntary disenrollment by the plan for failure to pay Part D plan premiums have already been accounted for under OMB control 0938–0964 (CMS–10141). Based on infrequent questions or complaints from Part D sponsors on these notices, we believe that these disenrollment requirements have been previously implemented and are currently being followed by sponsors. These updates do not add to the existing disenrollment process, so we do not believe there is any additional paperwork burden.

O. Possible End Dates for the SEP for Government Entity-Declared Disaster or Other Emergency (§§ 422.62 and 423.38)

Section 1851(e)(4)(D) of the Act authorizes the Secretary to establish MA special enrollment periods (SEP) for Medicare-eligible individuals to elect a plan or change the individual's plan election when the individual meets an exceptional condition, as determined by

the Secretary. Section 1860D-1(b)(3)(C) of the Act authorizes the Secretary to establish SEPs for exceptional circumstances for Medicare-eligible individuals to make Part D elections.

The SEPs for exceptional circumstances were historically included in our sub-regulatory guidance rather than in regulation. In 2020, we codified and amended a number of SEPs that had been adopted and implemented through sub-regulatory guidance as exceptional circumstances SEPs, including the SEP for Government Entity-Declared Disaster or Other Emergency (85 FR 33901, 33909). This SEP, as codified at § 422.62(b)(18) for enrollment in an MA or MA-PD plan and § 423.38(c)(23) for enrollment in a Part D-only plan, allows individuals who are or have been affected by an emergency or major disaster declared by a Federal, State, or local government entity, and did not make an election during another period of eligibility as a result of the disaster/emergency, to make an MA and/or Part D enrollment or disenrollment action. Although CMS originally proposed that this SEP would only apply to FEMA-declared disasters or emergencies, as finalized in 2020, the regulations also include State and local emergency or major disaster declarations (85 FR 33868). This SEP begins the date the disaster/emergency declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. This SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later.

In order to clarify the length of this SEP, we are proposing to revise the end date(s) for the SEP for Government Entity-Declared Disaster or Other Emergency. We are proposing two changes in §§ 422.62(b)(18) and 423.38(c)(23) regarding this SEP.

First, we are proposing that for State or local emergencies/disasters, the end date for the SEP may also be based on an emergency/disaster order automatically expiring pursuant to a State or local law, if such a law exists. Applicable State or local law could be statutes, regulations, local or municipal ordinance or code regarding the automatic expiration date of State or local emergency orders. If the announced incident period end date is different than the expiration date

specified in State or local law, the announced incident end date controls the SEP end date. Under this proposal, the SEP ends based on the end of the emergency/disaster period, regardless of whether that period ends based on an announcement by the applicable authority or expires based on applicable State or local law.

Second, we are proposing an automatic incident end date which will apply if no end date for the period of disaster/emergency is otherwise identified within 1 year of the start of the SEP. This automatic incident end date will fall 1 year after the SEP start date, meaning that if no end date is otherwise identified, the SEP will be 14 full calendar months in length. For example, under our proposed changes, if no incident end date was identified in the declaration, or announced later, and there is no applicable expiration date provided by State or local law, CMS would consider the incident end date to be 1 year after the SEP start date and the SEP would end 2 full calendar months after that incident end date, which would result in a 14-month maximum SEP. We are seeking public comment on this automatic 1-year incident end date to determine if the 14-month maximum eligibility period for this SEP is sufficient. We propose that if the emergency/disaster declaration is extended, then the automatic 1-year incident end date would be from the date of the extension. This would address situations where a declaration of emergency or major disaster is renewed or extended (perhaps multiple times) so that the state of emergency or major disaster lasts for a year or more. These proposed changes will provide clear end dates for this SEP and should allow stakeholders to more easily calculate SEP length and determine beneficiary eligibility for the SEP.

Because an individual may elect a Medicare Advantage or Part D plan only during an election period, Medicare Advantage organizations and Part D sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible. Our proposal would not add to existing enrollment processes, so we believe any burden associated with this aspect of enrollment processing would remain unchanged from the current practice, and would not impose any new requirements or burden. All information impacts of this provision have

already been accounted for under OMB control numbers 0938-0753 (CMS-R-267), 0938-1378 (CMS-10718), and 0938-0964 (CMS-10141). In addition, Medicare Advantage organizations and Part D sponsors have previously implemented and are currently following the process to determine applicant eligibility for this SEP. We believe that changing the possible end date for this SEP will make a negligible impact, if any. We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

P. Updating MA and Part D SEPs for Changes in Residence and Codifying Procedures for Developing Addresses for Members Whose Mail is Returned as Undeliverable (§§ 422.62, 422.74, 423.38 and 423.44)

Section 1851(b)(1)(A) of the Act provides that an individual is eligible to elect a Medicare+Choice (M+C), later known as Medicare Advantage (MA), plan only if the plan serves the geographic area in which the individual resides. Section 1851(b)(1)(B) of the Act provides for a continuation of enrollment option under which an MA organization offering an MA local plan may offer its enrollees the option to continue enrollment in the plan when they move out of the plan service area and into a continuation area, so long as the organization provides or arranges for coverage of all Medicare-covered benefits. In the June 1998 IFC, we adopted regulations to address the residency and continuation area requirements, at §§ 422.50(a)(3) and 422.54, respectively, as well as a regulation, at § 422.74(b)(2)(i), requiring that an MA organization must disenroll an individual who no longer resides in the plan service area.

Section 1860D-1(b)(1)(B)(i) of the Act generally directs CMS to use rules related to enrollment, disenrollment, and termination for Part D sponsors that are similar to those established for MA organizations under section 1851(b)(1)(A) of the Act. In addition, section 1860D-1(b)(3) of the Act provides CMS additional SEP authority, including the authority at 1860D-1(b)(3)(C) for the Secretary to establish special enrollment periods "[i]n the case of part

D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide."

In January 2005, we published a final rule (70 FR 4194) to establish at § 423.30(a) that an individual must reside in a Part D plan service area in order to be eligible to enroll in the plan and at § 423.44(b)(2) that a Part D plan sponsor is required to disenroll an individual who no longer resides in the plan service area.

Section 1851(e)(4)(B) of the Act establishes that an individual who is no longer eligible to elect an MA plan because of a change in the individual's place of residence is eligible for a special election period (SEP) during which the individual may disenroll from the current plan or elect another plan. In the June 1998 interim final rule with comment period (63 FR 35073), we established at § 422.62(b)(2) an SEP for an individual who is not eligible to remain enrolled in an MA plan because of a change in his or her place of residence to a location out of the service area or continuation area. Likewise, in the January 2005 Part D final rule (70 FR 4194), we established at § 423.38(c)(7) an SEP for an individual who is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) where the PDP is offered are eligible for an SEP.

Current sub-regulatory guidance for these SEPs that are codified at §§ 422.62(b)(2) and 423.38(c)(7), as reflected in section 30.4.1 of Chapter 2 of the Medicare Managed Care Manual for MA and in section 30.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, provide that these SEPs are available not only to individuals who become ineligible for their current plan due to a move out of the service area of their current plan, but also to those who move within the service area of their current plan and have new plan options available to them, as well as to those who are not currently enrolled in a Medicare health or drug plan who move and have new plan options available to them. We propose to address the wider scope of these SEPs, as they are currently set out in sub-regulatory guidance, by amending §§ 422.62(b)(2) and 423.38(c)(7) to include individuals who move within the service area of their current plan and

have new Medicare health or drug plan options available to them, as well as to those who are not currently enrolled in a Medicare health or drug plan who move and have new plan options available to them.

The intent of our proposal is to codify current policy as reflected in CMS's existing subregulatory guidance and that is being carried out currently by MA organizations and Part D plan sponsors. Codifying our current policy for these SEPs will provide transparency and stability for stakeholders about the MA and Part D programs and about the nature and scope of these SEPs.

Separate from, but related to, the aforementioned policy for disenrolling individuals who report that they no longer reside in the plan service area are the current regulations at § 422.74(d)(4)(ii) that require that MA organizations disenroll individuals who are absent from the service area for more than six months. However, § 422.74(d)(4)(iii) provides an exception for individuals enrolled in MA plans that offer a visitor/traveler benefit are permitted an absence from the service area for up to 12 months; such individuals are disenrolled if their absence from the service area exceeds 12 months (or the length of the visitor/traveler program if less than 12 months). As outlined at § 423.44(d)(5)(ii), PDP sponsors must disenroll PDP enrollees who are absent from the plan service area for more than 12 months.

In the event that member materials are returned to plan sponsors as undeliverable and a forwarding address is not specified, current sub-regulatory guidance directs the plan sponsor to document the return, retain the returned material and continue to send future correspondence to that same address, as a forwarding address may become available at a later date. See § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D. In sub-regulatory guidance, we state that plan sponsors are to consider returned mail as an indication of a possible change in residence that warrants further investigation. As such, we encourage the plan sponsor to attempt to locate the member using any available resources, including CMS systems, to identify new address

information for the member. We describe how plans should attempt to research a member's change of address at § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D. Plan sponsors that are unable to contact the member or obtain current address information will disenroll the member upon expiration of the 6- or 12-month period of permitted temporary absence from the plan service area, as previously discussed.

Current MA guidance in § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual regarding research of potential changes in address is consistent with the MA regulation at § 422.74(d)(4)(i) providing that "the MA organization must disenroll an individual if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved." The analogous Part D regulation at § 423.44(d)(5)(i) requires that the "PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area," but the Part D regulation does not provide a basis similar to the MA regulation for when PDPs may start the process of researching and acting on a change of address that the plan learns about from a source other than the member. Although current Part D guidance in § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual allows PDPs to use information they receive from sources other than the member, specifically from either CMS or the USPS, as an indicator that a beneficiary may no longer reside in the service area, this is not codified in the Part D regulation. Therefore, we propose to align the Part D regulation with MA regulation by amending § 423.44(d)(5)(i) to state that a PDP must disenroll an individual if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area.

Current sub-regulatory guidance does not identify returned mail as a basis for involuntary disenrollment. Materials plans send to members that include protected health information (PHI) and/or personal identifying information (PII), as well as materials intended to inform members of

plan-specific information, such as premiums, benefits, cost-sharing, network and network changes and plan rules, have the potential for greater adverse impact on individual members, if returned as undeliverable, than materials such as newsletters, flyers and other items covering general health and wellness. To provide additional clarity to plan sponsors in their efforts to ascertain the residency status of members when there is an indication of a possible temporary or permanent absence from the service area, we are proposing to amend § 422.74 by adding paragraphs (d)(4)(ii)(A) and (d)(4)(iii)(F) for MA and to amend § 423.44 by revising paragraph (d)(5)(ii) for Part D to state that an individual is considered to be temporarily absent from the plan service area when any one or more of the required materials and content referenced in §§ 422.2267(e) and 423.2267(e), if provided by mail, is returned to the plan sponsor by the US Postal Service as undeliverable and a forwarding address is not provided. Codifying current sub-regulatory guidance regarding the use of returned mail as a basis for considering a member potentially out of area would provide a regulatory basis for plan sponsors to apply the 6- and 12-month timeframes as previously described, as well as the current practice of disenrolling individuals when the plan sponsor is unable to communicate with them using the residence address provided by the individual to the plan sponsor. Since plan sponsors are required by regulation to continue to mail certain materials to enrollees until the point at which the individual is no longer enrolled in the plan, we believe that it is important to codify the basis on which plan sponsors are to consider an individual to be temporarily out of the plan service area and able to be disenrolled, after an appropriate period of time, thus bringing about the cessation of any additional member material mailings.

Codifying our current policy for temporary absences from the plan service area, the sources of information on which plan sponsors may make related eligibility determinations, and the implications for disenrollment will provide transparency and stability for stakeholders about the MA and Part D programs and about plan service area requirements for the MA and Part D programs.

These proposals are a codification of longstanding MA and Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. Because an individual may elect an MA or Part D plan only during an election period and may continue enrollment in an MA or Part D plan only if the individual resides in the plan service area, or for some MA plans, the plan continuation area, MA organizations and Part D plan sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible and to determine the point at which an enrollee is no longer eligible for the plan and must be disenrolled. Our proposal would not add to existing enrollment and disenrollment processes, so we believe any burden associated with these aspects of enrollment and disenrollment processing would remain unchanged from the current practices, and would not impose any new requirements or burden. All information impacts related to the determination of eligibility for an election period and to the disenrollment of individuals who become ineligible for an MA or Part D plan based on the residency requirements have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

Q. Codify the Term "Whole Calendar Months" (§§ 422.74 and 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that an MA organization may involuntarily terminate an individual's election in a MA plan if monthly basic and supplemental beneficiary premiums are not paid timely, and provides for a grace period for payment of such premiums. Consistent with this section of the Act, the Part C regulations set forth our requirements with respect to optional involuntary disenrollment procedures under § 422.74.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) enacted the Medicare Advantage (MA) program, which replaced the M+C program established under title XVIII of the Act, and amended title XVIII of the Act to add a new Part D (Voluntary Prescription Drug Benefit Program). Section 1860D-1(b)(1)(B)(v) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall

use rules similar to (and coordinated with) the rules for an MA plan established under section 1851(g) (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section) of the Act. Consistent with these sections of the Act, the Part D regulations set forth our requirements with respect to optional involuntary disenrollment procedures under § 423.44.

In 2010, CMS amended the Part C and Part D regulations regarding optional involuntary disenrollment for nonpayment of premiums to require a minimum grace period of 2 months before any disenrollment occurs. This timeframe was established to provide adequate time for organizations to respond to instances in which individuals fail to pay their premiums, and for affected enrollees to take steps to remedy the situation and avoid disenrollment. These requirements were codified at § 422.74(d)(1)(i)(B)(1) (75 FR 19804) and § 423.44(d)(1)(iii)(A) (75 FR 19816). CMS also revised these regulations to include the requirement that the grace period begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later. These regulations were codified at § 422.74(d)(1)(i)(B)(2) (75 FR 19804) and § 423.44(d)(1)(iii)(B) (75 FR 19816).

In subsequent subregulatory guidance in section 50.3.1, Chapter 2 of the Medicare Managed Care Manual and section 50.3.1, Chapter 3 of the Medicare Prescription Drug Benefit Manual we defined the grace period for nonpayment of plan premium as a *whole* number of calendar months, not fractions of months. As the term "whole calendar months" is not specifically mentioned in the Part C and Part D regulations, we are proposing to revise §§ 422.74(d)(1)(i)(B)(1) and 423.44(d)(1)(iii)(A) to include the requirement that the grace period be at least 2 whole calendar months, to begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later. To illustrate this proposal, we provide the following example.

An MA or Part D plan has a 2-month grace period for premium payment. The grace period cannot begin until the individual has been notified of (billed for) the actual premium amount due, with such notice/bill specifying the due date for that amount and providing an opportunity to pay. On January 10th, a member is billed for his or her premium which is due on February 1. The member does not pay this premium and on February 7th, the sponsor sends the notice required by § 422.74(d)(1)(ii) or § 423.44(d)(1)(ii). The member does not act in response to this notice or any subsequent premium bills and payments are not made for February or March. The grace period is the months of February and March. If the member does not pay the unpaid plan premiums before the end of March, the individual would be disenrolled as of April 1.

Codifying this policy that a plan must provide a grace period of at least 2 whole calendar months will provide transparency and stability for stakeholders, and align with longstanding sub-regulatory guidance described in section 50.3.1, Chapter 2 of the Medicare Managed Care Manual and section 50.3.1, Chapter 3 of the Medicare Prescription Drug Benefit Manual regarding timeframes for disenrollment, which establish that the grace period must be a whole number of calendar months and cannot include fractions of months.

Plan sponsors that have chosen to disenroll individuals based on unpaid premiums already have procedures in place to implement a grace period that is a minimum of 2 months in length. Based on infrequent complaints or questions from sponsors, we believe that plan sponsors are complying with this guidance, and we are not proposing any changes to the requirements or process for involuntary disenrollment that plan sponsors have previously implemented and are currently following. All burden impacts of these provisions have already been accounted for under OMB control number 0938-0753 (CMS-R-267) for Part C and OMB control number 0938-0964 (CMS-10141). There is also no impact to the Medicare Trust Fund.

R. Researching and Acting on a Change of Address (§§ 422.74 and 423.44)

As discussed in our proposal for Developing Addresses for Members Whose Mail is Returned as Undeliverable and SEP for Changes in Residence (§§ 422.62, 422.74, 423.38, 423.44), section 1851(b)(1)(A) of the Act provides that an individual is eligible to elect an MA plan only if the plan serves the geographic area in which the individual resides, and section 1860D-1(b)(1)(B) of the Act generally directs CMS to use rules related to enrollment, disenrollment, and termination for Part D sponsors that are similar to those established for MA organizations under section 1851(b)(1)(A) of the Act.

Pursuant to regulations at § 422.74(c) for MA and § 423.44(c) for Part D, MA organizations and Part D plan sponsors are currently required to issue a disenrollment notice when an enrollee is disenrolled for not residing in the plan service area. Existing sub-regulatory guidance includes a requirement that MA organizations and Part D plan sponsors issue the disenrollment notice within 10 days of the plan learning of the permanent move. See § 50.2.1.5 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.6 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, respectively. In the case of MA plan enrollees who are disenrolled because they are absent from the service area for more than six months, the disenrollment notice must be provided within the first ten calendar days of the sixth month. Individuals enrolled in MA plans that offer a visitor/traveler benefit are permitted an absence from the service area for up to 12 months; such individuals are disenrolled if their absence from the service area exceeds 12 months (or the length of the visitor/traveler program if less than 12 months). In this scenario, the MA organization must provide notification of the upcoming disenrollment to the enrollee during the first ten calendar days of the 12th month (or the last month of the allowable absence, per the visitor/traveler program). PDP enrollees are disenrolled if they are absent from the plan service area for more than 12 months. For these cases, the disenrollment notice must be provided within the first 10 calendar days of the 12th month. For instances in which a plan learns of an individual's absence from the service area after the

expiration of the period of time allowed under the applicable regulation, the plan would provide the disenrollment notice within 10 calendar days of learning of the absence.

Although we have previously codified the requirement to issue a disenrollment notice when an individual is disenrolled due to an extended absence from the plan service area, or a change in residence to a location outside the service area, the 10-day timeframe for issuing that notice is reflected only in sub-regulatory guidance. We propose to amend the MA and Part D plan disenrollment notification requirements to include the 10-day timeframe that is currently reflected in sub-regulatory guidance. Specifically, we are proposing to codify at § 422.74(d)(4)(iv) and at § 423.44(d)(5)(i) and (d)(5)(ii) a timeliness requirement of 10 calendar days for issuing notices for disenrollment's based on the residency requirements. Separate from the disenrollment notification requirements described in the preceding paragraphs is a documentation retention requirement currently reflected in § 50.2.1.3 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. It has been CMS policy that MA organizations and Part D plan sponsors document their efforts to determine whether an enrollee has relocated out of the plan service area or has been absent from the service for a period of time in excess of what is allowed; however, our expectation that plans document their research efforts, although outlined in sub-regulatory guidance, is not codified. As such, we propose to amend the MA and Part D regulations to include the requirement that plans document their efforts to determine an enrollee's residency status.

We are proposing to codify at § 422.74(d)(4)(i) and at § 423.44(d)(5)(i) and (d)(5)(ii) that MA organizations and Part D plan sponsors must document the basis for involuntary disenrollment actions that are based on the residency requirements.

The intent of our proposal is to codify current disenrollment notice policy, as reflected in § 50.2.1.5 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.6 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, and also codify the current

documentation policy that is currently reflected in § 50.2.1.3 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, all of which are policies that are being carried out currently by MA organizations and Part D plan sponsors. Codifying our current policies regarding notification of disenrollment and document retention will provide transparency and stability for stakeholders about the MA and Part D programs and about the nature and scope of these notification and retention policies.

These proposals are a codification of longstanding MA and Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. MA organizations and Part D plan sponsors already have procedures in place to provide disenrollment notifications and to retain documentation related to such disenrollments. Our proposal would not add to existing processes, so any burden associated with this aspect of disenrollment processing and document retention would remain unchanged from current practices and would not impose any new requirements or burden. All information impacts related to these existing practices have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS-10141) for Part D.

S. Part D Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members (§§ 423.32 and 423.36)

Section 1860D-1(b) of the Act establishes the enrollment and disenrollment process for Part D eligible individuals in prescription drug plans. This section of the Act grants the Secretary the authority to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. In January 2005, the Part D implementing regulations established the enrollment and disenrollment processes for Part D prescription drug plans. The enrollment and disenrollment processes for prescription drug plans are codified in regulation at §§ 423.32 and 423.36, respectively (70 FR 4525).

Section 1860D-1(b)(1)(B) of the Act directs the Secretary to adopt Part D enrollment rules "similar to" and coordinated with those under Part C. In 1998, Part C implementing regulations (and subsequent correcting regulations) added the requirement that allowed an exception for employer/union group health plan (EGHP) sponsors to process election forms for Medicare-entitled group members (63 FR 52612, 63 FR 35071). These requirements were codified in the Part C regulations but were not codified in the Part D regulations.

We are proposing to codify this existing policy to provide transparency and ensure consistency between the Part C and Part D programs. Specifically, we are proposing at new §§ 423.32(i) and 423.36(e) to permit a Part D plan sponsor that has a contract with an employer or union group to arrange for the employer or union to process enrollment and disenrollment elections for Medicare-entitled group members who wish to enroll in or disenroll from an employer or union sponsored Part D plan. As outlined in sections 60.5.1 and 60.5.2 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, retroactive enrollments and disenrollments are permitted for up to 90 days to conform to the payment adjustments described under §§ 422.308(f)(2) and 423.343(a). In addition, to obtain the retroactive effective date of the election, the individual must certify receipt of the group enrollment notice materials that include the summary of benefits offered under the PDP, as provided in sections 40.1.6 and 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. Once the enrollment or disenrollment election is received from the employer, the Part D plan sponsor must submit the disenrollment to CMS within the specified timeframes described in section 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Our intent is to align the Part D regulation with the requirements that MA organizations follow in existing Part C regulations at §§ 422.60(f) and 422.66(f) and codify existing policies in the sub-regulatory guidance in Chapter 3 of the Medicare Prescription Drug Benefit Manual. Under section 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, retroactive transactions may be necessary and are permitted if a delay exists between the time the individual

completes the enrollment or disenrollment request through the employer's election process and when the request is received by the Part D plan sponsor. Further, we state in current sub-regulatory guidance at section 60.5.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual that the option to submit limited EGHP retroactive enrollment and disenrollment transactions is to be used only for the purpose of submitting a retroactive enrollment into an EGHP made necessary due to the employer's delay in forwarding the completed enrollment request to the Part D plan sponsor.

This proposal is a codification of existing Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. Based on infrequent complaints and questions from plans and beneficiaries related to current policies, which have been previously implemented and are currently being followed by plans, we conclude that there is no additional paperwork burden. All information impacts related to this provision have already been accounted for under OMB control numbers 0938-1378 (CMS-10718) for Part D enrollment requests and 0938–0964 (CMS-10141) for Part D disenrollment requests.

T. Single-Tier Benefit Requirement for Defined Standard Coverage (§§ 423.100, 423.120, 423.2267)

We propose to codify our longstanding subregulatory policy, as described in the Final Coverage Year (CY) 2015 Part D Call Letter (hereinafter referred to as the "Final CY 2015 Part D Call Letter," and available at https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2015.pdf), that a plan offering Defined Standard coverage apply a single-tier benefit structure to drugs on its formulary (if it uses a formulary, as defined at § 423.4). In addition, we propose to codify our longstanding subregulatory policy that all communications and marketing materials (as these terms are defined at § 423.2260) for a plan offering Defined Standard coverage must reflect a single-tier benefit structure.

Under sections 1854(a)(1)(A) and 1860D-11(b) of the Act, initial bid submissions for all MA plans, MA-PD plans, and PDPs must be in a form and manner specified by the Secretary. To facilitate Part D sponsors' submission of their bids, we provided guidance regarding Incomplete and Inaccurate Bid Submissions on page 163 of the Final CY 2020 Part D Call Letter (hereinafter referred to as the "Final CY 2020 Part D Call Letter," and available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf) that a formulary crosswalk is one of the constituent components of a complete bid submission for a Part D sponsor that is offering a Part D plan with a formulary. Additionally, in the February 3, 2022 HPMS memo titled, "Contract Year (CY) 2023 Final Part D Bidding Instructions" (available at https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf), we referenced the Final CY 2020 Part D Call Letter policy on Incomplete and Inaccurate Bid Submissions as applicable for CY 2023. Further, the Bid Submission User Manual for Contract Year 2023, Chapter 10, Bid Submission Pre-Upload Requirements and Uploads (hereinafter referred to as "Chapter 10" and available in the HPMS via the following path: Plan Bids / Bid Submission / CY 2023 / View Documentation / Bid Submission User Manual / Chapter 10), provides detailed information about the formulary crosswalk.

Chapter 10 instructs all contracts that submitted a formulary through HPMS to submit a formulary crosswalk. Additionally, in order for the Formulary Crosswalk to be considered complete, Part D sponsors are also instructed to: (1) assign a formulary to all plans that offer Part D and are a part of the contract that submitted the formulary; and (2) assign all formularies submitted for an organization to at least one plan. Further, Chapter 10 provides that one formulary may be mapped to one or more plans. The ability for plans to assign a given formulary to multiple plans reduces Part D sponsor and CMS administrative burden by reducing the number of formularies that CMS must review and Part D sponsors must maintain.

Since the beginning of the Part D program, we have interpreted section 1860D-2(b) of the Act to provide two distinct types of standard prescription drug coverage – "Defined Standard coverage" and "actuarially equivalent standard coverage." Section 1860D-2(b)(2)(A)(ii) of the Act provides that Part D sponsors offering actuarially equivalent standard coverage will be permitted to substitute cost-sharing requirements (including multi-tier benefit structures tied to Part D plan formularies and particular pharmacies in a Part D plan's network) for costs above the annual deductible and up to the catastrophic coverage limit, provided that those alternative cost-sharing requirements are actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to catastrophic coverage. Also, since the beginning of the Part D program, we have interpreted this provision to permit multi-tier benefit structures for actuarially equivalent standard coverage but not for Defined Standard coverage (70 FR 4237).

As is noted on page 55 of the Final CY 2015 Part D Call Letter, for a plan using a formulary (as defined at § 423.4), we expect that the formulary structure submitted for a plan offering Defined Standard coverage will be consistent with a plan benefit package (PBP) submission that does not include a multi-tier benefit structure. Similarly, we have stated in our Formulary Submission Module and Reports Technical Manual (available at https://www.cms.gov/files/document/cy2022formularyplanmanual5.pdf) that formularies that will only be

associated with plans offering Defined Standard coverage must be submitted as having a single-tier benefit structure. We made an exception to this policy such that if a plan offering Defined Standard coverage uses a formulary that is linked (via the Formulary Crosswalk) to at least one other plan with a multi-tier benefit structure (that is, a plan offering Actuarial Equivalent Standard, Basic Alternative, or Enhanced Alternative coverage). In other words, a given formulary (as defined in § 423.4) applies to all plans to which such formulary has been assigned, but any submitted multi-tier benefit structures are plan-specific and only apply to the individual plans that offer coverage other than Defined Standard.

The Final CY 2015 Part D Call Letter also instructed that all marketing materials for plans offering Defined Standard coverage reflect a single-tier benefit structure regardless of whether such plan offering Defined Standard coverage uses a formulary that is associated with other plans that offer multi-tier benefit structures.

Because we continue to receive questions from Part D sponsors about our policy that a plan offering Defined Standard coverage have a single-tier benefit structure, we are taking this opportunity to clarify a common point of confusion by proposing to codify this longstanding subregulatory policy, as summarized below. Additionally, with regard to the formulary crosswalk policy, we have previously used the terms "associated," "mapped," "linked," and "assigned" synonymously, but in order to minimize confusion, we have chosen to use the term "assign" in our proposed regulatory requirements.

First, we propose to define the term "formulary crosswalk" at § 423.100 as the process during bid submission by which a formulary (as defined at § 423.4) is assigned to one or more Part D plans with single- or multi-tier benefit structures.

Second, we propose to add new paragraph § 423.120(b)(9) to codify that a Part D plan offering Defined Standard coverage may not apply multi-tier benefit structures to the formulary (as defined at § 423.4) to which it has been assigned via the formulary crosswalk (as defined at § 423.100) as part of the bid submission process. We also propose to codify an exception in the

case that such formulary has also been assigned to one or more other Part D plans that use multi-tier benefit structures such that the multi-tier benefit structures used by the other Part D plans offering coverage other than Defined Standard coverage would not apply to the plan offering Defined Standard coverage.

Finally, because various required marketing and communications materials, including (but not limited to) the formulary document, have been redesignated as communications materials, as defined at § 423.2260, we propose to codify our subregulatory policy that a plan offering Defined Standard coverage display a single-tier benefit structure in all relevant marketing and communications materials. Specifically, at new § 423.2267(e)(42), we propose to require that, when discussing the Part D plan's formulary, a plan offering Defined Standard coverage convey that all covered drugs have a single-tier benefit structure. This would be model content included in all relevant communications and marketing materials (as defined at § 423.2260) that pertain to the formulary or preferential status of the covered Part D drugs – including the complete and abridged formulary, Summary of Benefits, Evidence of Coverage, and other materials, as applicable.

We have been monitoring compliance with this policy via our annual formulary review and approval process, consistent with the requirements at § 423.120(b). Since this review is already being performed and plans are already in compliance, there is no additional paperwork burden associated with codifying this longstanding subregulatory policy.

We solicit comment on these proposals.

U. Shortages of Formulary Drug Products During a Plan Year (§ 423.120)

Drug shortages and their impact on the healthcare system have been a concern for decades. FDA reports that drug shortages peaked in 2011 with 251 new shortages, but have since declined to 43 in 2020.[160] Despite this progress, drug shortages received renewed attention as a

[160]U.S. Food and Drug Administration. Eighth Annual Report on Drug Shortages for Calendar Year 2020. Available from: https://www.fda.gov/media/150409/download.

result of supply chain disruptions during the Coronavirus Disease 2019 (COVID-19) pandemic. As part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, Congress commissioned the National Academies of Sciences, Engineering, and Medicine to examine and report on vulnerabilities in the U.S. medical supply chain.[161] While other government agencies pursue strategies to track and mitigate drug shortages, in this proposed rule, we propose to codify existing subregulatory guidance, first released in the July 21, 2009 Health Plan Management System (HPMS) memorandum titled "Shortages of Formulary Drug Products During a Plan Year" [162] and subsequently incorporated into chapter 5 of the Prescription Drug Benefit Manual,[163] describing expectations of Part D sponsors when shortages impact drugs on their Part D plan formulary. We also propose to broaden the scope of requirements beyond current guidance to reflect the availability of interchangeable biological products.

Section 1860D-11(e)(2)(D)(i) of the Act requires CMS to approve Part D plans only if CMS does not find that the design of the plan and its benefits, including any formulary, are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. Accordingly, CMS' annual formulary review and approval process includes extensive checks to ensure adequate representation of all necessary Part D drug categories or classes for the Medicare population. These checks have been previously described in CMS' January 10, 2014 proposed rule titled "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (79 FR 2019). Such formulary requirements are a beneficiary protection counterbalancing CMS' statutory prohibition against requiring a particular formulary or interfering with negotiations between Part D sponsors, manufacturers, and pharmacies, consistent with section 1860D-11(i) of the Act. Because Part D drug shortages have the potential to undermine the formulary approval process

[161]National Academies of Sciences, Engineering, and Medicine. 2022. Building Resilience into the Nation's Medical Product Supply Chains. Washington, DC: The National Academies Press. https://doi.org/10.17226/26420.
[162]https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/HPMS-Guidance-History-Items/CMS1224655
[163] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals

and interrupt beneficiary therapy, CMS is proposing to codify requirements for Part D sponsors relating to formulary drug shortages to mitigate potential disruption.

Existing guidance names FDA as the definitive source of drug shortage information. We are therefore proposing to add a new paragraph (g) to § 423.120 to specify that our proposed drug shortage requirements would apply in the case of shortages listed on the FDA website at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages and corresponding database at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm. If a shortage becomes market withdrawal and therefore the product is no longer listed on the FDA drug shortage website, then the proposed requirements would no longer apply.

In order to minimize unnecessary changes in therapy resulting from temporary shortages of multiple-source formulary drug and biological products, we propose at new paragraph § 423.120(g)(1) to require Part D sponsors to permit enrollees affected by a shortage to obtain coverage for a therapeutically equivalent drug or an interchangeable biological product, if any, for at least the duration of the shortage. As proposed at § 423.120(g)(1)(i), Part D sponsors would be required to permit enrollees affected by a shortage to obtain coverage for a therapeutically equivalent or interchangeable non-formulary alternative without requiring those enrollees to meet formulary exception requirements at § 423.578(b). In the case where a therapeutically equivalent or interchangeable alternative is on the formulary but requires prior authorization or step therapy, as proposed at § 423.120(g)(1)(ii), Part D sponsors would be required to permit enrollees affected by a shortage to obtain coverage for the formulary alternative without requiring those enrollees to satisfy prior authorization or step therapy requirements.

When applicable, Part D sponsors should allow pharmacies to utilize a value of "8" (Substitution Allowed - Generic Drug Not Available in Marketplace) in field 408-D8 (Dispense as Written/Product Selection Code) of the National Council for Prescription Drug Programs (NCPDP) version D.0 Telecommunication standard (or the applicable value and version at the

time) to specify that an equivalent brand product is being dispensed due to the unavailability of any generic formulary products. Nothing in this proposal supersedes State pharmacy laws, which determine a pharmacist's authority to automatically substitute therapeutically equivalent drugs or interchangeable biological products for the reference product, or vice versa. A new prescription for the alternative product may be required.

We are also proposing, at new paragraph (g)(2), to specify that the Part D sponsor would not be required to charge the cost sharing that applies to the unavailable formulary product for the alternative product and may charge the applicable sharing that would apply to the alternative therapeutically equivalent or interchangeable product's formulary status and the plan benefit design. That is, if the alternative product is on the formulary, the enrollee would be expected to pay the cost sharing that would normally apply based on the plan benefit design and if the alternative product is non-formulary, then the enrollee would be expected to pay the cost sharing associated with formulary exceptions. This policy would not preclude an enrollee affected by a shortage from seeking a formulary exception consistent with § 423.578(b) to obtain access to a non-formulary product or to a formulary product requiring prior authorization or step therapy beyond the duration of the shortage; nor would this policy preclude enrollees affected by a shortage from seeking a tiering exception, consistent with § 423.578(a), to obtain access to the alternative formulary product at a more favorable cost sharing.

Under the current proposal, Part D sponsors would be required to cover a therapeutically equivalent drug or interchangeable biological product as an alternative to the formulary product subject to shortage if there is claim submitted for the alternative. However, Part D sponsors may work with enrollees and providers to determine appropriate alternative drugs since suitable options may vary based on clinical needs, costs, or other factors. For example, if a generic formulary drug is unavailable but the therapeutically equivalent brand name product is available and on the formulary, an enrollee may prefer to switch to an alternative generic product rather than pay the associated brand cost sharing or pursue a tiering exception for the brand product.

The requirements we are proposing at § 423.120(g) would not require changes to the Part D sponsor's formulary; rather, they would require, for the duration of a shortage, coverage of alternative therapeutically equivalent products in lieu of the product in shortage. If a Part D sponsor decides to remove a product from its formulary due to long-term shortage or if the shortage becomes a market withdrawal, the requirements currently codified at § 423.120(b)(5), which we are proposing to revise as discussed in section III.Q. of this proposed rule, would apply.

We solicit comment on this proposal.

V. Validity of DEA Registration Numbers for Controlled Substances (§ 423.120(c))

In this section, we propose to amend § 423.120(c) to codify in regulation our current policy that Part D sponsors must confirm the validity of a prescriber's Drug Enforcement Administration (DEA) registration number for a controlled substance, if the number is on the drug claim. Or, if the prescriber's DEA registration number is not on the Part D claim, the sponsor must use prescriber identifier data sources to cross-reference the prescriber's individual National Provider Identifier (NPI) number, which is required on all Part D drug claims,[164] to the prescriber's DEA registration number for validation. Under § 423.104(h), a Part D sponsor may provide benefits only for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription. A "valid prescription" is defined in § 423.100 as a prescription that complies with all applicable State law requirements constituting a valid prescription.

Prescriptions are regulated under State laws which may incorporate Federal law and regulations. An example of such incorporation is the Drug Control Act of Virginia, Va. Code § 54.1-3408.01A, "Requirement for Prescriptions," which states that a prescription for a controlled substance other than one controlled in Schedule VI "shall also contain the Federal controlled substances registration number assigned to the prescriber."[165]

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[164] 42 CFR 423.120(c)(5)(i).

[165] DEA regulations also address requirements regarding prescriptions for a controlled substance. See 21 CFR 1306.

While compliance with applicable Federal and State laws related to dispensing of prescription drugs is primarily the responsibility of pharmacists, since plan year 2012, CMS has had a policy on DEA registration numbers in the Part D Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, Section 90.2.4 "Controlled Substances" (hereinafter referred to as "Manual Chapter 5"). The purpose of this policy is to support, as feasible, these frontline pharmacists' efforts to comply with State and DEA requirements with respect to controlled substances. We propose to codify this policy by requiring that Part D sponsors confirm the validity of DEA registration numbers on Schedule II-V drug claims or, if the prescriber's DEA registration number is not on the Part D claim, the sponsor must use prescriber identifier data sources to cross-reference the prescriber's Type 1 NPIs on these claims to the prescriber's DEA registration number for validation. In addition, we propose that sponsors be required to confirm that the controlled substance prescribed is consistent with the prescriber's DEA Schedule registration.

Type 1 NPIs are obtained by individual health care providers. (With respect to Part D claims, we refer to them in this section as "prescriber NPIs"). Type 2 NPIs are obtained by organization health care providers and organizational health care providers are discussed further below.[166]

Section 90.2 of Manual Chapter 5 notes that sources of State and Federal data on providers, in addition to prescriber identifier validation services from commercial vendors, are available to support sponsor efforts at such validation. This means that sponsors can use public and private data when cross-referencing prescriber NPIs to DEA registration numbers, if the prescriber has a DEA registration number. It is our understanding that this is indeed what Part D sponsors and their pharmacy benefit managers (PBMs) currently do – that is, they use databases

[166]MLN Booklet, "NPI:What You Need to Know" (March 2022), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/NPI-What-You-Need-To-Know.pdf.

to cross-reference prescriber NPIs to DEA registration numbers when they receive a Part D claim for a controlled substance.

We further propose that if a Part D sponsor finds a valid and active DEA registration number for the prescriber of a controlled substance, and an associated schedule that is appropriate for the drug, then the sponsor must process the claim under the other coverage parameters of applicable Part D plan. If the sponsor finds a DEA registration number, but it is not valid or active, or the associated schedule for the drug is not appropriate, the sponsor must reject the claim and send the pharmacy an electronic code with the reason for the rejection.

We note that in rejecting the claim, the sponsor should not return the designated code to trigger the delivery of the standardized pharmacy notice to the enrollee, as the claim has been rejected because it does not contain all necessary data elements for adjudication. (See section 40.12.3 -Part D Coverage Determination Notices – in the Parts C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance).[167] With respect to written member requests for reimbursement, we propose that if the Part D sponsor determines that the DEA registration number of the prescriber was not valid or not active or there was not an associated schedule that was consistent with the drug for which the member requested reimbursement, then the Part D sponsor not only must deny the member request for reimbursement, but must also provide the beneficiary with a written notice explaining the coverage determination consistent with the notice requirements at § 423.568(g).

It is our understanding that some prescribers, such as hospital residents, prescribe controlled substances under an organizational health care provider's DEA registration number. We received reports in the past that sponsors were rejecting claims for controlled substances when a prescriber was prescribing under a hospital's or institution's DEA registration number, and the prescriber did not have an individual DEA registration number. We expressed concern at

[167]See https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

the time through guidance[168] that such rejections may interfere with beneficiary access to needed medications and result from a misinterpretation of our guidance. We also stated that we did not believe that sponsors have reasonable access to the information necessary to research the relationship of individual prescribers to hospitals' or institutions' DEA registration numbers for every claim, and we noted in our guidance that this is not expected. Therefore, consistent with our current guidance, we propose that if there is no individual prescriber DEA registration number found to validate, a Part D sponsor is not required to take any further action when processing a claim for a controlled substance in terms of validating a DEA registration number. In other words, we are proposing that the sponsor must check the validity of the DEA registration number only when there is an individual prescriber DEA registration number associated with the Type I NPI on the Part D claim.

Although this proposal would codify our current policy, we understand that at least some sponsors reject all claims for controlled substances for which they cannot validate the prescriber's DEA registration number and schedule. We speculate that these sponsors want to have an electronic record of the pharmacist using an override code to validate that the prescriber is lawfully prescribing controlled substances. We solicit comment on whether we should require sponsors to reject all claims for controlled substances for which they cannot validate the DEA registration number and schedule, and what impact this adjustment in policy would have on beneficiary access to controlled substances covered by Part D, if any.

We propose to codify our existing DEA registration number policy at § 423.120 by updating the header for paragraph (c) and by adding a new paragraph (7) as follows:

- The header of paragraph (c) would be changed to "Use of standardized technology and identifiers."

[168]"HPMS Memo," Clarification of Chapter 5 of the Prescription Drug Benefit Manual, Section 90.2.4 – Controlled Substances" (May 21, 2013).

- New paragraph (c)(7)(i) would establish that a D sponsor must attempt to confirm the validity of a prescriber DEA registration number for a pharmacy claim for a Schedule II, III, IV or V drug, and that if the DEA registration number is not on the claim, the sponsor must cross-reference the prescriber's Type 1 NPI on the claim to any associated individual prescriber DEA number.

- New paragraphs (c)(7)(ii)(A) and (B) would specify that if the DEA registration number is not valid or active or the DEA registration number does not have an associated Schedule that is consistent with the drug for which a claim was submitted, the Part D sponsor must reject the claim and provide the pharmacy with the electronic reason code when rejecting the claim.

- New paragraph (7)(iii) would specify that if the pharmacy confirms the validity of the DEA registration number via electronic override code, or the sponsor is not able to cross-reference the Type 1 NPI to a prescriber DEA registration number, the sponsor must process the claim under the applicable benefit plan rules.

- New paragraph (c)(7)(iv) would specify that, with respect to written member requests for reimbursement, the Part D sponsor must determine whether the DEA registration number of the prescriber was valid and active for the date of service, and if the DEA registration number had an associated Schedule that was consistent with the drug for which the member request for reimbursement was submitted for the date of service. Consistent with proposed new paragraphs (7)(iv)(A) and (B), if the DEA number was not valid or active, or there was not an associated Schedule that was consistent with the drug, the Part D sponsor would be required to deny the member request for reimbursement and provide the beneficiary with a written notice consistent with § 423.568(g).

As is the case with our current subregulatory policy, the purpose of our proposal is to ensure, to the extent feasible, that covered Part D drugs are dispensed upon valid prescriptions. We solicit comment on this proposal. Also, given the interactions we have had with Part D

sponsors about our current controlled substances policy, we assume all sponsors are currently complying. Therefore, we conclude that there would be no additional paperwork burden for sponsors resulting from this proposal.

W. Codifying Current Part D Transition and Continuity of Care Policies (§§ 423.100 and § 423.120)

1. Overview and Summary

Under § 423.120(b)(3), Part D sponsors must provide certain enrollees a transition fill to avoid interruption in drug therapy when a drug is non-formulary, or on-formulary but subject to utilization management (UM) restrictions, so that the enrollee has time to switch to a therapeutic alternative drug or complete an exception request to maintain coverage of an existing drug based on medical necessity reasons. Thus, the purpose of providing a transition supply is to promote continuity of care and avoid interruptions in drug therapy.[169] Sponsors must also send enrollees a notice when they provide a transition fill.

The Part D transition requirement was first codified in our January 2005 Part D final rule (70 FR 4194)[170] under the authority of section 1860D-11(d)(2)(B) of the Act, which provides CMS with authority similar to that provided to the Director of the Office of Personnel Management with respect to health benefit plans to prescribe reasonable minimum standards for health benefits plans. We noted in that final rule that failure to appropriately transition certain beneficiaries could result in aggravation of certain medical conditions including, in some cases, hospitalization, which could ultimately increase costs to Medicare under Parts A and B (70 FR 4264).

Part D transition guidance is contained in Chapter 6 of the Medicare Prescription Drug Benefit Manual (Manual Chapter 6),[171] Section 30.4 – Part D Drugs and Formulary

[169]See also Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4 – Part D Drugs and Formulary Requirements.
[170]https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf
[171]https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf

Requirements. While most of the transition requirements are codified at § 423.120(b), there are some aspects of the current guidance in section 30.4 of Manual Chapter 6 that are not. Therefore, the purpose of this proposal is to codify those aspects of the current Part D transition guidance in regulation. In some cases, as detailed later in this section, our proposed regulation would clarify the policies reflected in current guidance.

Specifically, we propose to codify our policies with respect to the following topics: 1) quantity limits (QLs); 2) the minimum 108-day lookback period; 3) P&T committee role in transition; 4) transition notice timeframes; 5) level of care changes; and 6) (LTC) emergency supply.

2. Quantity Limits (QLs) During Transition

Currently, under § 423.120(b)(3), a sponsor is required to provide for an appropriate transition for an enrollee if the Part D drug is on the plan's formulary but requires prior authorization or step therapy. We propose to add to § 423.120(b)(3) that certain quantity limits (QLs) would require a sponsor to provide for an appropriate transition for an enrollee if the Part D drug is on the plan's formulary. This proposal, if finalized, would apply both for a current enrollee when a QL has been added to a drug on the plan's formulary that is lower than the beneficiary's current dose, and for a new enrollee when an existing QL for a formulary drug is lower than the beneficiary's current dose. This proposal is consistent with Section 30.4 of Manual Chapter 6.

We also propose an exception to the proposal that QLs would require a sponsor to provide for an appropriate transition for an enrollee if the Part D drug is on the plan's formulary. Specifically, we propose that QLs that are "safety-based claim edits," meaning those claim edits that are consistent with drug utilization review (DUR) requirements described at § 423.153(c)(2) to prevent unsafe or inappropriate dosing, would continue to be applied to transition supplies. We believe it is necessary to continue to allow "safety-based claim edits" that are QLs to be applied to transition fills, because not allowing them would mean that enrollees could obtain

transition fills that were unsafe or were inappropriate drug use under standard DUR reviews. This approach is consistent with our current transition policy in Manual Chapter 6, Section 30.4.8.

We propose to add a definition of "safety-based claim edit" to § 423.100. Our proposed definition of incorporates § 423.153(c)(2), which states that a review of each prescription must include but not be limited to:--

- Screening for potential drug therapy problems due to therapeutic duplication;
- Age/gender-related contraindications;
- Over-utilization and under-utilization;
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug therapy;
- Drug-allergy contraindications; and
- Clinical abuse/misuse.

In light of our proposal described in the preceding two paragraphs, we are also specifically proposing that § 423.120(b)(3) would state that a Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary, including Part D drugs that are on a sponsor's formulary, require prior authorization, step therapy, or under a plan's drug utilization management rules, are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100.

To illustrate these standards, the following QLs are examples of safety-based edits that could be applied to transition fills:

- A claim edit that is a QL based on the maximum dose in the FDA-approved label, such as an acetaminophen limit, would meet the standard at § 423.153(c)(2)(v) regarding prevention of incorrect drug dosage.

- A QL based on the dose, dosing frequency, and/or duration of therapy limits supported by the FDA-approved label, if no clearly stated maximum dosing limits are specified in the

FDA-approved label (for example, short- and long-acting opioids, would meet the standard at § 423.153(c)(2)(iii)).

- A QL that limits topical products to a reasonable quantity over time taking into consideration the indication, directions for use, and size of the area being treated would meet the standard at § 423.153(c)(2)(iii).

- A QL that supports dose optimization to promote adherence and ensure safe and appropriate utilization by reducing pill burden when multiple strengths of the same drug are available (for example, one 40 mg tablet daily instead of two 20 mg tablets daily when the appropriate dosing frequency is once daily) would meet the standard at § 423.153(c)(2)(v) to prevent incorrect drug dosage.

We also note that claim edits to help determine Part A or B vs. Part D coverage and to prevent coverage of a non-Part D drug are permitted during a transition period, as they reflect statutory limits on Part D coverage.

We propose to make a conforming change to § 423.120(b)(3)(iii) to include a reference to QLs. We solicit comment on this proposal.

3. Minimum 108-day Lookback Period

Under our current regulations at § 423.120(b)(3), Part D sponsors must provide for an appropriate transition process for certain enrollees. We have consistently interpreted an appropriate transition to be required for ongoing therapy—that is, when an enrollee is receiving a drug for the first time, there is nothing to transition from, and therefore a transition supply is not necessary. Therefore, in providing for appropriate transition, it is necessary for Part D sponsors to determine whether an enrollee is receiving a new prescription or a refill for ongoing therapy, and we have long recognized that distinguishing between "new starts" and ongoing therapy may be difficult.

As described in Section 30.4.3 of Manual Chapter 6, our longstanding Part D policy for distinguishing between new starts and ongoing therapy has been to treat all prescriptions that

could qualify for a transition as ongoing therapy unless the sponsor can make the distinction at the point of sale. More recently, Section 30.4 was updated to specify that when sponsors are able to access prior drug claims history for an enrollee of an affiliated plan, a minimum of a 108-day lookback is typically needed to adequately document ongoing drug therapy. That is, if a 108-day lookback does not show claims history for the drug for the beneficiary, the Part D sponsor treats it as a first fill, and does not provide a transition supply.

A 108-day lookback for this purpose accounts for the enrollee having a quantity of a Part D drug on hand prior to requesting a subsequent fill – meaning that CMS calculates the quantity on hand by assuming the enrollee has a 20 percent remaining balance of a previously dispensed 90-day supply prior to receiving a subsequent 90-day supply leading up to their transition period. The enrollee could have a total of 108 days supply on hand to use before they would need a transition supply and no claims for the drug during that 108-day period. Thus, on day 109, the sponsor would need to look back 108 days to catch the enrollee's last refill for the drug, which demonstrates ongoing therapy.

We propose to codify our policy by requiring at § 423.120(b)(3)(vii)(A) and (B) that, if a Part D sponsor has access to prior drug claims history for the enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history lookback period to determine at point-of-sale whether a pharmacy claim represents a new prescription which would not require a transition fill, or ongoing drug therapy which would require a transition fill. If a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or ongoing therapy, the sponsor must treat the prescription as ongoing therapy which would require a transition fill.

4. Pharmacy & Therapeutics (P&T) Committee Role in Transition

Section 30.1.7 of Manual Chapter 6 addresses the P&T Committee's role in transition. Last updated in 2008, some of its language is outdated vis-a-vis the current transition requirements of § 423.120(b)(3). However, we do wish to codify the P&T committee's role in

transition. As Manual Chapter 6 states, CMS looks to transition process submissions for assurances that a sponsor's P&T Committee will review and provide recommendations regarding the transition procedures. The manual guidance states the rationale for this policy – because a Part D sponsor's P&T committee must include a majority of members who are practicing physicians and/or pharmacists under § 423.120(b), when the sponsor's P&T committee reviews a sponsor's transition procedures, it ensures that persons with medical and pharmaceutical expertise have reviewed such procedures.

We propose to codify this policy by adding new § 423.120(b)(3)(viii) to require that the Part D sponsor's transition policies and procedures include assurances that the Part D sponsor's P&T Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures to comply with § 423.120(b)(3). We further propose to codify our current subregulatory guidance that such policies and procedures must be submitted through a process specified by CMS as part of the plan's annual bid.

5. Timing Clarifications for Transition Notices

Section 30.4.10 of Manual Chapter 6 provides guidance on transition notices, which must be sent by the Part D sponsor to the affected enrollee within 3 business days after adjudication of the temporary transition fill, in accordance with § 423.120(b)(3)(iv). We have received questions about how to calculate the three business days. While we have not previously provided specific guidance about this issue, we propose to specify in § 423.120(b)(3)(iv) that the first business day after adjudication of the transition fill – that is, the processing of the claim – counts as business day 1. For example:

- Claim adjudication occurs on either Friday, May 3, Saturday May 4, or Sunday, May 5.
- Monday, May 6 at 11:59 pm is the end of business day 1.
- Tuesday, May 7 at 11:59 pm is the end of business day 2.
- Wednesday, May 8 at 11:59 pm is the end of business day 3 and the deadline for sending the notice in this example.

6. Level of Care Changes

Section 30.4.7 of Manual Chapter 6 describes unplanned circumstances for current enrollees that can arise in which current drug regimens are not on sponsors' formularies. These circumstances usually involve level of care changes in which a beneficiary is changing from one treatment setting to another. For example, this includes beneficiaries who are discharged from a hospital to a home; end their skilled nursing facility Medicare Part A stay (where pharmacy charges were covered as part of the stay) and need to obtain their medications from their Part D plan thereafter; give up hospice status to revert to standard Medicare Part A and B benefits; end an LTC facility stay and return to the community; or are discharged from psychiatric hospitals with drug regimens that are highly individualized.

These admission and discharge scenarios potentially involve circumstances in which an enrollee's prescriptions are adjusted as they move through the health care system, and such adjusted prescriptions may include drugs that are not on a sponsor's formulary, or are on a sponsor's formulary but require prior authorization, step therapy, or are subject to an approved QL lower than the enrollee's current dose that is not a safety-based claim edit, as proposed at paragraph § 423.120(b)(3). Thus, these scenarios could involve interruptions in ongoing drug therapy for a Part D beneficiary.

Section 30.4.7 acknowledges that while Part A does provide reimbursement for "a limited supply" to facilitate beneficiary discharge, beneficiaries need to have a full outpatient supply available to continue therapy once this limited supply is exhausted. The guidance further notes that this is particularly true for beneficiaries using mail-order pharmacy services, using home infusion therapy, or residing in rural areas where obtaining a continuing supply of drugs may involve certain delays.

For these reasons, we propose at new paragraph § 423.120(b)(3)(i)(A)(5) to require Part D sponsors to apply their transition processes to current enrollees experiencing a level of care change, such as admission or discharge from a hospital, skilled nursing facility, long-term care

facility, and hospice. This would mean that, pursuant to § 423.120(b)(3), a Part D sponsor must provide for an appropriate transition process for enrollees experiencing a level of care change who are prescribed Part D drugs that are not on a sponsor's formulary, or are on a sponsor's formulary but require prior authorization, step therapy, or are, as proposed in section W.2. of this proposed rule, subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100.

However, acknowledging that a Part D sponsor may not have access to information about an enrollee's level of care changes, we propose new § 423.120(b)(3)(i)(A)(5) to specify that the sponsor would have to apply its transition process to enrollees experiencing a level of care change only if the sponsor were notified of such change by the enrollee or their representative, their prescriber, the hospital or facility, or a pharmacy before or at the time of the request for the fill referenced in § 423.120(b)(3)(iii). Such notification could be by electronic messaging.

7. LTC Emergency Supply

Section 30.4.6 of Manual Chapter 6 states, that as a matter of general practice, LTC facility residents need to receive their medications as ordered without delay. This is because the requirements for LTC facilities at § 483.45 state that the facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(g). Section 483.45(a) also requires that a facility provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

The State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities (Rev. 11-22-17)[172] contains guidance for complying with § 483.45. Paragraph A on page 455 of this guidance, titled "Provision of Routine and/or Emergency Medications" states, "The regulation at § 483.45 requires that the facility provide or obtain routine and emergency

[172]https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf

medications and biologicals in order to meet the needs of each resident…Whether prescribed on a routine, emergency, or as needed basis, medications should be administered in a timely manner. Delayed acquisition of a medication may impede timely administration and adversely affect a resident's condition."

Accordingly, our longstanding policy in section 30.4.6 has been that Part D sponsors must also cover emergency supplies of new starts of non-formulary Part D drugs for LTC facility residents, outside of any respective transition periods for them, while an exception or prior authorization request is being processed. We propose to codify this requirement. Specifically, we propose to add a paragraph (8) to § 423.120(b) that would require a Part D sponsor to cover such an emergency supply during any portion of the plan year when the enrollee did not otherwise qualify for a transition fill under § 423.120(b)(3). Additionally, we propose that for purposes of a LTC emergency fill requirement, "non-formulary" would have the same meaning as it does for transition fills at paragraph (b)(3) – that is, a non-formulary drug also means drugs that are on the Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization, step therapy, or are subject to a QL that is not a safety-based claim edit as defined in § 423.100 under the plan's drug utilization management rules). Also, in § 423.120(b)(8), we propose that this emergency supply must be for at least 31 days of medication, regardless of dispensing increments, unless the prescription is written by a prescriber for less than 31 days.

8. Summary of Proposals

In summary, we are proposing to codify current Part D transition guidance at § 423.120(b) as follows:

- Specify at paragraph (b)(3) that, for transition purposes, non-formulary drugs include drugs that are on the sponsor's formulary but are subject to a QL that is not a safety-based claim edit as we propose to define that term in § 423.100; and make a conforming change to § 423.120(b)(3)(iii) to include a reference to QLs.

- Add new paragraph (b)(3)(vii)(A) to require that if a Part D sponsor has access to prior drug claims history for the enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history lookback period to determine whether a pharmacy claim represents a new prescription which would not require a transition fill, or ongoing drug therapy which would require a transition fill. Paragraph (b)(3)(vii)(B) would state that if a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or ongoing therapy, the sponsor must treat the prescription as ongoing therapy which requires a transition fill.

- Add new paragraph (b)(3)(viii) to require that the Part D sponsor's transition policies and procedures include assurances that the Part D sponsor's P&T Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures to comply with § 423.120(b)(3), and that such policies and procedures must be submitted through a process specified by CMS as part of the plan's annual bid.

- Specify at paragraph (b)(3)(iv) that the first business day after adjudication of the transition fill counts as business day 1 for purposes of determining when a transition notice must be provided to an enrollee.

- Add new paragraph (b)(3)(i)(A)(5) to include a new group of enrollees experiencing a level of care change, to which a Part D sponsor's transition process must apply, if the sponsor is notified of such change by the enrollee or their representative, their prescriber, the hospital or facility, or a pharmacy before or at the time of the request for the fill referenced in § 423.120(b)(3)(iii).

In addition, we propose to codify our current long-term care (LTC) emergency supply guidance as follows:

- Add new paragraph § 423.120(b)(8) to codify a requirement that a Part D sponsor must cover an emergency supply of a non-formulary Part D drug for a long-term care facility resident after their respective transition period, including Part D drugs that are on a sponsor's formulary

but under a plan's drug utilization management rules, require prior authorization, step therapy, or are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100.

As the foregoing describes our proposal to codify existing guidance with which we believe Part D sponsors are currently complying, we conclude that there is no additional paperwork burden for sponsors from this proposal.

We solicit comments on these proposals.

X. Update of Terminology to "Individuals with Intellectual Disabilities" (§ 423.154)

Following the passage of Rosa's Law (Pub. L. 111-256) in 2010, CMS updated references in CMS regulations to the term "mentally retarded" (MR) and replaced that term with the term "individuals with intellectual disabilities" (IID) in the "Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" final rule which appeared in the **Federal Register** on May 16, 2012 (77 FR 29001). This global terminology change included updating the definition at § 435.1010 of individuals receiving active treatment in "intermediate care facilities for the mentally retarded" (ICF/MR)," changing the term for the facility to "intermediate care facilities for individuals with intellectual disabilities." However, at that time, we inadvertently neglected to update the Part D regulation at § 423.154(c), which provides a waiver for certain requirements regarding dispensing Part D drugs to individuals in intermediate care facilities (ICFs) "for the mentally retarded … as defined in § 435.1010" that otherwise apply to other types of long-term care facilities.

Additionally, in the "Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" final rule which appeared in the **Federal Register** on February 12, 2015 (80 FR 7911), we updated the abbreviation in regulation text in § 423.154 from ICFs/MR to ICFs/IID, but inadvertently neglected to change the corresponding text in the regulation from which the abbreviation derives.

Consequently, we are taking this opportunity to update the current language at § 423.154(c) (that is, intermediate care facilities for the mentally retarded) with the abbreviation

(that is, ICFs/IID) and the definition at § 435.1010. We propose to replace the term "the mentally retarded" at § 423.154(c) with "individuals with intellectual disabilities."

We welcome comments on this proposal.

Y. Technical Correction to Restore the Substantial Difference Requirement (§ 423.265)

We are proposing to make a technical correction to § 423.265(b)(2) to restore language on requirements for substantial differences between Medicare Part D sponsors' bids that was inadvertently removed in a recent revision of the section.

Section 1857(e)(1) of the Act authorizes us to establish contract terms that CMS finds ''necessary and appropriate.'' Section 1860D– 11(d)(2)(B) of the Act requires us to promulgate ''reasonable minimum standards'' for Part D sponsors through regulations. Accordingly, we added language to the regulatory text at § 423.265(b) to require Part D bid submissions to reflect substantial differences in benefit packages or plan costs as part of the "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" final rule, which appeared in the **Federal Register** on April 15, 2010 (75 FR 19678).

Additionally, 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 (hereinafter referred to as the April 2018 final rule, 73 FR 16440), we reorganized paragraph (b)(2) to incorporate a general rule in paragraph (b)(2)(i) and an exception in paragraph (b)(2)(ii), the latter of which excluded enhanced alternative plan bid submissions from the substantial difference requirement.

We added language placing limits on the number of Part D plan offerings as part of 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 **Federal Register** on January 19, 2021 (hereinafter referred to as

the January 2021 final rule, 86 FR 5864). However, the new language was incorrectly added to § 423.265(b)(2) rather than § 423.256(b)(3), and the previous regulatory text on substantial differences was inadvertently overwritten. To correct this inadvertent deletion, we propose to:

- Redesignate the regulatory text from our January 2021 final rule limiting the number of bids a Part D plan sponsor may submit currently at § 423.265(b)(2) as § 423.265(b)(3);
- Restore the language from our April 2018 final rule on substantial differences at § 423.265(b)(2)(i) and (ii); and
- Redesignate the regulatory text currently at § 423.265(b)(3) as paragraph (b)(4).

As described previously, all of the regulatory language that we propose to restore at § 423.265(b)(2) has previously undergone the full notice and comment process. This proposal would merely correct a technical error made by the January 2021 final rule.

We welcome comments on this proposal.

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

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

In this proposed rule, we propose to codify the definitions of "global reopening" and "targeted reopening." We also propose to modify the timeframe for performing a reopening for good cause from within 4 years to within 6 years to align with the 6-year overpayment look-back period described at § 423.360(f) and to help ensure that payment issues, including overpayments, can be rectified. In addition, we propose to codify the circumstances under which CMS will notify the sponsor(s) of our intention to perform a reopening and the requirement for CMS to announce when it has completed a reopening.

1. Summary of the Current Process

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

By calendar year 2013, CMS had completed reopenings of the 2006, 2007, and 2008 Part D payment reconciliations and began our pattern of completing reopenings for subsequent Part D payment reconciliations approximately 4 years after the completion of each Part D payment reconciliation (consistent with the timing described at § 423.346(a)(2)). These reopenings included all Part D contracts that met the following criteria: (1) were in effect during the contract year being reopened, and (2) were either in effect at the time CMS completed the reopening or, if nonrenewed or terminated pursuant to § 423.507 through § 423.510 (collectively referred to as "terminated" for the purposes of the proposed rule), had not completed the final settlement process by the time CMS completed the reopening. CMS has referred to this type of program-wide reopening as a "global reopening." See, for example, HPMS memorandum, "Reopening of

the 2006, 2007, and 2008 Part D Payment Reconciliations," April 2, 2012 (available at https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-2012-qtrs-1-4).

In addition to "global reopenings," CMS has performed reopenings as part of our process to correct certain issues. We would consider performing a reopening to correct issues such as those associated with CMS-identified problems with an internal CMS file that CMS used in a Part D payment reconciliation, a coverage gap discount program reconciliation, or a reopening; CMS corrections to a PDE edit that impacted a specific plan type (for example, EGWPs); fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor; or a Part D sponsor's successful appeal of a reconciliation result. See, for example, HPMS memorandum, "Second reopening of the 2011 Final Part D Payment Reconciliation," July 7, 2017 (available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3) and HPMS memorandum, "Reopening of the 2014 Final Part D Reconciliation for Employer Group Waiver Plans (EGWPs)," January 11, 2017 (available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr1). These reopenings are not program-wide, but rather are targeted to the Part D contracts that are impacted by the particular issue that needs to be addressed by CMS (that is, "targeted reopenings"). The targeted reopenings are not performed on a predictable schedule, and instead are utilized by CMS in the confines on the reopening timeframes described in the current regulation at § 423.346(a)(1) through (3).

Although in our most recent experience, CMS has utilized targeted reopenings as part of our process to correct certain issues (described above), under the current process, if a particular issue was program-wide, CMS would perform a global reopening to address that issue. This

global reopening could be in addition to the scheduled global reopening that CMS has performed approximately four years after the Part D payment reconciliation for that year.

2. Aligning the Timing of Reopenings to the Overpayment Look-back Period

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

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

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

This 6-year look-back period along with the 4-year reopening timeframe described at § 423.346(a)(2) results in overpayments being reported for a contract year after CMS has performed the global reopening for that contract year. Continuing from the example above, if a Part D sponsor identified a PDE or DIR related overpayment associated with contract year 2016

in May 2022 (that is, prior to the deadlines for submitting data for the 2021 Part D payment reconciliation), that overpayment falls within the 2015-2020 look-back period, and the sponsor would have reported the overpayment to CMS mid-2022. However, CMS completed the global reopening of the 2016 Part D payment reconciliation in January 2022. This discrepancy between the 4-year reopening timeframe and the 6-year overpayment look-back period results in operational challenges for CMS, discussed below.

CMS had described a process for recouping PDE and DIR related overpayments after the global reopening for the contract year at issue had been completed. In the preamble to our final rule, "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," 79 FR 29843 (May 23, 2014) and in subsequent subregulatory guidance, we stated that overpayments reported after the global reopening would be reported by the sponsor with an auditable estimate and that CMS would recoup the overpayment by either requesting a check or offsetting monthly prospective payments for the amount provided in the auditable estimate. See HPMS memorandum, “Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting,” April 6, 2018 (available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-Week1-Apr-2-6). For PDE and DIR related overpayments, that approach presents challenges primarily because sponsors have also reported PDE and DIR related underpayments after the global reopening, which we do not have a method to process other than the reopening process.

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

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

Should this proposal be adopted, CMS will provide operational guidance, as we have with every regularly scheduled global reopening. The following example describes the proposed timing for performing the scheduled global reopening. The data for the 2020 Part D payment reconciliation was due June 2021. That reconciliation was completed November 2021. Assuming the current 4-year schedule, the DIR data for the contract year 2020 global reopening would be due to CMS by the end of July 2025, PDE data would be due September 2025, and the 2020 global reopening would be completed the end of 2025 or early 2026. However, the 2020 contract year remains in the overpayment look-back period through June 2027. Under the proposed 6-year timeframe, data for the 2020 global reopening would be due middle to late 2027, and the global reopening would be completed late 2027 or early 2028, after the 6-year look-back period.

3. Standards for Performing Global and Targeted Reopenings

Consistent with the existing regulation at § 423.346(a) and (d), reopenings are at CMS' discretion. Under the current process, CMS has used its discretion to perform a scheduled global reopening on a Part D payment reconciliation within the timeframe specified at § 423.346(a)(2). Given the significant time and the costs associated with conducting a reopening, it is expected that CMS will use its discretion to conduct a targeted reopening (or an additional global reopening for a program-wide issue) only under limited circumstances. We would contemplate

using our discretion to perform a targeted reopening (or an additional global reopening) to correct or rectify a CMS file or CMS-created PDE edit-type issue, revise a payment determination that was based on PDE and/or DIR data that was submitted due to fraudulent activity of the sponsor or the sponsor's contractor, or pursuant to a successful appeal under § 423.350. CMS will not use its discretion to conduct a reopening to reconcile data that will be, or should have been, reconciled in the scheduled global reopening, which would include data from plan corrections, claims activity, and audits that were completed after the deadline for submitting data for the scheduled global reopening. In addition, we are unlikely to conduct a reopening solely pursuant to a sponsor's request. First, we propose that in order to be included in a reopening, a contract must have been in effect (that is, receiving monthly prospective payments and submitting PDE data for service dates in that year) for the contract year being reopened. Intuitively, if a contract was not in the reconciliation for a particular contract year, it cannot be included in the reopening of that contract year's reconciliation. Second, we propose that if CMS has sent a nonrenewed or terminated contract the "Notice of final settlement," as described at proposed § 423.521(a), by the time CMS completes the reopening, described at proposed § 423.346(f), CMS will exclude that contract from that reopening. We established the proposed exclusion based on the timing of the issuance of the "Notice of final settlement" and completion of the reopening, as opposed to the announcement of the reopening, due to the potentially lengthy reopening process and the likelihood that the "Notice of final settlement" will be issued prior to CMS completing the reopening process. For example, under the current timeframe for the scheduled global reopening, CMS has typically announced in the Spring and completed the reopening in December of that year or January of the next. During that timeframe, nonrenewed or terminated contracts will likely go through the final settlement process, and as a result, will not be able to complete the reopening process. This is because, pursuant to proposed § 423.521(f), after the final settlement amount is calculated and the "Notice of final settlement" is issued to the Part D sponsor, CMS will no longer apply retroactive payment adjustments, and

there will be no adjustments applied to amounts used in the calculation of the final settlement amount. We propose to codify these inclusion criteria at § 423.346(g).

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

4. Reopening Notification and Reopening Completion Announcement

We propose to add new paragraphs at § 423.346 to codify our existing policy regarding reopening notifications and reopening completion announcements. We propose to codify at § 423.346(e) that CMS will notify the sponsor(s) that will be included in the global or targeted reopening of its intention to perform a global or a targeted reopening – that is, the sponsor would receive prior notice of the reopening—only when it is necessary for the sponsor(s) to submit PDE data and/or DIR data prior to the reopening. In contrast, if it is not necessary for the sponsor(s) to submit data prior to a reopening, we propose to notify the sponsor(s) only after we have conducted the reopening. For example, if CMS identifies an error in an internal CMS file that CMS used in the reconciliation or reopening, CMS may correct that file and reopen (holding all other data originally used constant), without the need for the sponsor(s) to submit PDE data or DIR data. See, for example, HPMS memorandum, "Second reopening of the 2011 Final Part D

Payment Reconciliation," July 7, 2017 (available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3).

We propose at paragraph (e)(1) that CMS will include in the notification the deadline for submitting PDE data and/or DIR data to be included in the reopening. We also propose that the deadline to submit this data will be at least 90 calendar days after the date of the notice. Ninety days is consistent with our proposed PDE timeliness requirements at proposed § 423.325(b).

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

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

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

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

5. Definitions of "Global Reopening" and "Targeted Reopening"

We propose to adopt definitions of global reopening and targeted reopening at § 423.308. We propose that a global reopening is a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that the meet the inclusion criteria described at proposed § 423.346(g). We propose that the definition of the targeted reopening is a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsors contracts that the meet the inclusion criteria described at proposed § 423.346(g). Finally, consistent with these proposed definitions, we propose to add the terms "global reopening" and "targeted reopening" to existing § 423.346(a).

The proposals described previously are consistent with our current guidance and requirements. Nothing in this proposal places additional requirements on Part D sponsors. As such, the proposed changes to § 423.308 and § 423.346 do not place any additional burden on the Part D sponsors or their pharmacy benefit managers (PBMs). Our proposal will not change the extent to which Part D sponsors comply with the reopening process. Part D sponsors' compliance with this reopening process is evidenced by each Part D sponsor's signed attestation certifying the cost data (pursuant to § 423.505(k)(3) and (5)) that CMS uses in each of the reopenings. In addition, the burden associated with the submission of cost data is already approved under the OMB control numbers 0938-0982 (CMS-10174) and 0938-0964 (CMS-10141). Therefore, we do not believe that our proposal will result in additional burden and have not incorporated this provision in the COI section of this rule, nor are we are scoring this provision in the Regulatory Impact Analysis section because industry is already complying with this process.

AA. Part D Proposed Automatic Shipment Requirements (§ 423.505)

1. Background

An automatic shipment or automatic delivery (collectively referred to hereinafter as "auto-ship") service refers to the service whereby a pharmacy ships prescription refills to an individual's home when the refill is due without requiring the individual to make separate requests for each refill. Auto-ship service does not refer to the delivery of new prescription fills or prescription refills coordinated by long-term care (LTC) facilities for their residents. By "prescription refills," we mean all fills of a prescription for a medication after an individual has obtained an initial fill; including both refills with the same prescription number as well as prescription renewals for the same drug, dose, and instructions with new prescription numbers. Additionally, while often employed by traditional mail-order pharmacies, some retail pharmacies also offer auto-ship services.

Auto-ship services provide an added convenience for Part D enrollees and have the potential to improve adherence by preventing interruptions in therapy resulting from late refills. However, auto-ship services can also generate waste and additional costs for Part D enrollees and the Part D program when unneeded or unwanted refills are shipped. Once a drug leaves the pharmacy, it generally cannot be returned and reused. In an effort to address concerns with the potential waste, we provided guidance in the Final CY 2014 Call Letter instructing Part D sponsors to require their network pharmacies to obtain enrollee consent prior to shipping each new prescription or prescription refill (See page 144, published on April 1, 2013, and available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf). In effect, we were instructing Part D sponsors to prohibit their network pharmacies from providing auto-ship services because we were still requiring the individual to make separate requests for each refill.

Since the Final CY 2014 Call Letter, however, we have provided clarifications to the initial guidance, via Health Plan Management System (HPMS) memoranda and more recent Call

Letters, that have gradually allowed for additional auto-ship services. For example, the subsequent guidance provided exceptions for employer-group waiver plans (EGWPs) and for new prescriptions received directly from the prescriber for Part D enrollees with experience using auto-ship services. We applied these exceptions to pharmacies meeting certain conditions intended to balance the benefits of auto-ship services against the potential for waste and associated increased costs, such as providing that auto-ship services are for Part D enrollees that opt-in, and providing for refunds for any unwanted shipments. Most recently, we solicited feedback on proposed modifications to auto-ship services guidance as a part of the Draft CY 2020 Call Letter (See page 199 of Part 2, published on January 30, 2019, and available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRate Stats/Downloads/Advance2020Part2.pdf). The proposed modifications included expectations that pharmacies would obtain annual consent from enrollees to participate in an auto-ship program, only offer an auto-ship option for refills of drugs that a Part D enrollee has been on for at least four consecutive months, send at least two reminders in advance of each shipment, and provide a full refund for any refills auto-shipped that a Part D enrollee reported as unneeded or otherwise unwanted. After receiving overwhelmingly positive comments, we announced in the Final CY 2020 Call Letter (See page 230, published on April 1, 2019, and available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/ Downloads/Announcement2020.pdf) that, beginning in CY 2020, interested Part D sponsors could permit network pharmacies to offer opt-in, voluntary, auto-ship for refills of established therapies to further promote consistent access to medications, support medication adherence, and offer Part D enrollees additional choices in obtaining their covered Part D drugs. The final policy did not include the expectation that pharmacies obtain annual consent, or to auto-ship only to those enrollees that had been on the drug for at least four consecutive months. The guidance applied to auto-ship services for traditional multi-month mail-order supplies as well as auto-ship

services for shorter day supplies from pharmacies utilizing innovative dispensing models and specialized packaging.

We have not received concerns or complaints from Part D enrollees or Part D sponsors since we issued our current guidance in the Final CY 2020 Call Letter. We are now proposing to codify these policies for auto-ship services.

Section 1860D-12(b)(3) of the Act (42 U.S.C. 1395w-112(b)(3)) authorizes the Secretary to include contract terms for Part D sponsors that are consistent with Part C as found under sections 1857(a) and 1857(d) of the Act. We are committed to ensuring consistent and reliable access to Part D drugs for Part D enrollees, and propose to codify in regulation auto-ship policies with appropriate safeguards to prevent or limit unwanted or unnecessary auto-shipped prescriptions. Specifically, we propose to add a new paragraph at § 423.505(b)(28) to require Part D sponsors to require their network pharmacies that offer auto-ship services to--

- Provide automatic shipments only to Part D enrollees that opt-in, on a drug-by-drug basis, after an initial fill;
- Provide shipping reminders prior to each shipment;
- Refund any cost sharing paid by the Part D enrollee and reverse the claim when the enrollee reports the shipment is not needed or wanted; and
- Discontinue auto-ship services when a Part D enrollee requests to opt-out or when notified that a Part D enrollee has entered a skilled nursing facility or elected hospice coverage.

2. Voluntary Participation

We propose to add new paragraph § 423.505(b)(28)(i) to require Part D sponsors to require their network pharmacies that provide auto-ship services to provide automatic shipments only to Part D enrollees that opt-in to auto-ship services, on a drug-by-drug basis, after an initial fill. Drug-by-drug means that network pharmacies would be required to document that a Part D enrollee has opted to receive auto-ship services for each specific drug. A blanket opt-in option applying across multiple drugs would not satisfy this requirement. We

propose the qualifier "after an initial fill," because network pharmacies should not assume the Part D enrollee would consent to auto-ship services for a specific drug at the same time as an initial fill. A period of time is needed for the Part D enrollee to initiate therapy, and establish with their prescriber whether treatment with the new drug is tolerated and to be continued. Once a Part D enrollee voluntarily selects auto-ship services for a specific drug after an initial fill, a network pharmacy could consider this Part D enrollee to have chosen to have auto-shipped all prescription refills authorized for that drug. In addition, if a provider renews a prescription for a drug for which an enrollee previously selected auto-ship services, we propose that the network pharmacy may extend the Part D enrollee's previous consent for auto-ship services to the new prescription and its authorized refills, unless instructed otherwise by the Part D enrollee, their provider, or an authorized representative. In turn, auto-ship services may be cancelled by a Part D enrollee, their provider, or an authorized representative.

We welcome comments on this proposal.

3. Enrollee Notification

We propose to add new paragraph § 423.505(b)(28)(ii)(A)) to require Part D sponsors to require their network pharmacies to provide a minimum of two (2) shipping reminders to the Part D enrollee prior to shipment through auto-ship services. Such reminders would need to be received prior to shipment so that a Part D enrollee can modify or cancel an order, if needed. Part D sponsors may specify an approximate shipping date range (for example, 2-3 calendar days) in lieu of an exact date in shipping reminders.

We also propose to add new paragraph § 423.505(b)(28)(ii)(B) to specify that network pharmacies must provide the shipping reminders by hard copy mailing, telephone, electronic delivery, or other comparable means of communication such as a fax machine. The method of delivery should be based on the Part D enrollee's stated preference when feasible. A missed call with no message left, bounce-back e-mail messages, or returned direct mailings would not count

as successful shipping reminders because they indicate that the enrollee never received the reminder.

Additionally, we propose to add for § 423.505(b)(28)(ii)(C) the requirement that all types of reminders must, at a minimum, include the name of the Part D drug, any applicable cost sharing, the scheduled shipping date, instructions on how to cancel the pending automatic shipment, and instructions on how to opt-out of any future automatic shipments. In turn the pharmacy would be required to honor the request to cancel the specified drugs from further auto shipment.

We welcome comments on this proposal.

4. Refund Policy

We propose to add new paragraph § 423.505(b)(28)(iii) to require Part D sponsors to require their network pharmacies that provide auto-ship services to refund any cost sharing paid by the Part D enrollee for any shipped prescriptions that such Part D enrollee reports as unneeded or otherwise unwanted, regardless of whether the drug is returned to the pharmacy, and reverse the claim. Part D sponsors would be required to delete the associated Prescription Drug Event (PDE) for these reversed claims. We believe a full refund policy is necessary to protect the Part D enrollee from the potential cost, safety risk, and inconvenience of unneeded or unwanted prescriptions being filled, charged, and shipped. Unlike a retail pharmacy setting where a Part D enrollee can review a medication, including its use and cost, prior to purchasing, auto-ship services remove the opportunity for the Part D enrollee (or their authorized representative) to provide a final in-person check and confirmation of understanding prior to purchase. In addition, should a Part D enrollee report a drug enrolled in auto-ship services as unneeded or unwanted, this presents an opportunity for discussion between the network pharmacy and the Part D enrollee on continuing auto-ship services for the drug in question, or any other drugs enrolled in auto-ship services for the Part D enrollee. Given the proposed reminder requirements discussed in section IV.AA.3 of this proposed rule,, combined with the fact that we have received no

complaints since our current guidance on auto-ship services has been in effect, we believe network pharmacies are well positioned to evaluate the appropriateness and safety of auto-ship services in collaboration with Part D enrollees. Moreover, we believe the lack of complaints received are also an indication that the potential for abuse of such a refund policy is low.

We welcome comments on this proposal.

5. Discontinuation

We propose to add new paragraph § 423.505(b)(28)(iv) to require Part D sponsors to require their network pharmacies that offer auto-ship services to discontinue auto-ship services if A) the enrollee requests to opt-out of automatic shipments or B) the network pharmacy receives notification that a Part D enrollee entered a skilled nursing facility (SNF) or elected hospice. Notification that an enrollee has entered a SNF or elected hospice coverage may come via the Part D enrollee, the Part D enrollee's provider, the Part D enrollee's authorized representative, or the Part D sponsor. A Part D sponsor could receive such information via a data system, such as daily Transaction Record Reports (TRR) or the MARx system. Section 1860D-2(e)(2)(B) of the Act states that a drug prescribed to a Part D eligible individual cannot be considered a covered Part D drug if payment for such drug is available (or would be available but for the application of a deductible) under Part A or B for that individual as prescribed and dispensed or administered, such as during an inpatient hospital stay or home health episode. Thus, it is imperative that a network pharmacy discontinue auto-ship services for any drug that should be covered under Parts A or B due to a change in the Part D enrollee's status that has drug coverage implications.

We welcome comments on this proposal.

6. Summary of Proposals

In summary, consistent with our longstanding subregulatory guidance, we are proposing to codify in regulation at new paragraph § 423.505(b)(28) the following requirements for auto-ship services that Part D sponsors would be required to include in their network pharmacy contracts:

- The proposed § 423.505(b)(28)(i) would require that participation is voluntary;
- The proposed § 423.505(b)(28)(ii)(A) would require a minimum of two (2) shipping reminders prior to shipment, and § 423.505(b)(28)(ii)(B) would require that all types of reminders include all relevant information, such as the name of the Part D drug, any applicable cost sharing, the scheduled shipping date, instructions on how to cancel the pending automatic shipment ; and instructions on how to opt-out of any future automatic shipments;
- The proposed § 423.505(b)(28)(iii) would require a refund policy; and
- The proposed § 423.505(b)(28)(iv) would require discontinuation of auto-ship services if the network pharmacy receives a request from the enrollee, enrollee's prescriber, or authorized representative to opt-out of automatic shipments or notification that the Part D enrollee entered a skilled nursing facility or elected hospice coverage.

Additionally, as discussed in the preamble to this section, we have been monitoring compliance to this policy by monitoring complaints from both Part D sponsors and Part D enrollees. Consequently, there is no additional paperwork burden associated with codifying this longstanding policy.

We solicit comments on these proposals.

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

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

Part D sponsors contract with FDRs to perform many of the services critical to the operation of the Part D program. For example, FDRs administer formularies, process beneficiary

enrollments into plans, contract with pharmacies, process Part D claims at the point of sale, and administer enrollee appeals and grievance processes. Many Part D sponsors do not have the internal capability to take over administration of these functions from their FDRs on short notice. If an FDR ceases operations under a contract, enrollees in an affected plan may therefore be left without access to their Part D benefits until the sponsor is able to make alternative arrangements.

For these reasons, CMS has a critical interest in ensuring Part D sponsors' contracts with these FDRs protect beneficiaries and the program. We have codified a variety of requirements for sponsors' relationships with FDRs at § 423.505(i). For instance, we require that contracts protect enrollees from liability for fees that are the responsibility of the Part D sponsor (§ 423.505(i)(3)(i)) and that the FDR must provide services in a manner that is consistent with the Part D sponsor's contractual obligations (§ 423.505(i)(3)(iii)). These requirements promote consistent and competent administration of the Part D program.

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

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

To protect beneficiaries and the Part D program from the consequences of mid-month terminations of certain FDR contracts, we propose to establish at § 423.505(i)(6) a requirement that all Part D sponsors' contracts with FDRs that perform certain key Part D functions require a minimum of 60-days' prior notice of termination with an effective date that coincides with the end of a calendar month. We are adopting this change pursuant to our authority at section 1857(e) of the Act, made applicable to Part D through section 1860D-12(b)(3)(D), which authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate and not inconsistent with the Part D statute. This proposed policy is consistent with the existing

requirement that FDRs must comply with Part D requirements and support the sponsor's performance of its Part D functions, including ensuring access to covered Part D drugs under § 423.120(a), as required at § 423.505(i)(3)(iii) and (iv). Since Part D sponsors are paid prospectively and in units of no less than one calendar month, their subcontractors should be able to negotiate arrangements with their sponsors to access to covered Part D drugs in no less than 1-month increments by, for example, requiring sponsors to provide a surety bond to compensate the FDR in the event of the sponsors' fiscal insolvency. We do not believe that this will result in significant additional expense for sponsors because mid-month terminations have been very rare to date.

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

● Authorization, adjudication, and processing of prescription drug claims at the point of sale;

● Administration and tracking of enrollees' drug benefits in real time;

● Operation of an enrollee appeals and grievance process; and

● Contracting with or selection of prescription drug providers (including pharmacies and non-pharmacy providers) for inclusion in the Part D sponsor's network.

All of these functions are critical to beneficiaries maintaining access to Part D drugs and ensuring that they pay appropriate out of pocket costs. The disruption of any one of these functions could result in beneficiaries not receiving necessary drugs or incurring unnecessary costs.

We solicit comments on this proposal.

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

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

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

Given the significance of plan availability on a per region basis under the Part D statute, it makes sense to treat each PDP multiregion contract as, in effect, a set of distinct contracts, one for each PDP region, when CMS is taking action to protect market stability. For example, pursuant to § 423.859(a), CMS is required to make available to each beneficiary the choice of at least two Part D plans that serve the area in which they reside. At least one of those plans must

be a PDP. Also, each PBP may only serve one PDP region. PDP sponsors submit separate bids for each PDP region. CMS uses those region-specific bids to determine the regional premium benchmarks and identify PBPs into which LIS beneficiaries will be automatically enrolled. As such, a PDP sponsor exiting or reentering one region has little or no effect on the market for PDP products in any other region.

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

We believe the effective administration of the Part D program is best served by promoting stability at the PDP region level and preventing sponsors exiting and re-entering regions each year, which may cause disruption to the regional PDP offerings. We do not believe that we need to prohibit sponsors from entering new regions for two years after they have opted

to exit other regions in order to accomplish this goal. Therefore, we propose to modify §§ 423.507(a) and 423.508(e).

We propose to modify § 423.507(a)(3) as follows:

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

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

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

We solicit comments on these proposals.

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

1. Overview and Summary

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

We request comment on whether and under what circumstance we should permit crosswalks from PBPs offering basic prescription drug coverage to PBPs offering enhanced prescription drug coverage, whether we should require sponsors that non-renew an enhanced alternative PBP while continuing to offer individual market coverage in the same PDP region to

crosswalk affected beneficiaries into another PBP, and on limitations we should place on premium and cost increases for enrollees who are crosswalked between different PBPs. We are particularly interested in how best to balance avoiding gaps in prescription drug coverage, preserving beneficiary choice and market stability, and preventing substantial increases in costs to beneficiaries resulting from crosswalks.

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

2. Summary of Current PDP Crosswalk Policy

CMS has set forth its current PDP crosswalk policy in "Guidance for Prescription Drug Plan (PDP) Renewals and Nonrenewals" (hereinafter referred to as the PDP Renewal and Nonrenewal Guidance), issued in April 2018 and posted the CMS website at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Guidance-for-Prescription-Drug-Plan-PDP-Renewals-and-Non-Renewals-.pdf. We developed the guidance to prevent beneficiary disruptions when a PDP sponsor discontinues PBPs and to allow the consolidation of PDP contracts of subsidiaries of the same parent organization. We also developed guidance related to continuation of enrollment in renewing PDP PBPs in order to facilitate "evergreen" enrollments, as required by sections 1851(c)(3)(B) and 1860D-1(b)(1)(B)(ii) of the Act, by not requiring additional enrollment transactions when a PBP renews in a new plan year.

Consistent with the requirement in sections 1851(c)(3)(B) and 1860D-1(b)(1)(B)(ii) of the Act that an individual who has elected a plan is considered to make the same election until the individual changes an election or the plan is discontinued in the area in which the individual resides, enrollees remain in a renewing PBP for the following year if they do not make another election (or opt to discontinue Part D coverage). CMS requires the PBP's plan ID number to remain the same, and beneficiaries remain enrolled in the PBP unless they make another election.

If a Part D sponsor discontinues a PBP but continues to offer individual market coverage under the same PDP contract, CMS currently "crosswalks" enrollment from the non-renewing PBP into another active PBP under the same contract. This means that beneficiaries enrolled in the non-renewing PBP during the current plan year will be enrolled in another surviving PBP offered under the same contract the following year unless the beneficiary selects alternative coverage during the Annual Election Period (AEP). These plan crosswalks are referred to as "consolidated renewal" crosswalks. We use consolidated renewal crosswalks primarily to prevent beneficiaries from losing Part D coverage, as past experience indicates that about 20 percent of beneficiaries enrolled in Part D plans that non-renew without a subsequent plan crosswalk fail to select new coverage. In those cases, the beneficiaries not only lose Part D coverage, but also are subject to the Part D late enrollment penalty. We also use plan crosswalks in these situations in order to prevent plans from "dumping" beneficiaries who are high cost or whom the organization otherwise no longer wishes to cover.

Consolidated renewal crosswalks occur only with respect to non-renewing PBPs offering enhanced alternative coverage, as defined at § 423.100. Consistent with § 423.104(f)(2), we do not permit organizations to non-renew a PBP offering basic prescription drug coverage, as defined at § 423.100, unless they are non-renewing all individual market PBPs in a PDP region because a basic prescription drug plan offering is a requirement in order for a sponsor to offer enhanced alternative coverage within the same service area. In consolidated renewal crosswalks, sponsors may transfer affected enrollees into a PBP offering either enhanced alternative or basic prescription drug coverage. The enrollment of a non-renewing PBP is not "split" among multiple PBPs – that is, all beneficiaries enrolled in a non-renewing PBP are crosswalked to the same PBP in the following year.

If a Part D sponsor or multiple Part D sponsors under a single parent organization (as defined in § 423.4) operate multiple PDP contracts that they wish to consolidate in the following contract year, we permit plan crosswalks between the PBPs of the non-renewing contract(s) and

the PBPs in the surviving contract. These plan crosswalks are referred to as "contract consolidation" crosswalks. We do not permit plan crosswalks between PBPs under different PDP contracts held by subsidiaries of different parent organizations. We currently encourage contract consolidations when multiple subsidiaries of a parent organization offer individual market PDP coverage in the same region(s) in order to promote meaningful choices and competition in the PDP market. We are proposing in section III.V. of this proposed rule to limit the number of PDP contracts a parent organization may offer through its subsidiaries to one per PDP region, but we do not think this proposal will cause significantly more contract consolidations because, historically, few parent organizations have declined to consolidate contracts in this situation.

All the enrollment in a non-renewing contract subject to contract consolidation is crosswalked into the surviving contract. The surviving PDP contract must offer individual market plans in all the PDP region(s) covered by the non-renewing contract(s). As with consolidated renewal crosswalks, enrollment from a non-renewing PBP is not "split" into multiple PBPs and all enrollees from non-renewing enhanced alternative PBPs are transferred into another PBP offering either enhanced alternative or basic coverage.

Unlike with consolidated renewal crosswalks, contract consolidation crosswalks can involve the non-renewal of PBPs offering basic coverage. For contract consolidation crosswalks, enrollees in non-renewing PBPs offering basic coverage are crosswalked into the PBP in the surviving contract that offers basic coverage. We do not permit contract consolidation crosswalks from PBPs offering basic coverage to PBPs offering enhanced alternative coverage, in order to protect beneficiaries receiving low income subsidies ("LIS") from unexpected cost increases. A portion of the premium for an enhanced alternative PBP is supplemental premium. Under § 423.780(b)(1)(i), the LIS can only be used for the portion of the monthly beneficiary premium attributable to basic coverage. This does not include the amount attributed to supplemental coverage for enhanced alternative plans. Any LIS-eligible individuals enrolled in a non-renewing PBP offering basic prescription drug coverage that were transferred into a PBP

offering enhanced alternative coverage, and who did not change their election, might therefore have to pay more than they would for a PBP offering basic prescription drug coverage even if the enhanced alternative PBP had a lower overall premium.

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

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

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

We propose at § 423.530(a)(2)(i) through (iii) to adopt the crosswalk prohibitions in current CMS subregulatory guidance, described in the PDP Renewal and Nonrenewal Guidance. First, we propose to prohibit crosswalks between PBPs in different PDP contracts unless the PDP contracts are held by the same Part D sponsor or by sponsors that are subsidiaries of the same parent organization. Second, we propose to prohibit crosswalks that split enrollment of one PBP into multiple PBPs. Third, we propose to prohibit crosswalks from PBPs offering basic coverage to PBPs offering enhanced alternative coverage.

In the past, organizations have sought exceptions to the prohibition of basic-to-enhanced alternative crosswalks on the grounds that one of the available enhanced alternative PBPs is lower cost or otherwise a better alternative for enrollees in a non-renewing basic PBP than the available basic PBP. These requests come in the context of proposed contract consolidations crosswalks and, because CMS prohibits PDP contracts from offering more than one PBP offering

basic coverage in a region under § 423.265(b)(2), there would only be one option for the enrollees in non-renewing basic PBP to be transferred into. PBPs offering basic prescription drug coverage can vary widely in premium and estimated out of pocket costs. Enhanced alternative PBPs sometimes offer lower premiums than basic PBPs under the same contract. However, as discussed previously in section IV.AD.2. of this proposed rule, a portion of the premium for an enhanced alternative PBP is the "supplemental" premium and any LIS-eligible individuals transferred from a basic to an enhance PBP might therefore have to pay more than they would in the available basic PBP, even if the enhanced alternative PBP has lower overall premium. Therefore, we propose to continue our current policy in order to protect LIS-eligible beneficiaries from unanticipated premium increases.

We solicit comments on whether and under what circumstances to allow crosswalks from PBPs offering basic prescription drug coverage to enhanced alternative coverage. For instance, should CMS allow plan crosswalks under these circumstances if the premiums and/or estimated total beneficiary cost of the plan offering enhanced alternative coverage would be substantially lower than for the plan offering basic coverage. CMS is interested in how and to what extent permitting such crosswalks would affect the market for basic prescription drug coverage. CMS is particularly interested in how such crosswalks could be administered in a way that protects LIS-eligible beneficiaries from premium and other cost increases.

Plan crosswalks often occur in the context of contract renewals and non-renewals. We propose at § 423.530(a)(3) to require sponsors seeking crosswalks to comply with rules in §§ 423.507 and 423.508 governing non-renewals and contract terminations, respectively. This requirement is consistent with the requirement for MA plan crosswalks codified at § 422.530(a)(3).

We propose at § 423.530(a)(4) to make clear that only enrollees eligible for enrollment under § 423.30 can be crosswalked from one PBP to another. Individuals who are not eligible for

Part D enrollment cannot be enrolled in a Part D plan, so CMS cannot allow crosswalks of non-eligible individuals into new Part D plans.

Finally, we propose at § 423.530(a)(5) to continue to allow enrollees in employer group health or waiver PBPs to be transferred between PBPs in accordance with the usual process for enrollment in employer group health or waiver plans, rather than in accordance with the proposed provisions of § 423.530. This proposal ensures that the process for enrollment in employer group health or waiver plans is not disrupted by this proposed rule.

We solicit comments on these proposals.

4. Mandatory Crosswalks (§ 423.530(b))

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

We solicit comment on this proposal.

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

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

For consolidated renewals, we propose to codify current policy at § 423.530(c)(1) with four major modifications that balance concerns for beneficiaries in non-renewing plans losing coverage with concerns about market stability and limiting unexpected premium increases. As

we state in the PDP Renewal and Nonrenewal Policy, we currently expect sponsors that non-renew a PBP while continuing to offer individual market plans in the PBP's service area to crosswalk affected enrollees into a renewing PBP. As noted previously in section IV.AD.2. of this proposed rule, in recent years about 20 percent of beneficiaries in non-renewing plans that were not crosswalked failed to select new Part D coverage. These beneficiaries not only lose Part D coverage, but also may be subject to higher premiums when they reenroll in Part D because of the late enrollment penalty required under § 423.46. CMS has also sought to prevent sponsors from engaging in adverse selection by discontinuing a PBP, dropping its enrollees, and immediately starting a new PBP with the intention of attracting lower cost or otherwise more desirable enrollees.

However, in recent years, some plan crosswalks in these situations have resulted in premium increases of as much as 381 percent. In 2021, the median premium increase for such crosswalks was over 234 percent. While not every consolidated renewal crosswalk results in a premium increase, and increases are typically much smaller than those experienced in 2021, such large premium increases create a significant burden for beneficiaries. CMS has received significant complaints from beneficiaries who were surprised by large premium increases following a crosswalk. Affected contracts had more complaints than other contracts in the first three months after enrollees were crosswalked. To address this concern, we propose requirements for consolidated renewals that would reflect our current subregulatory policy, but with four significant differences.

First, we propose at § 423.530(c)(1) to allow, but not require, plan crosswalks in consolidated renewal scenarios. PDP sponsors could request a crosswalk of enrollment from a non-renewing PBP to another PBP under the same contract, provided it meets the requirements we are proposing.

We propose at § 423.530(c)(1)(i) through (iv) to codify provisions of our current policy for consolidated renewal crosswalks:

● The plan ID for the upcoming contract year PBP must be the same plan ID as one of the PBPs for the current contract year;

● The PBPs being consolidated must be under the same PDP contract;

● A PBP offering basic prescription drug coverage may not be discontinued if the PDP contract continues to offer plans (other than employer group waiver plans) in the service area of the PBP; and

● Enrollment from a PBP offering enhanced alternative coverage may be crosswalked either into a PBP offering either enhanced alternative or basic prescription drug coverage.

Our second major proposed change from current policy, at § 423.530(c)(1)(v), is that when a PDP sponsor chooses to crosswalk in a consolidated renewal scenario, to require enrollees from non-renewing PBPs offering enhanced alternative coverage to be crosswalked into the PBP that will result in the lowest premium increase. We intend for this requirement to minimize the premium increases experienced by beneficiaries who are crosswalked to new PBPs under a consolidated renewal crosswalk. Under this proposed requirement, we would permit an otherwise allowable plan crosswalk into any eligible PBP that offered the same or lower premium compared to the nonrenewing plan, but would not allow a crosswalk into a PBP with a $30 higher premium if an eligible plan with a $10 higher premium were available. We recognize that premiums are not the only aspect of a PBP's structure that affect costs to beneficiaries or the beneficiary experience. The PBP's formulary and cost-sharing structure are also important elements affecting beneficiary costs. However, premiums for a PBP are the same for every enrollee and are therefore the most straightforward factor to use to protect enrollees from unexpected cost increases. We are soliciting comments on whether we should use other factors, such as differences in estimated out of pocket costs (OOPC) between the non-renewing and surviving PBPs, rather than simply the difference in plan premiums, to determine whether approving a plan crosswalk exception is the best option for enrollees in a non-renewing PBP. We are also requesting comments on whether to allow plan crosswalks to a higher premium plan if

the difference between the higher premium plan and the lower premium plan is less than a certain dollar amount – for example, should CMS permit a crosswalk to a higher premium surviving PBP despite the availability of a lower premium surviving PBP if the difference between the premiums is less than a fixed dollar amount.

Third, we propose at § 423.530(c)(2)(vi) to prohibit plan crosswalks for consolidated renewals if the crosswalk would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), compared to the current year premium for the non-renewing PBP. CMS does not currently explicitly limit premium increases for renewing PBPs; however, CMS does have the authority under section1860D-11(d)(3) of the Act and § 423.265(b)(3) to decline to approve a bid that proposes significant increases in cost sharing or decreases in benefits. CMS negotiates with sponsors pursuant to this authority in order to limit increases in cost sharing or decreases in benefits, but not to explicitly limit premium increases.

Renewing PBPs therefore sometimes experience high premium increases. Despite this, in the past two years a larger share of consolidated renewal crosswalks have had premium increases of 100 percent or more compared to renewal PBPs. Only 0.8 percent of 906 PDP PBPs renewing for 2021 and 1.8 percent of 729 PBPs renewing for 2022 had premium increases greater than 100 percent. By contrast, 94.3 percent of 35 consolidated renewal crosswalks for 2021 and 29.6 percent for 2022 had premium increases greater than 100 percent.

Premium changes are also more variable year-to-year for consolidated renewal crosswalks. For the past 5 years, the average premium change for renewal PBPs ranged from an increase of 3.3 percent in 2019 to an increase of 15.9 percent in 2022. In the same time period, consolidated renewal crosswalks resulted in average premium changes that ranged from a decrease of 38.7 percent in 2019 to an increase of 229.5 percent in 2021. The data is summarized in Table 3.

TABLE 3: PREMIUM CHANGES FOR RENEWING PDP PDPS COMPARED TO CHANGES FOR CONSOLIDATED RENEWAL AND CONTRACT CONSOLIDATION CROSSWALKS

	Mean Premium Change for Renewal PDP PBPs	Mean Premium Change for Consolidated Renewal Crosswalks	Mean Premium Change for Contract Consolidation Crosswalks
2017-2018	11.6%	-7.6%	No Crosswalks
2018-2019	3.3%	-38.7%	29.2%
2019-2020	7.8%	-27.1%	No Crosswalks
2020-2021	7.4%	229.5%	No Crosswalks
2021-2022	15.9%	46.4%	47.1%

Because of the compressed time frames between bid submission and approval, CMS would base its assessment of premiums for the following plan year on information received with the initial bids on the first Monday in June. Bids are subject to change during the bid negotiation process, so a premium increase that appears acceptable in June may be higher by the time final bids are approved in August. However, the timing of plan crosswalk exceptions and bid review prevent CMS from basing crosswalk exception approvals on final bid amounts. Based on historical experience, we do not believe that there is significant risk that final premiums will differ substantially from those in the initial bid. We are soliciting comments on whether this timing may result in manipulation of bids and whether another measure of beneficiary costs, such as estimated OOPC, would be a more reliable measure to use given the difficulty of basing crosswalk approvals on final approved bids.

We recognize that some non-renewing plans may have very low premiums. A 100 percent increase for beneficiaries in a non-renewing plan with a current year premium of $14 would bring the following year's premium to only $28, which is less than 2022's base beneficiary premium of $33.37. We do not wish to prohibit plan crosswalk exceptions that would result in a large percentage increase and a relatively small dollar amount increase. Therefore, we propose to allow plan crosswalk exceptions where the premium increase would exceed 100 percent if the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), for the current year. We propose to use the current year's base beneficiary premium because the base beneficiary premium for the following year is not

known at the time bids are submitted. CMS also does not wish to reveal an estimated base beneficiary premium before the official release of the date in late July.

We seek comment on alternatives to using the base beneficiary premium. Potential alternatives include a fixed dollar amount, the low-income premium subsidy amount, described in § 423.780(b), for the non-renewing PBP's region, or the national average monthly bid amount, described in § 423.279.

The fourth and final proposed major modification to CMS's policy for consolidated renewal crosswalks at § 423.530(c)(1)(vii) is that sponsors that fail to request and receive a plan crosswalk exception would not be permitted to offer a new enhanced alternative PBP for the contract year after they non-renew an enhanced alternative PBP. For example, if a sponsor non-renews an enhanced alternative PBP effective 12/31/2023 and did not request and receive a plan crosswalk exception, we would decline to approve a new enhanced alternative PBP starting January 1, 2024. In other words, the earliest the sponsor would be permitted to create new PBP to replace the non-renewed PBP would be the 2025 plan year. We propose to adopt this restriction pursuant to the Secretary's authority at section 1857(e) of the Act, made applicable to the Part D program by section 1860D-12(b)(3) of the Act, to adopt additional terms and conditions as the Secretary may find necessary and appropriate. The proposed limitation on creating new PBPs would encourage sponsors to request plan crosswalk exceptions and discourage them from using the non-renewal process to disenroll beneficiaries who are high cost or who they otherwise no longer wish to serve. We believe this proposed policy will prevent discrimination and instability in the market. This policy is also consistent with other requirements in the Part D regulation, such as the restrictions at §§ 423.507(a)(3), 423.508(e), and 423.510(e)(1) on CMS entering into a new contract with sponsors that non-renewed or terminated a Part D contract for two years following the nonrenewal or termination.

These four proposed changes represent a significant shift from current policy. As such, we are soliciting comments on alternative approaches. Possible alternatives include, but are not

limited to: (1) requiring plan crosswalks when a sponsor non-renews an enhanced alternative PBP while continuing to offer individual market coverage under the same PDP contract, but prohibiting sponsors from creating a new PBP to replace the non-renewing PBP; (2) adopting the requirements as proposed, but prohibiting sponsors from creating new PBPs to replace non-renewing PBPs even if a plan crosswalk exception is requested and received; (3) using an alternative measure, such as OOPC, instead of or in addition to plan premiums to assess whether a plan crosswalk exception should be granted; or (4) adopting the current subregulatory policy without modification.

We are also proposing requirements for contract consolidations that would reflect our current subregulatory policy, but with two significant differences that parallel the proposals with respect to consolidated renewals. For contract consolidations, consistent with our current policy, we propose at § 423.530(c)(2) to approve plan crosswalk exceptions from non-renewing PBPs into PBPs in the surviving contract when the surviving contract is held by the same sponsor or by a subsidiary of that sponsor's parent organization. We propose at § 423.530(c))(2)(i) – (iv) to adopt the following requirements of current subregulatory policy:

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

The first significant change we propose to current subregulatory policy for contract consolidations is at § 423.530(c)(2)(v), which would require plan crosswalks from non-renewing PBPs offering enhanced alternative coverage into the PBP that would result in the lowest

premium increase. Second, we propose at § 423.530(c)(2)(vi) to prohibit plan crosswalks that would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), compared to the current year premium for the non-renewing PBP. We are proposing these modifications to current contract consolidation crosswalk policy for the same reasons outlined with respect to consolidated renewal crosswalks. We acknowledge that contract consolidations are infrequent compared to consolidated renewals – as shown in Table 3, contract consolidation crosswalks occurred in only 2 of the last 5 years – and that data unique to contract consolidation crosswalks is therefore less available. However, we believe that requirements for the different types of plan crosswalk exceptions should be as consistent as possible and are therefore proposing to apply the same requirements with respect to premium increases for consolidated renewal crosswalks to contract consolidation crosswalks.

We solicit comments on these proposals.

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

We propose to codify current procedures for submitting plan crosswalks and or making plan crosswalk exception requests at § 423.530(d), as described in "Bid Pricing Tool for Medicare Advantage Plans and Prescription Drug Plans" CMS-10142, posted for final comment pursuant to the Paperwork Reduction Act of 1995 at 87 Fed. Reg. 2441 (February 14, 2022). We propose that a Part D sponsor must submit all allowable plan crosswalks in writing through the bid submission process in HPMS by the bid submission deadline. Through the bid submission process, the Part D sponsor may indicate if a plan crosswalk exception is needed at that time; however, the Part D sponsor must also request a crosswalk exception through the crosswalk exception functionality in HPMS. CMS would verify the exception request and notify the requesting Part D sponsor of the approval or denial of the request after the plan crosswalk exception request deadline. CMS would approve any plan crosswalk exception that met the requirements of the proposed regulation. Because plan crosswalks are requested when a PBP is

non-renewing, a denied crosswalk request would result in the PBP being non-renewed without enrollment being crosswalked. Part D sponsors would be required to submit these exception requests to ensure that PBP enrollment is allocated properly.

We solicit comments on this proposal.

7. Summary of Proposals

In summary, we are proposing to add a new § 423.530 codifying plan crosswalk requirements and policy for PDP contracts. We propose making the following changes:

- At proposed paragraph (a)(2)(i), prohibit plan crosswalks between PBPs under one PDP contract to PBPs under a different contract, unless the contracts are held by the same Part D sponsor or by sponsors that are subsidiaries of the same parent organization;
- At proposed paragraph (a)(2)(ii), prohibit plan crosswalks that split the enrollment of one PBP into multiple PBPs;
- At proposed paragraph (a)(2)(iii), prohibit plan crosswalks between a PBP offering basic prescription drug coverage to a PBP offering enhanced alternative coverage;
- At proposed paragraph (b), require that renewing PBPs keep their enrollment and plan IDs from the previous year;
- At proposed paragraph (c), codify policy for plan crosswalk exceptions – including consolidated renewals and contract consolidations – with certain modifications relative to current subregulatory policy;
- At proposed paragraph (c)(1), permit consolidated renewal crosswalks when a sponsor non-renews an enhanced alternative PDP PBP while continuing to offer individual market coverage under the same PDP contract;
- At proposed paragraphs (c)(1)(iv) and (c)(2)(v), require that enrollment for enhanced alternative PBPs crosswalked pursuant to a crosswalk exception be crosswalked to the available PBP with the lowest premium increase;

- At proposed paragraphs (c)(1)(v) and (c)(2)(vi), prohibit plan crosswalks that would result in premium increase greater than 100 percent or higher than the base beneficiary premium for the current year, whichever is greater; and

- At proposed paragraph (c)(1)(vi), prohibit an organization that non-renews an enhanced alternative PBP without requesting and receiving a plan crosswalk exception from creating a new enhanced alternative PBP in the following contract year.

- At proposed paragraph (d), codify the process for requesting plan crosswalks for renewals and crosswalk exceptions.

We solicit comment on these proposals.

AE. Drug Management Program (DMP) Appeal Procedures (§ 423.562)

The Comprehensive Addiction and Recovery Act of 2016 (CARA) amended section 1860D-4(c)(5)(A) of the Act to provide that Part D plan sponsors may establish drug management programs (DMPs) for at-risk beneficiaries to reduce opioid overutilization in the Part D program. Subsequently, section 2004 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act provided that Part D plan sponsors must implement a DMP for plan years beginning on or after January 1, 2022.

We are proposing a technical change at § 423.562(a)(1)(v) that would remove discretionary language as it relates to a Part D plan sponsor's responsibility to establish a DMP under § 423.153(f) with appeal procedures that meet the requirements of subpart M for issues that involve at-risk determinations. This would eliminate the discretionary language and improve consistency with § 423.153(f), which requires each Part D plan sponsor to establish and maintain a drug management program and include appeal procedures that meet the requirements of subpart M for issues involving at-risk determinations. This provision would be strictly a technical change to the wording at § 423.562(a)(1)(v) and would not impact the underlying burden related to processing appeals of at-risk beneficiaries. Therefore, this proposal is not

expected to have an economic impact beyond current operating expenses, and there is no paperwork burden or associated impact on the Medicare Trust Fund.

We solicit comments on this proposal.

AF. Part D Sponsor Website Requirements (§§ 423.2265(b)(12) and 423.2265(c)(1)(vi))

As required under §§ 422.111(h)(2), 422.2265, 423.128(d)(2), and 423.2265, all plans must have a website that includes specific posted materials and content. We are proposing two changes to the Part D sponsor website requirements at § 423.2265.

At paragraph § 423.2265(b)(12), we are proposing a technical correction to delete a duplicate reference to the prescription drug transition policy, as this information is already listed as required website content at § 423.2265(b)(10). We propose to remove the reference to the "Prescription Drug Transition policy" at paragraph (b)(12) and redesignate that paragraph as reserved.

We are also proposing to clarify the requirements at § 423.2265(c)(1)(vi) to be consistent with longstanding policy. Specifically, we wish to clarify that a Part D sponsor's utilization management criteria, as approved by CMS, must be posted on the plan's website by October 15 prior to the plan year. The regulation currently indicates that utilization management forms must be posted; however, we recognize that utilization management criteria themselves are distinct from the forms used to submit a coverage determination to satisfy said criteria. We understand that historically, Part D sponsors would post utilization management criteria within a customized coverage determination form for a particular drug. Part D sponsors still have the option of taking this approach; however, we have learned that in recent years, Part D sponsors have favored the approach of posting utilization management criteria without generating drug-specific utilization management forms. Specifically, Part D sponsors have used the CMS Part D Model Coverage Determination Request form referenced at § 423.2265(c)(2)(ii). This model form does not contain plan specific utilization management criteria. Plans may continue to take either approach – that is, posting plan-specific utilization management criteria within a custom form or separately

from the model form. However, to account for the evolution in plan practice, we propose modifying paragraph § 423.2265(c)(1)(vi) to clarify the requirement that utilization management criteria (whether contained in a form or other format) must be posted on the plan's website by October 15 prior to the beginning of the plan year. By doing so, we ensure that beneficiaries can take the utilization criteria required to access a particular drug into account when evaluating their Part D plan options during the Annual Election Period (AEP). This revision also aligns the regulatory requirement with longstanding instructions from CMS in the "Medicare Parts C and D Annual Calendar" for Medicare Advantage (MA) plans, Medicare Advantage Prescription Drug (MA-PD) plans, and Prescription Drug Plans (PDPs) which specifies that Part D sponsors must post prior authorization and step therapy criteria on their websites by October 15 prior to the start of the benefit year.

We solicit comment on these proposals.

AG. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors that are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)

In this proposed rule, we propose to amend 42 CFR part 422, subpart K, and part 423, subpart K, to codify in regulation our final settlement process for Medicare Advantage (MA) organizations and Part D sponsors whose contracts with CMS have been consolidated with another contract, non-renewed, or otherwise terminated.

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

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

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

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

made to the MA organization or Part D sponsor or an amount is charged to the MA organization or Part D sponsor.[173]

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

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

For a given consolidated, nonrenewed, or otherwise terminated contract, the *final settlement amount* is then calculated by summing the applicable reconciliation amounts from these 4 processes and any retroactive payment adjustments that accumulated after a contract has consolidated, nonrenewed, or otherwise terminated. Note that these reconciliation amounts represent all of the reconciliation amounts that could be included in the final settlement

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

calculation. Whether each reconciliation amount will factor into the final settlement amount for a particular contract will depend on the specifics of that contract. For example, MA risk adjustment reconciliation would not be performed for a prescription drug plan contract.

The *final settlement adjustment period* is the period of time between when the contract consolidates, nonrenews, or otherwise terminates and the date the MA organization or Part D sponsor is issued a notice of the final settlement amount (also referred to herein as the *notice of final settlement*). The length of the final settlement period is determined by the time it takes for these reconciliations and related payment adjustments to be completed. During this time, CMS continues to calculate payment adjustments that reflect changes in beneficiary status.[174] CMS tracks all payment adjustments for a terminated contract for use in the final settlement for that contract.

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

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

otherwise terminated contracts, either on the part of CMS or on the part of the MA organization or Part D sponsor.[175]

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

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

[175] Once a contract has completed final settlement, the MA organization or Part D sponsor may still have financial responsibilities under section 1128J(d) of the Act.

amount. CMS would strongly encourage MA organizations and Part D sponsors to communicate their acceptance to CMS to facilitate prompt payment.

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

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

If an MA organization or Part D sponsor that owes a final settlement amount to CMS does not request an appeal or provides an optional response acknowledging and confirming the amount owed to CMS within 15 calendar days of the date of the notice of final settlement, the MA organization or Part D sponsor would be required to remit full payment to CMS within 120 calendar days of receiving the notice of final settlement. If an MA organization or Part D sponsor is owed money and does not appeal the final settlement amount, CMS would remit payment to the MA organization or Part D sponsor within 60 calendar days of the date of issuance of the

notice of final settlement. If an MA organization or Part D sponsor does not owe or is not owed a final settlement amount and does not request an appeal of the $0 final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement, no further actions would occur. If an MA organization or Part D sponsor does not appeal the final settlement amount indicated in the notice of final settlement within 15 calendar days of the issuance of the notice of final settlement no subsequent requests for appeal would be considered.

2. Process for Responses Requesting an Appeal of the Final Settlement Amount.

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

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

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

If the MA organization or Part D sponsor does not agree with CMS's reconsideration decision, it would be able to request an informal hearing from a CMS hearing officer. The MA organization or Part D sponsor would have to submit a request for review within 15 calendar

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

CMS would provide written notice of the time and place of the informal hearing at least 30 days before the scheduled date and would provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer. The CMS hearing officer would not receive new testimony or accept new evidence in addition to the evidence submitted by the MA organization or Part D sponsor during CMS' reconsideration to support its assertion that CMS' calculation of the final settlement amount is incorrect.

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

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

The CMS Administrator would have the discretion to elect to review the hearing officer's decision or decline to review the hearing officer's decision within 30 calendar days of receiving

the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision would be final and binding. If the Administrator elects to review the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor, the Administrator would review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor and determine whether to uphold, reverse, or modify the hearing officer's decision. The Administrator's decision would be final and binding and no other requests for review would be considered.

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

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

We solicit comments on this proposal.

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

a. Definitions

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

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

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

b. Final Settlement Process and Payment

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

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

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

At proposed paragraph (c), we propose to codify the actions that would take place if an MA organization or Part D sponsor does not appeal the final settlement amount. Specifically, at paragraph (c)(1), we propose to specify that, if an MA organization or Part D sponsor owed a final settlement amount from CMS does not appeal, CMS would remit payment within 60 calendar days of the date of the issuance of the notice of final settlement. At proposed paragraph

(c)(2), we propose that an MA organization or Part D sponsor that owes money to CMS and does not appeal would have to remit payment in full to CMS within 120 calendar days from issuance of the notice of final settlement. We further specify that an MA organization or Part D sponsor that does not appeal and does not remit payment within 120 calendar days of issuance of the notice would be subject to having any debts owed to CMS referred to the Department of Treasury for collection.[176]

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

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

c. Requesting an Appeal of the Final Settlement Amount

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

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

Specifically, at proposed paragraph (a)(1), we propose to establish the process under which an MA organization or Part D sponsor may request reconsideration of the final settlement amount. We propose to specify that the 15-calendar-day period for filing the request would begin

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

on the date the notice of final settlement from CMS is issued. We also propose that MA organizations and Part D sponsors would have to include in their request the calculations with which they disagree and that the MA organization or Part D sponsor would have the obligation to provide evidence supporting the assertion that the CMS calculation of the final settlement amount is incorrect. We further specify that MA organizations and Part D sponsors should not submit new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS would not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

At proposed paragraph (a)(1)(iii), we propose to establish that the CMS reconsideration official would review the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the MA organization or Part D sponsor. We further propose to establish that the CMS reconsideration official would inform the MA organization or Part D sponsor of their decision on the reconsideration in writing and that their decision would be final and binding unless the MA organization or Part D sponsor requests a hearing officer review.

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

Specifically, at paragraph (a)(2)(i), we establish that MA organizations and Part D sponsors would have to submit their requests for an informal hearing within 15 calendar days of the date of the reconsideration decision. At paragraph (a)(2)(ii), we propose that MA organizations and Part D sponsors would have to include in their request a copy of CMS' decision, the specific findings or issues with which they disagree, and the reasons for which they disagree. At paragraph (a)(2)(iii), we propose to establish the informal hearing procedures. Specifically, we propose that CMS would provide written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date and would provide a copy of

the record that was before CMS when CMS made its reconsideration decision to the hearing officer. We further propose that the hearing would be conducted by a hearing officer who would neither receive testimony nor accept new evidence. We finally propose that the hearing officer would be limited to the review of the record that was before CMS when CMS made its decision. At paragraph (a)(2)(iv), we propose that the CMS hearing officer would send a written decision to the MA organization or Part D sponsor explaining the basis for the decision. At proposed paragraph (a)(2)(v), we propose to establish that the hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator.

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

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

At proposed paragraph (b), we propose to establish the matters subject to appeal and that an MA organization or Part D sponsor bears the burden of proof. At proposed paragraph (b)(1),

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

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

Proposed paragraph (d) clarifies that nothing in this section would limit an MA organization or Part D sponsor's responsibility to comply with any other applicable statute or regulation, including section 1128J(d) of the Social Security Act.

We solicit comments on this proposal.

AH. Gross Covered Prescription Drug Costs (§423.308)

Section 1860D-15(b)(3) of the the Act defines "gross covered prescription drug costs" as, "with respect to a part D eligible individual enrolled in a prescription drug plan or MA-PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage." In our final rule, "Medicare Program; Medicare Prescription Drug Benefit," published in the **Federal Register** on January 28, 2005 (70 FR 4194), we codified the

definition of "gross covered prescription drug costs" at § 423.308. This regulatory definition refers to "gross covered prescription drug costs" as "actually paid costs." The term "actually paid" has a specific meaning in Medicare Part D and is separately defined at § 423.308 to mean costs actually incurred by the plan that are net of direct and indirect remuneration (DIR), including discounts, rebates, or other price concessions typically received and applied after the point of sale. However, unlike the statutory definitions of "allowable reinsurance costs" and "allowable risk corridor costs" at sections 1860D-15(b)(2) and 1860D-15(e)(1)(B) of the Act, respectively, the statutory definition of "gross covered prescription drug costs" at section 1860D-15(b)(3) of the Act does not use the phrase "actually paid" or otherwise specify that such costs must be net of all DIR. Because the definition of "gross covered prescription drug costs" was codified in regulation for the sole purpose of describing the methodology for calculating the reinsurance payment amount, in using the phrase "actually paid" in said regulatory definition of "gross covered prescription drug costs," CMS was incorporating a requirement from the statutory definition of "allowable reinsurance costs" to emphasize that DIR would be netted out in the calculation of costs eligible for Part D reinsurance as required by the statute.

We note that certain provisions added to the Social Security Act by the Inflation Reduction Act of 2022 (IRA) refer to "gross covered prescription drug costs as defined in section 1860D–15(b)(3) [of the Act]" (see sections 1191(c)(5) and 1860D-14C(g)(4)(D) of the Act). Accordingly, we believe it is an appropriate time to revisit our regulatory definition of "gross covered prescription drug costs" to mirror the statute's language and to remove any ambiguity that might arise from the current regulatory definition as it may now also be applicable outside of the reinsurance context. Therefore, we propose to amend the definition of "gross covered prescription drug costs" at § 423.308 to remove the phrase "actually paid."

Revising the definition as proposed would not change the fact that Part D reinsurance is ultimately based on net drug costs or change the final reinsurance payment amount a Part D sponsor receives. Rather, as explained further below, allowable reinsurance costs would continue

to be defined at § 423.308 as the subset of gross covered prescription drug costs actually paid. The proposed revision, therefore, would not constitute a change in policy or require a change in operations under Part D, and thus would not place any additional burden or reduce burden on Part D sponsors, nor result in government savings or costs.

1. Background

The term "gross covered prescription drug costs" (hereinafter referred to as "GCPDC") is defined and used at section 1860D-15(b) of the Act for the purpose of describing the methodology for calculating the reinsurance payment amount. As specified in section 1860D-15(b)(1)(A) of the Act, the reinsurance payment amount for a year preceding 2025 is equal to "80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B)." As noted above, although the statutory definition of "allowable reinsurance costs" at paragraph (2) of section 1860D-15(b) of the Act specifies that such costs are the subset of GCPDC that are "actually paid (net of discounts, chargebacks, and average percentage rebates)," the statutory definition of GCPDC at paragraph (3) of that provision does not use the phrase "actually paid" or otherwise specify that such costs must be net of all DIR. This distinction, coupled with the use of the modifier "gross" to describe these costs indicates that the best reading of section 1860D-15(b)(3) of the Act is that GCPDC should reflect gross costs, not net costs that reflect all DIR that a Part D sponsor may receive. As stated above, CMS's use of the phrase "actually paid" in the current regulatory definition of GCPDC was intended to emphasize that all DIR would be netted out in the calculation of costs eligible for Part D reinsurance consistent with the plain language of the statute, which requires that the reinsurance payment amount be based on net drug costs. While the use of the phrase in the current regulatory definition of GCPDC is consistent with the statute for this reason, we recognize that that it may have led to ambiguity as to when the DIR would be netted out. We also

recognize that the use of the phrase could create ambiguity when GCPDC is referenced outside of the reinsurance context (as it now is by the IRA).

It is important to note that the statutory definition of GCPDC further describes these costs as "not including administrative costs, but including costs directly related to the dispensing of covered Part D drugs during the year and costs relating to the deductible." CMS has long held that costs directly related to the dispensing of covered Part D drugs are most logically calculated as the accumulated total of the negotiated prices that are used for purposes of determining payment to the pharmacy or other dispensing entity for covered Part D drugs, and which are required under section 1860D-2(d)(1) of the Act to be made available to Part D beneficiaries and are used to adjudicate the Part D benefit (that is, used to determine plan, beneficiary, manufacturer, and government liability during the course of the payment year).[177, 178] As stated in several past rulemakings, we interpret the statutory definition of "negotiated prices" at section 1860D-2(d)(1)(B) of the Act as allowing the application of DIR at the point of sale, to reduce the negotiated price, either at the discretion of Part D plan sponsors or at the direction of CMS (see, for example, 70 FR 4244, 74 FR 1511, and 87 FR 27833). Therefore, even if the phrase "actually paid" were not included in the regulatory definition of GCPDC, GCPDC would continue to be reduced by POS DIR reflected in negotiated prices. However, such an accounting of POS DIR

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[177] This logic is borne out in the portion of our current regulatory definition of GCPDC at § 423.308 that states that GCPDC reflect "actual costs." "Actual cost" is defined at § 423.100 as the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy.

[178] The different components of the negotiated price of a drug, and ultimately of GCPDC, are required to be reported separately using the following cost fields on the Prescription Drug Event (PDE) record submitted to CMS by Part D plan sponsors for payment purposes, the sum of which must equal GCPDC: Ingredient Cost, Dispensing Fee, Vaccination Administration, and Sales Tax. GCPDC are also required to be reported using the following two payment fields on the PDE record depending on whether the costs fall in the catastrophic phase: Gross Drug Cost Below the Out of Pocket (OOP) Threshold (GDCB) and Gross Drug Cost Above the OOP Threshold (GDCA). The amounts reported in these fields are then used to update the Total Gross Covered Drug Cost (TGCDC) Accumulator on the PDE record, which tracks and indicates which non-catastrophic phase of the Part D benefit the beneficiary is in. See, for example, 2006 Prescription Drug Event Data Training Participant Guide, available at https://www.csscoperations.com/internet/csscw3_a.nsf/DIDC/K3V5B8PN1H~Prescription%20Drug%20Program%20(Part%20D)~Training, and 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, available at https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training.

would not make the resulting amount "actually paid," which requires the accounting for all DIR, including DIR not applied at the POS.

To mirror the statute's language and to remove any ambiguity that might arise from the current regulatory definition of GCPDC as described above, we propose to amend the definition of "gross covered prescription drug costs" at § 423.308 as discussed in greater detail below.

2. Proposed Change

Consistent with the language of section 1860D-15(b) of the Act, policy, including the current reporting requirements, and operations, including how the industry tracks and reports costs (that is, industry practice), we propose to amend the definition of "gross covered prescription drug costs" at § 423.308 to remove the two references to "actually paid" to clarify that GCPDC are not net of all DIR.

The proposed change would have no impact on Part D payment calculations or reporting requirements. Consistent with section 1860D-15(b)(2), the reinsurance payment amount would continue to be calculated based on drug costs net of DIR. Outside of the reinsurance context, CMS' long-standing operational guidance has instructed plans to report costs without first netting out DIR applied after the point of sale, and, thus, the guidance would not need to be adjusted as a result of this proposed change to the regulatory definition of GCPDC. For instance, the amounts reported in the Ingredient Cost, Dispensing Fee, Vaccine Administration, Sales Tax, GDCB, GDCA, and the TGCDC Accumulator fields on the PDE record are required to include costs incurred by the Part D sponsor and all amounts paid by or on behalf of an enrollee under a Part D plan.[179] Further, CMS guidance instructs Part D sponsors to net out only plan

[179] See 2006 Prescription Drug Event Data Training Participant Guide, available at https://www.csscoperations.com/internet/csscw3_a.nsf/DIDC/K3V5B8PN1H~Prescription%20Drug%20Program%20(Part%20D)~Training, and 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, available at https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training.

administrative costs and any DIR applied at the POS when reporting GCPDC.[180] Hence, a key step in calculating the Part D reinsurance payment amount is to determine the allowable reinsurance cost amount by subtracting from the GCPDC incurred in the catastrophic phase all DIR attributable to the proportion of catastrophic phase spending that was not already accounted for at the POS in order to determine the amount "actually paid" by the Part D plan and ensure that the reinsurance payment amount is ultimately calculated based on net drug costs. As we would continue to take this important step in determining allowable reinsurance costs for purposes of calculating the reinsurance payment amount even if "actually paid" were removed from the regulatory definition of GCPDC as proposed, there would be no change in the final reinsurance payment amount a Part D sponsor receives.

Moreover, no other rules or policies would be affected by this proposed change, including the rules regarding how to account for coverage not provided by the Part D sponsor, and instead provided by other payers, because they do not directly address the calculation of the reinsurance payment amount and thus do not rely on the current regulatory definition of GCPDC. For example, under rules regarding Medicare secondary payer (MSP) or subrogated claims, the amounts reported in the cost and payment fields of the PDE record reflect a reduction in the Part D plan's incurred cost for a drug resulting from other payer arrangements, which are currently and will continue to be captured in GCPDC.

We note that in a rulemaking published earlier this year, we amended our regulations at § 423.100, to add a new definition of "negotiated price" effective January 1, 2024. The new definition specifies, among other things, that the negotiated price for a Part D drug is the lowest possible reimbursement a network pharmacy will receive, in total, for the drug, net of all pharmacy price concessions. Thus, as of January 1, 2024, all price concessions from network

[180] See page 1-15 of the 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, available at https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training.

pharmacies, negotiated by Part D sponsors and their contracted pharmacy benefit managers (PBMs), will be reflected in the negotiated price that is made available at the POS and reported to CMS on a PDE record, meaning that these pharmacy price concessions will be reflected in GCPDC even if the phrase "actually paid" is removed from the regulatory definition of the term as proposed. As noted above, accounting for DIR, including pharmacy price concessions, applied at the point of sale in the calculation of GCPDC, does not make the resulting amount "actually paid," which requires accounting for all DIR, including DIR not applied at the POS.

While this proposed change to the regulatory definition would not be a change in policy and would not directly affect the way in which GCPDC are calculated and used for purposes of Part D, we believe it is important to revise the definition to remove any ambiguity regarding the meaning of the term "gross covered prescription drug costs." As noted previously, the Inflation Reduction Act of 2022 added provisions to the Social Security Act that refer to "gross covered prescription drug costs as defined in section 1860D–15(b)(3) [of the Act]." Removing the phrase "actually paid" from the regulatory definition of GCPDC as proposed would eliminate any ambiguity in the regulation text and help to ensure there is a consistent understanding of the meaning of this term for purposes of both the Part D program and the relevant provisions of the IRA.

Nothing in this proposal places additional requirements on Part D sponsors or beneficiaries or changes how CMS currently uses the GCPDC reported by the Part D sponsor on the PDE for purposes of determining payments under Part D. This proposal is consistent with our current policy and operations, including the current reporting requirements. As such, the proposed change to the definition of "gross covered prescription drug costs" at § 423.308 would not place any additional burden on Part D sponsors, nor do we expect that this change would result in savings.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA) /Part C and Part D plans based on the requirement to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act and 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 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 Part 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 plan 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. This includes clarifications as well as improvements related to the current methodology based on our recent

experiences related to the impact of COVID-19 on quality measurement. The current CMS National Quality Strategy encourages the highest quality outcomes, safest care, equity, and accessibility for all individuals (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy). In addition to focusing on a person-centric approach as individuals move across the continuum of care, the current CMS Quality Strategy aims to create a more equitable, safe, and outcomes-based health care system and, where feasible, works to align performance metrics, programs, and policy across CMS programs.

In this proposed rule, we are proposing a health equity index reward to further incentivize Part C and D plans to focus on improving care for enrollees with social risk factors (SRFs), and this proposal supports CMS efforts to ensure attainment of the highest level of health for all people. We are also proposing to make changes in the specific measures used in the Star Ratings System:

- Remove the Part C Diabetes Care – Kidney Disease Monitoring measure;
- Remove the stand-alone Part C Medication Reconciliation Post-discharge measure;
- Add the updated Part C Colorectal Cancer Screening measure with the NCQA specification change;
- Add the updated Part C Care for Older Adults – Functional Status Assessment measures with the NCQA specification change;
- Add the updated Part D Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) measures (including non-substantive changes to the specifications).
- Add the Part C Kidney Health Evaluation for Patients with Diabetes measure;
- Add the Part D Concurrent Use of Opioids and Benzodiazepines measure;
- Add the Part D Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults measure; and

- Add the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measure.

We are also proposing to make several methodological changes:

- Reduce the weight of patient experience/complaints and access measures to further align the Part C and Part D Quality Rating System with other CMS quality programs;
- Remove guardrails when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures;
- Modify the hold harmless policy for the Health Plan Quality Improvement and Drug Plan Quality Improvement measures;
- Add an additional basis for the subregulatory removal of Star Ratings measures; and
- Remove the 60 percent rule for the adjustment for extreme and uncontrollable circumstances (generally called the adjustment for disasters).

Finally, we are also proposing a series of technical clarifications of the existing rules related to adjustments for disasters, QBP appeals processes, contract consolidations, and weighting of measures with a substantive specification change, as well as a technical amendment to §§ 422.162(a)(2)(i) and 423.186(a)(2)(i) to fix a codification issue. Unless otherwise stated, proposed changes would apply (that is, data would be collected and performance measured) for the 2024 measurement period and the 2026 Star Ratings.

Section VIII includes simulations of the cumulative impact of these proposals on overall Star Ratings using data from the 2021 Star Ratings, including simulations by contract size and by geographical area – specifically, by State, DC, and Puerto Rico.

B. Definitions (§§ 422.162 and 423.182)

We propose to add the following definition for Part 422, Subpart D (for Part C plans) and Part 423, Subpart D (for Part D plans) in paragraph (a) of §§ 422.162 and 423.182, respectively. This proposed new definition is relevant for our proposed policies discussed in section V.G. of this proposed rule and would be used in that context.

● Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

C. Contract Ratings (§§ 422.162(b) and 423.182(b))

1. Contract Type

In the April 2018 final rule (83 FR 16440) at §§ 422.162(b) and 423.182(b), we codified the methodology for calculating the same overall and summary Star Ratings for all plan benefit packages (PBPs) offered under each MA-only, MA-PD, or PDP contract.

As different organization or contract types offer different benefits, the overall and summary Star Ratings differ across contract types when the set of required measures differs. For example, non-SNP contracts do not submit the following measures and, therefore, their overall and Part C summary ratings do not include them: SNP Care Management, Care for Older Adults - Medication Review, and Care for Older Adults - Pain Assessment.

We propose to amend §§ 422.162(b)(1) and 423.182(b)(1) to add a sentence at the end to clarify that the overall and summary Star Ratings are calculated based on the measures required to be collected and reported for the contract type being offered for the Star Ratings year. This is our current practice and how the Star Ratings have historically been calculated. For example, the 2023 Star Ratings are calculated for the 2023 contract year using data primarily from measurement year 2021.[181] The 2023 Star Ratings are published on Medicare Plan Finder in October 2022 to provide comparative quality performance information about plans for people with Medicare to use in making enrollment decisions for the 2023 calendar year. If a contract offered a SNP PBP in measurement year 2021, but is no longer offering a SNP PBP for the 2023 contract year, the 2023 Star Ratings exclude the SNP-only measures and the contract would be rated as "Coordinated Care Plan without SNP". This is our current (and historical) process and

[181]There are exceptions to this for some measures. For example, as adopted in the April 2018 final rule and used now, the measures from the CAHPS survey are based on the most recent data submitted from surveys of enrollees; the surveys ask about the experience of the enrollees over the last six months. The annual Medicare Part C & D Star Ratings Technical Notes (available online here: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData) identify the measures and their data sources for each year's Star Ratings.

how the proposed regulatory clarification will be applied. We welcome comments on this proposal.

2. Contract Consolidations

The process for calculating measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). As described in the April 2018 final rule (83 FR 16528 through 16531), we use the enrollment-weighted means of the measure scores of the consumed and surviving contract(s) to calculate the measure-level ratings for the first and second years following the contract consolidation. For all contracts, under §§ 422.164(f)(4) and 423.184(f)(4), the Part C and Part D improvement measures compare current contract-level measure scores with scores from the prior year across all measures included in the improvement measures calculations. Given there are no comparable prior year measure-level scores available for contracts in the first year of the consolidation, historically we have not calculated the Part C and D improvement measures for the first year after a consolidation.

We propose to amend §§ 422.162(b)(3)(iv)(A)(*1*) and 423.182(b)(3)(ii)(A)(*1*) to clarify the calculation of the Part C and Part D improvement measures for contracts that consolidate. For the first year after a consolidation, we propose to clarify that the Part C and Part D improvement measures will not be calculated for the consolidated contract. The prior year measure-level scores only include data from the surviving contract; using those as the comparison point for a consolidated contract would not be an accurate comparison because it does not include any information about performance of the consumed contract(s). For the second year after a consolidation, the improvement measure is calculated, using the enrollment-weighted measure scores for the current and prior year because scores for both years are available for the consolidated contract. This is our current (and historical) process and how the proposed regulatory clarification will be applied.

We propose to revise the current regulation text at §§ 422.162(b)(3)(iv)(A)(*1*) and 423.182(b)(3)(ii)(A)(*1*) to clarify that the Part C and Part D improvement measures are not

calculated for the first year after a contract consolidation. This proposal codifies our current application of the ratings rules. We welcome comments on this proposal.

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

The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. In the April 2018 final rule, at 83 FR 16532, 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 (83 FR 16537). 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 measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2024 unless noted otherwise. We are also proposing a new rule for the removal of measures and an additional example of a non-substantive measure update.

1. Proposed Measure Removal

a. Diabetes Care - Kidney Disease Monitoring (Part C)

We are proposing to remove the Diabetes Care – Kidney Disease Monitoring measure because it has been retired by the measure steward.[182] NCQA, the measure steward, announced the retirement of the Diabetes Care – Kidney Disease Monitoring measure after measurement year 2021. As we stated in the Announcement of Calendar Year (CY) 2023 Medicare Advantage

[182]The measure, which has the HEDIS label "Comprehensive Diabetes Care (CDC) – Medical Attention for Nephropathy" was retired after the 2021 performance period as noted here https://www.ncqa.org/wp-content/uploads/2022/07/Summary-Table-of-Changes-HEDIS-MY-2022.pdf
and does not appear in the list for the 2022 performance period.

(MA) Capitation Rates and Part C and Part D Payment Policies, since NCQA will no longer be collecting data for this Healthcare Effectiveness Data and Information Set (HEDIS) measure beginning with measurement year 2022, CMS will not have data for this measure to be included in the 2024 Star Ratings. The measure will be included in the 2023 Star Ratings using data from measurement year 2021. We are proposing to replace this measure with the Kidney Health Evaluation for Patients with Diabetes measure (described in section V.D.3.a. of the preamble to this proposed rule).

CMS is proposing to permanently remove the Diabetes Care – Kidney Disease Monitoring measure starting with the 2024 Star Ratings because we will not have data to calculate the measure.

b. Medication Reconciliation Post-Discharge (Part C)

We are proposing to remove the Medication Reconciliation Post-Discharge (MRP) measure as it would be duplicative of the MRP component of the Transitions of Care (TRC) measure to be included in the 2024 Star Ratings. In the January 2021 final rule at 86 FR 5921-24, CMS finalized inclusion of the TRC measure in the 2024 Star Ratings. The TRC measure includes four indicators: MRP, Notification of Inpatient Admission, Patient Engagement After Inpatient Discharge, and Receipt of Discharge Information. Currently, MRP appears in both the Medicare Part C and Part D Star Ratings as a stand-alone measure and on the Medicare Part C and D display page as one of the four indicators included in the TRC measure. As discussed at 86 FR 5921 through 5924, transitions from an inpatient stay back to home often result in poor care coordination, including communication gaps between inpatient and outpatient providers; planned and inadvertent medication changes; incomplete diagnostic work-ups; and insufficient understanding of diagnoses, medication, and follow-up care needs. The Merit-based Incentive Payment System (MIPS) also includes MRP[183] which is one component of the TRC measure.

[183] Quality ID #46 (NQF 0097): Medication Reconciliation Post-Discharge – National Quality Strategy Domain: Communication and Care Coordination - Claims (cms.gov).

Although at this time CMS is only implementing the TRC measure in the Part C Star Ratings program, it is a HEDIS measure and over time, it may be used in other programs. Based on the importance of care coordination in the Part C program and how the TRC measure provides a more comprehensive picture of how plans manage transitions across settings for care, we believe its inclusion in the Part C Star Ratings is appropriate.

For measurement year 2020, NCQA provided multiple updates to the TRC measure as described at 86 FR 5921 and 5922. In one of these updates, NCQA revised the requirement of using one medical record from a specific provider to, instead, allow numerator information to be captured from additional communication forms accessible to the primary care provider or ongoing care provider (for example, admissions, discharges, and transfers (ADT) feeds, shared electronic medical records (EMRs)) that occur regularly in the field and meet the intent of the measure. This change also ensured that scores for the MRP indicator in the TRC measure and the stand-alone MRP measure would match. Currently, the MRP measure for the Part C and Part D Star Ratings comes from the MRP indicator collected through the TRC measure. This is because NCQA decided that the stand-alone MRP measure no longer needed to be separately reported since it could be pulled from the medication reconciliation indicator in the TRC measure.

CMS is proposing to remove the stand-alone MRP measure from the 2026 Star Ratings for measurement year 2024 since the same information about medication reconciliation is now also incorporated as a component of the TRC measure and, consequently, it is duplicative to have MRP as a stand-alone measure and as a component of the TRC measure. We welcome comments on this proposal.

2. Proposed Measure Updates

In the April 2018 final rule, we specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. (83 FR 16534 and 16535). Where an update by the measure steward is substantive within the scope of §§ 422.164(d)(2) and 423.184(d)(2), CMS will initially solicit feedback on whether to make

substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then engage in rulemaking to make substantive changes to a Star Ratings measure. Per §§ 422.164(d)(2) and 423.184(d)(2), CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings. This 2 year period for the updated measure to be on the display page may overlap with the period during which CMS solicits comment and engages in rulemaking. Further, the legacy measure may continue to be used in the Star Ratings during this period.

a. Colorectal Cancer Screening (Part C) – Substantive Change

CMS is proposing a substantive update to the existing colorectal cancer screening measure because of changes in the applicable clinical guidance and by the measure steward. In May 2021, the U.S. Preventive Services Task Force (USPSTF) released updated guidance for the age at which colorectal cancer screenings should begin. Subsequently, NCQA, the measure steward, has updated its colorectal cancer screening measure to include a rate for adults 45-49 years of age for measurement year 2022. Therefore, CMS proposes expanding the age range for the Colorectal Cancer Screening measure to adults age 45-49, for an updated age range of 45-75, for the 2024 and subsequent measurement years. The expanded age range for this screening measure significantly increases the size of the population covered by this measure and is therefore a substantive measure specification change within the scope of § 422.164(d)(2). Other CMS programs, such as for the qualified health plans (QHPs)[184] and the adult core set for Medicaid plans,[185] are planning to introduce this change into their programs as they also use the same HEDIS measure.

CMS solicited feedback on making this substantive update to the measure in the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA)

[184] https://www.cms.gov/files/document/final-2022-call-letter-qrs-qhp-enrollee-survey.pdf
[185] https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html

Capitation Rates and Part C and Part D Payment Policies, and most commenters supported this change. As described in the April 2018 final rule (83 FR 16534), we may keep a legacy measure in the Star Ratings during the period that an updated version of the measure is on the display page. The legacy measure with the narrower age range of 50-75 years will remain available and be used in Star Ratings until the updated measure has been adopted through rulemaking and has been on the display page for 2 years. The updated measure will be on the display page for the 2024 Star Ratings, starting with the 2022 measurement year data.

b. Care for Older Adults – Functional Status Assessment (Part C) – Substantive Change

We are proposing to add the Care for Older Adults (COA) – Functional Status Assessment measure back to the Star Ratings after it has been on the display page following a substantive measure specification change. The COA measure is collected for Special Needs Plans (SNPs) and includes three indicators – Medication Review, Functional Status Assessment, and Pain Assessment.

For HEDIS 2021, based on the 2020 measurement year, NCQA implemented a change for the COA – Functional Status Assessment. Previously the measure specification was that documentation of a complete functional status assessment must include: (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; (3) result of assessment using a standardized functional assessment tool; or (4) notation that at least three of the following four components were assessed: (a) cognitive status, (b) ambulation status, (c) hearing, vision, and speech (that is, sensory ability), (d) other functional independence (for example, exercise, ability to perform job). Because the clinical field of functional status assessment was moving toward agreement on assessment using ADLs, IADLs, or another standardized tool, and to improve the clarity of the specification, NCQA removed the fourth option for meeting the numerator requirements for this indicator for HEDIS 2021.

The measure change for the COA – Functional Status Assessment measure was considered substantive under § 422.164(d)(2) because removal of a mechanism for positive performance on the measure may meaningfully impact the numerator. The updated measure was moved to the display page starting with the 2022 Star Ratings.

CMS is proposing to return this updated measure to the Star Ratings, beginning with the 2026 Star Ratings and 2024 measurement period. With the updated specification, documentation of a complete functional status assessment must include: (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; or (3) result of assessment using a standardized functional assessment tool. For weighting purposes, a substantively updated measure is treated as a new measure, and as described at § 422.166(e)(2), will receive a weight of 1 for the first year in the Star Ratings; this treatment of substantively updated measures as new measures for purposes of weighting was addressed in the January 2021 final rule (86 FR 5919) and is proposed to be more clearly addressed in § 422.166(e)(2) in section V.E.2 of this proposed rule. Therefore, this measure will receive a weight of 1 for its first year and will be treated as a process measure in subsequent years.

c. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D) – Substantive Change

CMS proposes to implement risk adjustment (also sometimes referred to as case-mix adjustment) based on sociodemographic status (SDS) characteristics, a substantive update, to the three Part D medication adherence measures for the 2028 Star Ratings (2026 measurement year). Health outcomes are affected by patient-related and external factors such as existing clinical conditions and SDS. Currently, the medication adherence measures (Diabetes, Hypertension, and Cholesterol) are included in the determination of the Star Ratings Categorical Adjustment Index (CAI) because they are not excluded by the criteria established in §§ 422.166(f)(2) and

423.186(f)(2); for example, the measures are not case-mix adjusted for socioeconomic status. The CAI was implemented in the 2017 Star Ratings to adjust for average within-contract disparity in performance associated with the percentages of beneficiaries who receive low income subsidy and/or dual eligible (LIS/DE) and/or have disability status. The CAI was initially developed as an interim analytical adjustment to address concerns about disparities while longer-term solutions were explored, including engaging with measure stewards to examine if re-specification is warranted for measures used in the Star Ratings. The methodology for the CAI was codified at §§ 422.166(f)(2) and 423.186(f)(2); the factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part D for MA-PDs, and Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

In addition, the National Quality Forum (NQF) convened an expert panel in 2014 and recommended that performance-based measures should be risk adjusted for socioeconomic status (SES) and other socio demographic factors in 2017. On June 28, 2020, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) submitted a second Report to Congress[186]; ASPE is required under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) to study the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use in Medicare value-based purchasing programs.

CMS contracted with the Pharmacy Quality Alliance (PQA), the steward of these measures, to examine the medication adherence measures for potential risk adjustment. PQA recommended sociodemographic status (SDS) risk adjustment for the Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. PQA recommended and endorsed the following changes related to SDS in their Measure Manual:

[186] https://www.aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.

- All three adherence measures should be risk adjusted for SDS characteristics to adequately reflect differences in patient populations.

- The measures should be adjusted for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/low-income subsidy (LIS) status, and disability status.

- The measures should be stratified by these four beneficiary-level SDS characteristics (listed in the prior bullet) to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA measure specifications were endorsed by NQF in the 2019 Spring cycle (NQF endorsed #0541).

CMS has included stratifications by age, gender, dual eligibility/LIS status, and disability status in the Medication Adherence patient safety reports to Part D sponsors beginning with the 2019 measurement year.

We are proposing to implement risk adjustment for the medication adherence measures based on the PQA specifications, which would be reflected in the Star Ratings. Additionally, because the medication adherence measures will be risk adjusted based on SDS characteristics (that is, for age, gender, dual eligibility/LIS, and disability status), the medication adherence measures will be excluded from the CAI adjustment per §§ 422.166(f)(2)(ii)(A) and 423.186(f)(2)(ii)(A). We found in our analysis that implementing the SDS risk adjustment to the patient safety reports can be very time consuming and should be incorporated at one period of time. Therefore, since we are proposing to implement the SDS risk adjustment to the medication adherence measures and remove these measures from the Star Ratings CAI determination, we also intend to incorporate the SDS risk adjustment operationally to the medication adherence measures reported by CMS to Part D sponsors in the last monthly patient safety report for the measurement year.

In developing this proposal, we considered how this change might affect Star Ratings for MA-PD and PDP contracts. We calculated SDS risk adjusted medication adherence measure rates using year of service (YOS) 2019 measurement year data and recalculated the CAI values excluding these three adherence measures. We then recalculated the overall and Part D summary ratings using the SDS risk adjusted medication adherence measure rates, revised CAI values, the final 2021 Star Ratings for other measures, and the reward factor. In our analysis, we found that the threshold shifts for measure-level cut points with SDS risk adjustment were minimal for both MA-PD and PDP contracts, ranging from -2 to +1 percentage point(s) for MA-PD contracts and about -2 to +3 percentage points for PDP contracts. We found that for both MA-PD and PDP contracts, approximately 60-70 percent of contracts retained the same star level across the Medication Adherence for Hypertension (RAS Antagonists) and Medication Adherence for Cholesterol (Statins) measures. When a star level shift was observed, most of the MA-PD and PDP contracts shifted by one-star level and usually shifted upwards when the SDS risk adjustment was applied to the adherence measures. One percent of MA-PD contracts shifted two-star levels for the Medication Adherence for Hypertension (RAS Antagonists) and Medication Adherence for Cholesterol (Stains) measures. The two-star level shifts were primarily upwards, but one contract did shift down two stars in the Medication Adherence for Cholesterol (Stains) measure. For the Medication Adherence for Diabetes Medication measure, 82 percent of MA-PD contracts and 59 percent of PDP contracts retained the same star level. When a star level shift was observed for the Medication Adherence for Diabetes Medications measure, most MA-PD and PDP contracts saw a one-star downward movement with the SDS risk adjustment applied to the measure.

As previously noted, if CMS implements SDS risk adjustment for the three medication adherence measures, the measures would no longer be included in determining the Star Ratings CAI. Therefore, we also conducted an analysis to simulate calculating the CAI values without case-mix adjusting the three adherence measures for LIS/DE and disability; these simulated CAI

values were used in the application of the simulated summary rating calculations. For most MA-PD contracts, this resulted in a negative shift in the CAI adjustment values for the overall and Part D summary ratings, and in contrast, most PDPs had a positive shift in values. Additionally, the analysis found a minimal change in reward factor thresholds, ranging from -0.07 to +0.02 for mean percentile thresholds and -0.08 to +0.008 for variance percentile thresholds. In the analysis of the overall and Part D summary rating, 91 percent of MA-PD contracts retained the same overall rating, 7 percent decreased by half a star, and 2 percent increased by half a star. We found that 81 percent of MA-PD contracts retained the same Part D summary rating, 11 percent decreased by half a star, and 7 percent increased by half a star. The impact on PDP contracts was neutral or positive; 63 percent of PDP contracts retained the same Part D summary rating star level while 37 percent increased by a half a star. No PDP contracts had a decrease in their Part D summary rating.

The Part C and Part D improvement measures were not recalculated for this simulation. The final 2021 Star Ratings for both improvement measures were used for the summary rating recalculations in the simulations to illustrate the impact of this proposed change to the three medication adherence measures. Additionally, the final 2020 Star Ratings for both improvement measures and for the three adherence measures were used for the CAI value recalculations in the simulations. It is possible that the simulated differences could vary if or when we are able to have two consecutive years of adjusted data for recalculating these components.

Per § 423.184(d)(2), the change to implement SDS risk adjustment for the three Part D medication adherence measures would be a substantive update. We signaled this potential update and solicited initial feedback on incorporating the SDS risk adjustment in the Advance Notice and Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. A majority of the commenters supported SDS risk adjustment for the medication adherence measures. Some commenters also requested information on how the CAI will be affected by this update. We completed testing of the impact

of the adjustment and are including the additional information about the simulations in this proposed rule, as summarized previously. If finalized, the legacy medication adherence measures would remain in the Star Ratings and the updated medication adherence measures with the SDS risk adjustment would be on the display page for at least 2 years (beginning with the 2024 measurement year for the 2026 display page). Beginning with the 2026 measurement year and 2028 Star Ratings, CMS would then move the re-specified measures from display page to Star Ratings and the legacy measures would be removed under this proposal. We solicit comments on this substantive update to incorporate SDS risk adjustment for the medication adherence measures.

d. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D) – Non-Substantive Changes

In addition to the substantive changes (to add risk adjustment for SDS for the three adherence measures), our analysis of the proposed substantive updates incorporated two non-substantive changes to the adherence measures, based on the current PQA measure specifications, which are endorsed by NQF. While we do not need to propose non-substantive changes through rule-making, given that we intend to make the non-substantive changes to the measures along with the proposed substantive changes to risk adjust the adherence measure, we describe the non-substantive updates as well in this preamble in order to provide a full picture of the changes to these measures. However, implementing these non-substantive updates is not dependent on finalizing the SDS risk adjustment proposal and will be included in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. These specification changes are non-substantive in accordance with § 423.184(d)(1) because they narrow the denominator population or do not change the target population or intent of the measure: (1) apply continuous enrollment (CE)

instead of member-years (MYs) adjustment and (2) no longer adjust for stays in inpatient (IP) settings and skilled nursing facilities (SNFs).

Currently, the Part D enrollment used by CMS in the medication adherence measures is adjusted monthly based on MYs to account for beneficiaries who are enrolled for only part of the contract year enrollment (for example, if a beneficiary is enrolled in the Part D contract for 6 out of 12 months of the year, the beneficiary will count only as 0.5 member-years in the rate calculation). Moving forward when applying the SDS risk adjustment for the medication adherence measures, CMS intends to discontinue the use of MY of enrollment, which is a non-substantive update. Rather, we intend to align with PQA measure specifications of CE as defined by the treatment period and exclude beneficiaries with more than 1-day gap in enrollment during the treatment period.

According to the current PQA measure specifications, the treatment period begins on the earliest date of service for a target medication during the measurement year which is the index prescription start date (IPSD) and extends through whichever comes first: the last day of the enrollment during the measurement year, death, or end of the measurement year. The treatment period should be at least 91 days. Therefore, a beneficiary may meet the requirements of enrollment in more than one contract in a measurement year but partial enrollment during the measurement year will no longer be adjusted using MYs methodology; this beneficiary may be eligible to be included in the measure calculation if continuously enrolled in one contract even if the beneficiary disenrolls from the contract prior to the end of the measurement year and enrolls into a different contract based on the PQA definition of CE. To clarify, per the current PQA measure specifications of treatment period, beneficiaries can have only one treatment period per contract - meaning if a beneficiary disenrolls after the IPSD and then re-enrolls (in the same Part D plan) in the same contract during the same measurement year, the beneficiary would not be included in the measure calculation for that particular contract if there is more than a one day gap in enrollment during the treatment period. If a beneficiary is enrolled in a Part D plan offered

under one contract but then disenrolls and enrolls into a Part D plan offered under another (that is, different) contract and subsequently the beneficiary meets the measure criteria for one or both contracts, the beneficiary will be included in the measure rate calculation for all the applicable contract(s). The beneficiary partial enrollment would no longer be adjusted for partial MY enrollment (for example, 0.5) which accounts for a fraction of the beneficiary's enrollment in a contract but would now be calculated as 1 for rate calculation purposes under the CE methodology. CMS conducted an analysis of beneficiaries who met CE in the same contract using the YOS 2019 Patient Safety reports. Approximately 95 percent of beneficiaries met the definition for being continuously enrolled for the Medication Adherence for Diabetes Medications measure and about 96 percent for the Medication Adherence for Hypertension Medications (RAS Antagonists) and Medication Adherence for Cholesterol Medications (Statins) measures.

Using YOS 2019 data, CMS analyzed the impact of implementing both the proposed SDS risk adjustment and the use of the current PQA measure specification definition of CE (instead of MY) for the three medication adherence measures. The analysis was limited to Part D contracts that were included in the 2021 Star Ratings for comparison purposes. Based on our analysis, we found that most MA-PD contract measure rates remained the same after the SDS risk adjustment and CE updates were applied. The change in distribution of rates among MA-PDs was negligible (at most 1 percentage point difference on average) between the current MY methodology and the SDS risk adjustment with CE methodology for all three medication adherence measures. Similarly, for PDPs, the change in distribution of rates among PDPs was minimal (at most 1 to 2 percentage point difference on average).

Currently, we also adjust for Part D beneficiaries' stays in IP settings and SNFs. However, CMS plans to make a non-substantive change to discontinue adjusting for SNF and IP stays in calculating these measures. Our overall goal in making these non-substantive changes to the adherence measures is to fully align with current PQA measure specifications endorsed by

the NQF; the PQA specifications do not include IP/SNF stay adjustments in the adherence measures. In addition, during our testing of both this adjustment and the SDS risk adjustment, we found that applying IP and SNF stay adjustments added a level of complexity and concerns about the accuracy of the SDS risk adjustment.

In our analysis of comparing SDS adjusted rates with and without IP/SNF stays, the impact of the IP/SNF stay adjustment had very minimal impact to the distribution of measure rates for all three adherence measures for MA-PDs and PDPs. For the Medication Adherence for Diabetes measure, the mean rates remained the same for both MA-PDs (85 percent) and PDPs (84 percent) regardless of whether the IP/SNF stay adjustment was included or not. Similarly, for the Medication Adherence for Hypertension (RAS antagonists) measure, the mean rates for the MA-PDs remained the same at 86 percent regardless of IP/SNF stay adjustment, and for PDP contracts, there was a 1 percentage point difference seen in the mean rates between the two methods (86 percent with IP/SNF stay adjustment and 85 percent without IP/SNF adjustment). Likewise, for the Medication Adherence for Cholesterol (Statin) measure, there was a 1 percentage point difference in the mean rates for the MA-PDs (85 percent with IP/SNF stay adjustment and 84 percent without IP/SNF adjustment), and the mean rates remained the same for PDPs (84 percent) regardless of whether IP/SNF stay adjustment was included or not.

We plan to implement CE starting with the 2024 measurement year for the 2026 Star Ratings. We plan to remove the IP/SNF stay adjustment from the adherence measures starting with the 2026 measurement year for the 2028 Star Ratings, which is the same time we propose to implement the SDS risk adjustment change, but is not dependent on finalizing that proposal.

3. Proposed Measure Additions

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. 83 FR 16521, 16533. For example, we regularly review measures

developed by NCQA and PQA. CMS is proposing to adopt the new measures described in this rule, which are measures developed by NCQA or PQA. The Kidney Health Evaluation for Patients with Diabetes measure has been collected since 2020 measurement year and the new Part D measures are calculated from prescription drug event or CMS administrative data so they do not require any new data collections.

a. Kidney Health Evaluation for Patients with Diabetes (Part C)

We propose to add the Kidney Health Evaluation for Patients with Diabetes (KED) measure to the 2026 Star Ratings. This measure was introduced as a HEDIS measure for the 2020 measurement year. NCQA, in collaboration with the National Kidney Foundation, developed a kidney health evaluation measure, and NCQA tailored the measure specifically for health plans. The KED NCQA measure assesses whether adults who have diabetes received an annual kidney profile evaluation, defined by an estimated Glomerular Filtration Rate (eGFR)[187] and a Urine Albumin-Creatinine Ratio (UACR) during the measurement year. This new measure aligns with recommendations from the American Diabetes Association and provides critical information for screening and monitoring of kidney health for patients with diabetes. This measure would replace the prior related measure, Diabetes Care – Kidney Disease Monitoring.

CMS began reporting this measure on the display page for the 2022 Star Ratings. As provided at §§ 422.164 (c)(3) and (4) and 423.184(c)(3) and (4) (83 FR 16534), as new performance measures are developed and adopted they are initially posted on the display page for at least 2 years.

We have submitted the KED plan measure through the 2022 Measures Under Consideration process for review by the Measures Application Partnership, which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and

[187] NCQA added the new Logical Observation Identifiers Names and Codes (LOINC) for the new race-free eGFR equations to the KED value sets.

efficiency measures for CMS programs. The MIPS program has also submitted it to the 2021 Measures Under Consideration process and this measure will also be implemented for QHPs[188].

We propose to add the KED measure to the 2026 Star Ratings.

b. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D)

CMS proposes to add the following measures to the 2026 Star Ratings (2024 measurement year): COB, Poly-ACH, and Poly-CNS. Additionally, the measures will include a non-substantive update: to align with the PQA measure specifications by using continuous enrollment (CE) and no longer adjusting for member-years (MYs). CMS has reported the following three Pharmacy Quality Alliance (PQA) measures for the Part D program on the 2021 display page (using 2019 data) and 2022 display page (using 2020 data) on www.cms.gov as announced in the Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. These measures reflect the following performance:

- Concurrent Use of Opioids and Benzodiazepines (COB) (Part D) - analyzes the percentage of Medicare Part D beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines.
- Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) (Part D) - analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of two or more unique ACH medications during the measurement period.
- Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS) (Part D) - analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of three or more unique CNS-active medications during the measurement period.

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[188] https://www.cms.gov/files/document/final-2022-call-letter-qrs-qhp-enrollee-survey.pdf.

These are important areas of focus for the Medicare Part D population. Concurrent use of opioids and benzodiazepines can increase the risk of respiratory depression and fatal overdoses.[189,190] In addition, concurrent use of two or more unique anticholinergic medications in older adults was associated with an increased risk of cognitive decline, and the concurrent use of three or more unique CNS active medications in older adults was associated with increased risk of falls and fractures.[191] Therefore, we initially monitored these measures starting with the 2021 display page (2019 measurement year) and now propose to transition them to the Star Ratings. We anticipate that the COB, Poly-ACH, and Poly-CNS measures will continue to help plans identify enrollees who are at risk of respiratory depression or fatal overdoses, cognitive decline, or falls and fractures, respectively, and facilitate plans to encourage appropriate prescribing when clinically necessary.

We observed that the overall rates for the COB measure have slightly improved from 2021 to 2022 display page for both MA-PD and PDP contracts from 17 percent to 16 percent. For the Poly-CNS measure, MA-PD and PDP contract rates remained the same at 6 percent. Lastly in the Poly-ACH measure, we found that the MA-PD and PDP contract rates slightly increased from 8 percent to 9 percent. There is room for further improvement for all three measures. Per §§ 423.184(c)(3) and (4), new Part D measures added to the Star Ratings program must be on the display page for a minimum of 2 years prior to becoming a Star Ratings measure. In addition, the measures, as previously discussed, were submitted through the 2021 Measures Under Consideration (MUC) process, a pre-rulemaking process for the selection of quality and efficiency measures under section 1890A of the Act. These measures were reviewed by the

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[189] US Food and Drug Administration. FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning [Internet]. 2016 [2016 Nov 9]. Available at http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm.

[190] Centers for Disease Control and Prevention. Drug Overdose Deaths. N.d. Available at https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html.

[191] American Geriatrics Society 2019 Beers Criteria Update Expert Panel. Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019 Apr;67(4):674-694. PMID: 30693946.

Measure Applications Partnership (MAP) for input and recommendations to HHS on measure selection for CMS programs. All three measures received conditional approval.

We propose to add the COB, Poly-ACH, and Poly-CNS measures for the 2026 Star Ratings (based on 2024 measurement year). We will also align these three measures with the PQA measure specifications to use continuous enrollment (CE) and no longer adjust for member-years (MYs) to account for beneficiaries who are enrolled for only part of the contract year. On the display page, these three measures currently use the MY methodology; however, when the measures are transitioned to Star Ratings, the measures will not be calculated based on MY adjustment but will be calculated based on CE measure specifications defined by PQA. Based on the 2022 PQA Measure Manual, the beneficiary's index prescription start date (IPSD) begins on the earliest date of service for an opioid, ACH, or CNS-active medication, respectively, during the measurement year. Beneficiaries are continuously enrolled during the measurement year with one allowable gap of up to 31 days in enrollment during the measurement year. The change to use CE for these measures, compared to the measures as they have been used for the display page since 2021 with the MY adjustment, would be a non-substantive update under § 423.184(d)(1) because the updates do not modify the intent of the measure or the target population but may narrow the denominator population. We described these non-substantive updates here to provide complete information on the measures we propose to add to the Star Ratings and will describe the non-substantive updates in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies as required by § 423.184(d)(1).

We solicit comments on adding the three Part D measures to the Star Ratings.

Table 4 summarizes the additional and updated measures addressed in this proposed rule for the 2026 Star Ratings, unless otherwise noted. The measure descriptions listed in this table are high-level descriptions. The annual Star Ratings measure specifications supporting document, Medicare Part C & D Star Ratings Technical Note*s*, provides detailed specifications

for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year. For example, Stars Ratings for the year 2026 are produced in the fall of 2025. If a measurement period is listed as "the calendar year 2 years prior to the Star Ratings year" and the Star Ratings year is 2026, the measurement period is referencing the January 1, 2024 to December 31, 2024 period.

Table 4. Summary of Proposed New and Revised Individual Star Rating Measures for Performance Periods Beginning on or after January 1, 2024

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Colorectal Cancer Screening (COL)*	Percent of plan members aged 45 to 75 who had appropriate screenings for colorectal cancer.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	#0034	Clustering	MA-PD and MA-only
Kidney Health Evaluation for Patients with Diabetes (KED)	Percent of plan members ages 18-85 with diabetes (type 1 and type 2) who received a kidney health evaluation during the measurement year.	Managing Chronic (long term) conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Care for Older Adults (COA) – Functional Status Assessment*	Percent of Special Needs Plan enrollees 66 years and older who received a functional status assessment	Managing Chronic (long term) conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans
Part D Measures								
Medication Adherence for Diabetes Medication*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for diabetes medications during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Medication Adherence for Hypertension (RAS Antagonists)*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for RAS antagonists during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Medication Adherence for Cholesterol (Statins)*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for statins during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Concurrent Use of Opioids and Benzodiazepines (COB)	The percentage of individuals ≥18 years of age with concurrent use of prescription opioids and benzodiazepines.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#3389	Clustering	MA-PD and PDP
Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)	The percentage of individuals ≥65 years of age with concurrent use of ≥2 unique anticholinergic medications.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS)	The percentage of individuals ≥65 years of age with concurrent use of ≥3 unique central-nervous system (CNS)-active medications.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP

*Revised Measures

++Updates for 2028 Star Ratings (2026 Measurement Year)

We welcome comments on the measure updates and additions.

4. Revising the Rule for Non-substantive Measure Updates (§§ 422.164(d) and 423.184(d))

We are proposing to add collection of survey data through another mode of survey administration to the non-exhaustive list of non-substantive measure updates that can be made without rulemaking. The rules CMS adopted to address measure updates based on whether an update is substantive or non-substantive are specified at §§ 422.164(d) and 423.184(d). As described at 83 FR 16534, we incorporate updates without rulemaking for measure specification

changes that do not substantively change the nature of the measure. In paragraphs (d)(1)(i)-(v) of §§ 422.164 and 423.184, we provided a non-exhaustive list of circumstances that would constitute a non-substantive update. Currently, paragraph (d)(1)(v) of each regulation identifies the addition of an alternative data source as a non-substantive update; the proposed additional example is the collection of alternative data sources or expansion of modes of data collection. These two examples are similar but not exactly the same, so we are proposing to clarify in the regulation that an expansion in the data sources used, whether by adding an alternative source of data or adding an alternative way to collect the data, is a non-substantive change in measure specifications. The expansion of how data are collected is non-substantive because there would be no change to the information that is being collected; the only change would be the way in which it is collected. For example, if a web mode of survey administration is added to the current mail with telephone follow-up of non-respondents survey administration that is currently used for CAHPS and HOS, this would be considered a non-substantive change that could be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act since this does not change what is being measured, but just expands the way the data can be collected.

We propose to revise the regulation text at §§ 422.164(d)(1)(v) and 423.184(d)(1)(v) by adding that another example of a non-substantive change would include a new mode of data collection.

We welcome comments on this proposal.

5. Measure Removal (§§ 422.164(e)(1) and 423.184(e)(1))

CMS proposes adding a new rule for measure removal. We propose that CMS will have the authority to remove a measure from calculations of Star Ratings when a measure steward other than CMS retires the measure. CMS continually reviews measures that are used in calculations of Star Ratings. As codified at §§ 422.164(e)(1) and 423.184(e)(1), CMS may remove a measure 1) when the clinical guidelines associated with the specifications of the

measure change such that the specifications are no longer believed to align with positive health outcomes, or 2) when a measure shows low statistical reliability. See also 83 FR 16533–16537. In both of these circumstances, as codified at §§ 422.164(e)(2) and 423.184(e)(2), CMS will announce the removal of any measure in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

We propose adding a rule at §§ 422.164(e)(1)(iii) and 423.184(e)(1)(iii) to allow removing a Star Ratings measure for another reason. We propose that when a measure steward other than CMS (for example, NCQA or PQA) retires a measure, CMS will have the authority to remove the measure from calculations of Star Ratings through the process described at §§ 422.164(e)(2) and 423.184(e)(2). When a measure steward such as NCQA retires a measure, they go through a process that includes extensive review by their various measurement panels and they solicit public comment regarding proposed measure retirements so health plans, purchasers, consumers and other stakeholders have an opportunity to weigh in on the relevance and scientific soundness of any changes to the HEDIS measurement set. This proposal will allow CMS to respond more quickly to measure removals by external measure stewards to ensure that measures included in Star Ratings are clinically meaningful, reliable, and up-to-date. We solicit comment on this proposal.

E. Measure Weights (§§ 422.166(e) and 423.186(e))

1. Patient Experience/Complaints and Access Measures (§§ 422.166(e)(1)(iii) and (iv), 423.186(e)(1)(iii) and (iv))

CMS is proposing to lower the weight of patient experience/complaints and access measures to 2 beginning with the 2026 Star Ratings covering the 2024 measurement period. The weight for the patient experience/complaints and access measures is codified at §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv). Process measures receive a weight of 1, outcome measures receive a weight of 3, and the Part C and D Improvement measures

receive a weight of 5. In the April 2018 final rule, we finalized an increase in the weight of patient experience/complaints and access measures from 1.5 to 2, starting with the 2021 Star Ratings. (83 FR 16575-77). These measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints measures. We also stated in the April 2018 final rule (83 FR 16575–16576) that, given the importance of hearing the voice of patients when evaluating the quality of care provided, CMS intended to further increase the weight of patient experience/complaints and access measures in the future. In the June 2020 final rule, CMS finalized an additional increase in the weight of patient experience/complaints and access measures from 2 to 4 for the 2023 Star Ratings. At that time, we said we were putting more weight on this category of measures that primarily reflect patient experience of care measures to put patients first and to emphasize CMS's goal of listening to the voice of the patient to identify opportunities to improve care delivery. (85 FR 33837) We still believe these measures focus on critical aspects of care such as care coordination and access to care from the perspective of enrollees, but taking into consideration additional stakeholder feedback we have received and the effect of the policy on the 2023 Star Ratings, we have reconsidered our position from the June 2020 final rule and now believe these measures currently receive an undue weight in the Star Ratings program.

One of the guiding principles of the Part C and Part D Star Ratings program is to align with the CMS Quality Strategy (83 FR 16521). As part of the current CMS Quality Strategy, CMS is trying to create a resilient, high-value health care system that promotes quality outcomes, safety, equity, and accessibility for all individuals, as described at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy. One of the goals of the CMS Quality Strategy is to increase alignment across the CMS quality programs to improve value. Currently, the measure weight of 4 for the patient experience/complaints and access measures is not consistent with the contribution of these types of measures in the overall performance scores for other CMS quality

measurement programs. For example, in the hospital value-based purchasing program, person and community engagement measures which are measures collected through the Hospital CAHPS Survey account for 25 percent of the total performance score for hospitals (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospital-value-based-purchasing-). As another example, one-sixth of the global score for the Quality Rating System for QHPs is based on enrollee experience (https://www.cms.gov/files/document/2022-qrs-and-qhp-enrollee-survey-technical-guidance.pdf). In contrast, for the 2023 Star Ratings, with a weight of 4, the patient experience/complaints and access measures account for approximately 58 percent of the overall rating for MA-PDs. For the Part C and Part D Star Ratings, we include a broader set of measures related to person and community engagement relative to other CMS quality programs. For example, we include appeals measures given the importance of access to care and services for Part C plan enrollees. However, if the patient experience/complaints and access measures had a weight of 2, these measures would account for 41 percent of the overall rating. Reducing the weighting to 2 for this category of measures would align the patient experience/complaints and access measures more closely with other programs, without exactly matching the lower influence measures of this type have on the overall (that is, total performance or global) score in these other programs. We are not proposing to reduce the weight further than 2 given the important link between patient experience, adherence, and health outcomes. Reducing the weight for these measures from 4 to 2 is a significant change and a more extensive change may be too much to adopt at this time. Prior to the April 2018 final rule, the weight of 1.5 given to the patient experience/complaints and access measures in the Part C and Part D Stars Ratings had been in place since the 2012 Star Ratings, so we have extensive experience with how using a weight lower than 2 for these categories of measures influence plan behavior. We continue to believe that a weight higher than 1.5 is appropriate.

The weighting of measures within the Star Ratings program is important as not all measures contribute equally to the goals of the program. Patient experience, complaints, and access to care have been linked to improved clinical outcomes and are important aspects of health care. For example, patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary health care use, and fewer inpatient complications (Anhang Price et al., 2014; Anhang Price et al., 2015; Quigley et al., 2021)[192]. We also recognize that whether clinicians acknowledge patient preferences[193] may be another factor that is important to measure and include in the Star Ratings program; consequently, we are currently testing a question for the CAHPS survey related to whether an enrollee's personal doctor dismisses symptoms that are important to them for potential incorporation in the survey and Star Ratings in the future. CMS continues to believe, as we stated in the April 2018 final rule at 83 FR 16576, that we must listen to the perceptions of care from people with Medicare, as well as ensure they have access to needed care. While focusing on patient experiences of care and ensuring that care is person-centric are critical, health and drug plans also have a responsibility to consider and work toward improving clinical outcomes. Improving clinical outcomes is an important goal for the Part C and Part D programs to meet the CMS Quality Strategy goal of promoting the highest quality outcomes and safest care for all individuals. High-value care does not always align with patient experiences of care, and we must take this into consideration as we consider how to weight the different Star Ratings measures. Clinical quality measures, for example, are also important in that they measure health outcomes, clinical processes and

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[192]Anhang Price, R., Elliott, M.N., Zaslavsky, A.M., Hays, R.D., Lehrman, W.G., Rybowski, L., Edgman-Levitan, S., & Cleary, P.D. (2014). Examining the role of patient experience surveys in measuring health care quality. Medical Care Research and Review, 71(5), 522–554.
Anhang Price, R., Elliott, M.N., Cleary, P.D., Zaslavsky, A.M., & Hays, R.D. (2015). Should health care providers be accountable for patients' care experiences? Journal of General Internal Medicine, 30(2), 253–256.
Quigley D.D., Reynolds K., Dellva S., & Anhang Price, R. (2021). Examining the business case for patient experience: a systematic review. Journal of Healthcare Management, 66(3), 200–224.
[193] Cohen, Marc A., Hwang, Ann and Hawes, Frances M. (July 13, 2022). Could Person-Centered Care Be The Secret To Achieving the Triple Aim? Health Affairs Forefront.

adherence to clinical guidelines. They measure whether plans are following the best practices for healthcare delivery, including providing preventive care such as immunizations and cancer screenings and caring for enrollees with ongoing health problems such as diabetic enrollees who need blood sugar tests, eye exams and blood pressure monitoring. It is also important to create incentives for health and drug plans to continuously focus on quality improvement by giving sufficient weight to the Health Plan Quality Improvement and Drug Plan Quality Improvement measures relative to the patient experience/access and complaints measures. We believe the weight given to measures in the Part C and Part D Star Ratings program should be in line with the how the measures are linked to health care and the value they have in improving health care.

Subsequent to finalizing the weight of 4 for patient experience/complaints and access measures in the June 2020 final rule, we have received significant stakeholder feedback on this issue through the Part C and D Advance Notices, the 2023 Part C and D proposed rule (CMS-4192-P), the COVID-19 interim final rules (CMS-1744-IFC and CMS 3401-IFC), letters sent to CMS and meetings with plans. A number of concerns have been raised by stakeholders related to a weight of 4, including devaluing measures of health outcomes, encouraging plans to abandon efforts to drive clinically appropriate care, sending the message that preventive care such as cancer screenings are not important, and not balancing appropriately clinical excellence and patient experience. Stakeholders have also raised concerns around disproportionately overweighting patient experience measures which in turn diminishes the importance of other measures. MedPAC noted in their response to the CY 2021 and 2022 proposed rule (CMS-4190-P) that the increased weight would give disproportionate weight to patient experience measures relative to outcome measures and create an imbalance between the two most important measure groupings—outcome and patient experience measures. Stakeholders have continued to raise concerns about the disproportionate weight given to patient experience/complaints and access measures. Stakeholders have continued to suggest that clinical outcomes should count more than patient experience of care measures. Additionally, we have received feedback that cancer

screenings, medication reconciliation, and other Star Ratings measures are critical areas of focus in particular in underserved communities but have a diminished role in the Star Ratings program due to the high weight of patient experience/complaints and access measures.

Given these concerns, as well as the impact of the weighting policy on the 2023 Star Ratings, CMS is re-evaluating its decision to weight these measures higher than outcome measures. We are concerned that the higher weight of 4 may create incentives for plans to not focus as much on patient outcomes, screenings, and preventive care. This could lead to ineffective or inappropriate care and increased costs if providers primarily focus on patient experiences. Although patient experience/complaints and access to care measures have been linked to improved clinical outcomes and are important aspects of health care, we are proposing to move back to a weight of 2 to more appropriately balance the value these measures contribute to achieving high quality care without weighting them higher than clinical outcome measures and to better align the total contribution of patient experience and outcome measures with other CMS quality reporting programs.

To better align the Part C and Part D Star Ratings with the current CMS Quality Strategy and other CMS quality programs and to better balance the contribution of the different types of measures in the Star Ratings program, we propose to modify § 422.166 at paragraphs (e)(1)(iii) and (iv) and § 423.186 at paragraphs (e)(1)(iii) and (iv) to decrease the weight of patient experience, complaints, and access measures from 4 to 2 beginning with the 2026 Star Ratings. At a weight of 2, the patient experience, complaints, and access measures would be weighted higher than process measures but not as high as outcome measures. This is in line with the value these measures add to achieving high quality care without weighting them higher than clinical outcome measures. In addition, this would align more closely with the weight these types of measures are given in other CMS quality programs.

We welcome feedback on this change.

2. Weight of Measures with Substantive Updates (§§ 422.166(e)(2) and 423.184(e)(2))

We are proposing to adopt regulation text clarifying how we treat measures with substantive updates when they return to the Star Ratings program. The general rules that govern updating measures are specified at §§ 422.164(d) and 423.184(d), including rules for non-substantive and substantive measure updates. As described at 83 FR 16534, the process for adopting substantive measure specification updates is similar to the process for adopting new measures. Historically, we have treated measures with substantive updates as new measures when they are added back to the Star Ratings following two or more years on the display page and adoption through rulemaking.

Currently, new measures receive a weight of 1 for their first year in the Star Ratings program as specified at §§ 422.166(e)(2) and 423.186(e)(2). We propose to add language to §§ 422.166(e)(2) and 423.186(e)(2) to clarify that when a measure with a substantive update moves back to Star Ratings from the display page following rulemaking, it is treated as a new measure for weighting purposes and therefore would receive a weight of 1 for its first year back in the Star Ratings program. This is consistent with our current and prior practice and with the explanation provided in the January 2021 final rule about the weight provided to substantively updated measures for the first year they are returned to the Star Ratings (86 FR 5919). In subsequent years, the measure (both new measures and substantively updated measures) would be assigned the weight associated with its category, which is what happens with new measures as well. In addition, we are proposing to revise the heading for paragraph (e)(2) to reflect how the provision addresses the weight of both new and substantively updated measures.

We welcome comments on this proposal.

F. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by adding guardrails, which are measure-specific caps to Star Ratings cut points in both directions so that the measure-threshold-specific cut points do not increase or decrease more than the value

of the cap from one year to the next. The intent of this change in methodology was to increase the predictability and stability of cut points. As described in the April 2019 final rule at 84 FR 15754, a trade-off of increasing the predictability of cut points is the inability to keep pace with any unanticipated changes in industry performance. Based on recent experience with calculating Star Ratings during the COVID-19 PHE and analyses of the data for the 2022 Star Ratings, we are proposing to modify the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by eliminating the guardrails that restrict the maximum allowable movement of non-CAHPS measure cut points.

When we initially proposed guardrails so that the cut points for non-CAHPS measures do not increase or decrease more than the cap from one year to the next, we recognized that with guardrails there may be an inability for thresholds to fully keep pace with changes in performance across the industry. A cap on upward movement can inflate the measure-level Star Ratings if true improvements in performance cannot be fully incorporated in the current year's ratings. If overall industry performance shifts upward on a measure, the Star Ratings cut points affected by a cap for that measure may not fully take into account this upward shift in industry performance. While we recognized the possibility at the time we finalized the guardrails policy, we now have evidence from the 2022 and 2023 Star Ratings that shows that unintended consequence of the policy. For example, for the 2023 Star Ratings for Part C Osteoporosis Management in Women who had a Fracture, the four star threshold without the cap was greater than or equal to 60 percent, but this threshold was reduced to greater than or equal to 55 percent when guardrails were applied. In effect, the cap makes it easier for contracts to receive four stars than it would have been if there was no cap. In this example, because of the cap, a contract with performance of 57 percent would receive a four star rating when, without the cap, the contract would receive a three star rating. This is diluting the value of receiving four stars for contracts that would have received four stars without the cap since some contracts received four stars for

performance that ordinarily would not qualify for four stars. Conversely, a cap on downward movement can decrease the measure-level Star Ratings when industry performance overall shifts downward, since the ratings cannot be adjusted fully for downward shifts in performance. For example, for the 2023 Star Ratings for Colorectal Cancer Screening, the one star cut point was higher (43 percent) than it would have been without a cap (38 percent), and therefore more contracts received a one star rating on that measure than they would have if there were no cap. During the COVID-19 PHE, we saw that industry performance declined on some measures included in the 2022 Star Ratings and for other measures industry performance increased. In order to allow non-CAHPS cut points to move with these changes in industry performance, we adopted a delay in the implementation of guardrails in the interim final rule titled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency" which appeared in the **Federal Register** on April 6, 2020 with a March 31, 2020 effective date[194] at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i).

The intent of guardrails was to improve predictability and stability of cut points from one year to the next. At the time the addition of guardrails to the Star Ratings methodology was finalized, we also finalized the addition of mean resampling to the hierarchical clustering methodology to reduce the sensitivity of the clustering algorithm to outliers and reduce the random variation that contributes to fluctuations in cut points. Mean resampling was implemented beginning with the 2022 Star Ratings. Since the addition of guardrails was finalized, we also finalized in the June 2020 final rule at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) adding Tukey outlier deletion to the hierarchical clustering methodology to improve the predictability and stability of cut points. (85 FR 33833-36). Tukey outlier deletion will be implemented beginning with the 2024 Star Ratings and will remove extreme outliers before the clustering algorithm is applied; this will improve the predictability and stability of cut points,

[194] www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public.

which in turn minimizes the need for the guardrails to achieve such goals and weakens the rationale of the guardrails policy at the time the policy was finalized.

After the April 2019 final rule was published, we have learned during the COVID-19 pandemic that it is important for cut points to adjust for unforeseen circumstances that may cause overall industry performance to either increase or decrease. During the 2020 measurement year, we saw both significant increases and significant decreases in scores across some of the Star Ratings measures[195]. As an example, there was a significant shift downward in performance for the Breast Cancer Screening measure during the 2020 measurement year. For Breast Cancer Screening, the 5-star cut point for the 2021 Star Ratings was greater or equal to 83 percent, while for the 2022 Star Ratings it was greater or equal to 76 percent. This drop in the 5-star cut point reflects the change in industry performance. If bi-directional guardrails had been applied for the 2022 Star Ratings, this cut point would have been 78 percent rather than 76 percent, resulting in more contracts earning 4 stars rather than the 5 stars that they would have earned when compared to the performance of their peers in the absence of guardrails. Similarly, there was a significant shift downward in performance for the Diabetes Care – Eye Exam measure during the 2020 measurement year. For Diabetes Care – Eye Exam the 1-star cut point for the 2021 Star Ratings was less than 63 percent, while for the 2022 Star Ratings it was less than 52 percent. This significant drop in the 1-star cut point reflects the downward shift in industry performance. If bi-directional guardrails had been applied for the 2022 Star Ratings, this cut point would have been 58 percent, resulting in some contracts earning 1 star for this measure rather than 2 stars when compared to the performance of their peers in the absence of guardrails. There was also a significant shift upward in performance for the MTM Program Completion Rate for CMR for PDPs during the 2020 measurement year. The MTM 5-star cut point for the 2021 Star Ratings was greater than or equal to 61 percent, while for the 2022 Star Ratings it was greater than or

[195] 2022 Star Ratings Fact Sheet. https://www.cms.gov/files/document/2022-star-ratings-fact-sheet1082021.pdf

equal to 74 percent. This increase in the 5-star cut point reflects the change in industry performance. If bi-directional cut points had been applied for the 2022 Star Ratings, this cut point would have been 66 percent rather than 74 percent resulting in more contracts receiving 5 stars. These examples from the 2020 measurement year have led us to believe that bi-directional guardrails can inappropriately limit the ability of cut points to shift when there are unanticipated shifts in industry performance, causing misclassification in the measure-level Star Ratings assignments.

In addition, the combination of mean resampling and Tukey outlier deletion, with Tukey outlier deletion being finalized after the bi-directional guardrails policy, will provide sufficient predictability and stability of cut points from one year to the next when there are not significant changes in overall industry performance, but at the same time allow cut points to adjust when there are significant changes in performance as there was during the COVID-19 pandemic. We believe it is important for cut points to be allowed to shift by more than 5 percentage points when there are unanticipated, large changes in industry performance in the future. We are proposing at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to modify the language so that guardrails for non-CAHPS measures will only be effective through the 2025 Star Ratings released in October 2024, and not apply for the 2026 Star Ratings or beyond.

We welcome feedback on these changes.

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

As discussed in section III.A of this proposed rule, advancing health equity is the first pillar of the 2022 CMS Strategic Plan and a goal of the CMS national quality strategy. In reports on accounting for Social Risk Factors (SRFs) in value-based purchasing programs, the National Academies of Sciences, Engineering, and Medicine (NASEM) define Social Risk Factors (SRFs) as factors related to health outcomes that are evident before care is provided, are not

consequences of the quality of care, and are not easily modified by healthcare providers.[196] CMS agrees with the NASEM definition of SRFs because it captures the elements we consider important in defining SRFs. There are often disparities in health care and outcomes between groups with and without social risk factors (SRFs). For example, the within-contract LIS/DE and non-LIS/DE differences in performance for Part C and D Star Ratings measures can be found at: 2022 Categorical Adjustment Index Measure Supplement Dec 10 2020 (cms.gov).

The current approach to addressing SRFs in the Part C and Part D Star Ratings program has focused on adjusting for the average within-contract disparities in performance through the Categorical Adjustment Index (CAI), as described at §§ 422.166(f)(2) and 423.186(f)(2), in order to not inappropriately penalize or reward health and drug plans for factors that are difficult for plans to control. For certain current Star Ratings measures, it may be more difficult for most plans to achieve the same level of care for groups that are socioeconomically disadvantaged, disabled, or more complex due to a variety of issues, including transportation issues, lower health literacy, communication challenges, and residential instability. The CAI is a factor that can be positive or negative and is added to a contract's overall and summary Star Ratings that adjusts for the average within-contract performance disparity based on a contract's composition of Low Income Subsidy/Dual Eligible (LIS/DE) and disability status enrollees.

The CAI was implemented in the Part C and Part D Star Ratings program to address SRFs while measure stewards evaluated adjustment on a measure-specific basis. The CAI is a data-driven approach to account for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. The CAI does not incentivize contracts to focus on reducing disparities. Although all contracts have incentives in the Star Ratings program to

[196]Social Risk Factors: Definitions and Data | Accounting for Social Risk Factors in Medicare Payment |The National Academies Press | https://nap.nationalacademies.org/read/23635/chapter/4.

improve performance, there are currently no methodological adjustments that specifically create incentives to address disparities of care among a contract's enrollees.

In addition to adjusting for within-contract disparities through the CAI, we also want to encourage MA organizations, cost plans, and Part D plan sponsors to better identify and then address disparities in care provided to enrollees with a particular SRF, with the ultimate goal of reaching equity by eliminating health disparities or differences in contract performance by SRFs, consistent with CMS efforts to advance health equity.

CMS has developed a health equity index (HEI) that we are proposing for use in the Part C and Part D Star Ratings that would reward contracts for obtaining high measure-level scores for the subset of enrollees with specified SRFs. Our intent in implementing an HEI is to improve health equity by incentivizing MA, cost plan, and PDP contracts to perform well among enrollees with specified SRFs. The CAI is designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts; in contrast, our proposed HEI reward is specifically designed to create an incentive to reduce disparities in care. The HEI, therefore, does not replace the CAI but rather assists plan sponsors in better identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reaching equity in the level and quality of care provided to enrollees with SRFs. There would be no changes to the current CAI with the implementation of the proposed HEI reward.

We are proposing to replace the current reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) with the new HEI reward at proposed §§ 422.166(f)(3) and 423.186(f)(3) starting with the 2027 Star Ratings; the HEI for the 2027 Star Ratings would be calculated using data collected or used for the 2026 and 2027 Star Ratings. The current reward factor was included in the Part C and Part D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across

measures (that is, a mix of low performance and high performance across measures). At the beginning of the Star Ratings program, the distribution of ratings across contracts looked very different, with overall performance much lower than it is today. Over time, we have established additional methodological enhancements to incentivize performance improvement across measures, such as the addition of the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures as described at §§ 422.164(f) and 423.184(f). MA organizations have also responded to the incentive to perform well across measures as a result of the link between Star Ratings and Quality Bonus Payment ratings for MA contracts. CMS believes if we finalize the removal of the current reward factor from the Star Ratings methodology, contracts would still have incentives to perform well and improve because high performance on individual Star Ratings measures, including the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures, translates into better overall and summary ratings. The removal of the current reward factor is contingent on finalizing the addition of the proposed HEI reward.

CMS is proposing to add the HEI reward as a methodological enhancement to the Part C and Part D Star Ratings program starting with the 2027 Star Ratings because, similar to the current reward factor, it provides a summary of how performance varies across existing Star Ratings measures. The proposal to add the HEI reward is a methodological enhancement using data from existing Star Ratings measures; it is not a proposal to add a new measure with additional burden for contracts. In the case of our proposed HEI, however, this summary of performance would be based on performance related to a subset of enrollees with specified SRFs. Adding the HEI as a reward also allows for the methodology to include a performance threshold below which contracts will not be eligible for the HEI reward, which will incentivize improved performance by contracts for their enrollees with the specified SRFs and help reduce disparities. CMS could also potentially increase this performance threshold over time to incentivize continued efforts to reduce disparities in care.

In developing the proposed HEI reward, we considered a number of goals to ensure the incentives of the HEI and the associated reward were in line with our intent. We aim to improve health equity by incentivizing MA plans, cost plans, and Part D plan sponsors to perform well among enrollees with certain SRFs. These goals include:

- Avoiding rewarding large contracts over small contracts that may be providing high quality care for enrollees with the SRFs included in the HEI but lack the number of enrollees needed to reliably calculate the HEI.
- Avoiding rewarding contracts that may do well among enrollees with the SRFs included in the HEI but serve very few enrollees with those SRFs, making it easier to do well.
- Only rewarding contracts that have high relative performance among enrollees with the SRFs included in the HEI compared to other contracts to incentivize high performance for enrollees with the SRFs included in the HEI.
- Ease of use and understanding for contracts and other stakeholders.
- Minimizing the number of years of data needed to calculate the HEI and HEI reward such that the data used are as current as possible.
- Allowing for updates to the measure set included in the HEI and updates to accommodate the addition of other SRFs to the HEI over time.
- Promoting improvement in performance and enrollment of individuals with certain SRFs in MA plans, cost plans, and Part D plans.
- Accurately reflecting true performance among contracts serving enrollees with certain SRFs and minimizing sensitivity to measurement error.

The proposed HEI would summarize contract performance in relation to enrollees with certain SRFs across multiple existing Star Ratings measures into a single score using data from the most recent two measurement years. We propose at §§ 422.166(f)(3)(i)(A) and 423.186(f)(3)(i)(A) to initially include receipt of the LIS or being dually eligible (LIS/DE) or having a disability as the group of SRFs used to calculate the HEI. Prior research has shown that

dual eligibility is one of the most influential predictors of poor health outcomes, and disability is also an important risk factor linked to health outcomes.[197] The SRFs included in the HEI may be expanded over time. For purposes of the HEI, we propose to define an LIS/DE beneficiary as one who was designated as a full-benefit or partial-benefit dually eligible individual or who received a low-income subsidy (LIS) at any time during the applicable measurement period, as we do currently for the calculation of the CAI. If a person meets the criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. We intend to use the original reason for entitlement to the Medicare program to identify enrollees with a disability for purposes of the HEI as we do for the calculation of the CAI.

We are interested in feedback on potential additional ways to identify enrollees who have a disability that could be incorporated over time and whether the same process and standards should be used for the CAI adjustment as well. In particular, we are interested in how we could expand the definition to include enrollees who develop a disability after aging into the Medicare program. LIS/DE and disability are the SRFs that have been used in the CAI for many years and are included in the confidential Part C and D Stratified Reports provided to MA and Part D contracts in HPMS as of 2022. As currently proposed, enrollees with these SRFs will be identified for the HEI the same way they are identified for the CAI at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B).

We also considered including the Area Deprivation Index (ADI) in the HEI at this time. The ADI is a measure of socioeconomic neighborhood deprivation, including measures of income, employment, housing, education, social environment, and readmissions. However, consistent with literature on the ADI, and other neighborhood-based indices,[198] our analyses showed the ADI explains very little of the variation in the quality of care received beyond

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[197]https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?_ga=2.49530854.1703779054.1662938643-470268562.1638986031

[198]Beckett MK, Martino SC, Agniel D, Mathews M, Hudson Scholle S, James C, Wilson-Frederick S, Orr N, Darabidian B, Elliott MN. (2021). "Distinguishing neighborhood and individual social risk factors in health care" *Health Services Research*: 1-14.

enrollee-level LIS/DE and disability information. We will continue to explore the feasibility of adding other SRFs to the HEI over time. The addition of other SRFs or other mechanisms to identify enrollees with one or more of the SRFs that are part of the proposed HEI would be proposed through future notice-and-comment rulemaking.

The proposed HEI would examine performance among those with certain SRFs for all Star Ratings measures unless they meet one of the specified exclusions. As provided in proposed §§ 422.166(f)(3)(ii)(A)-(D) and 423.186(f)(3)(ii)(A)-(D), measures would be excluded from the HEI if one or more of the following criteria are met:

- The focus of the measurement is not the enrollee but rather the plan or provider (for example, the appeals and call center measures focus on the plan and its operations rather than on the enrollee). Measures meeting this criterion would be excluded because enrollee-level SRF information for these measures is not available for inclusion in the HEI.

- The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI. Measures meeting these criteria would be excluded because there is not enough data to calculate the HEI for these measures.

- The measure is applicable only to SNPs. Measures meeting this criterion would be excluded because these measures are not relevant for all contracts.

- At least 25 percent of contracts are unable to meet the criteria described at proposed paragraph (f)(3)(iv), which provides that a measure is only included for the HEI for a contract if the measure has a reliability of at least 0.7 for the contract when calculated for the subset of enrollees with the specified SRF(s) and the contract meets the measure denominator requirement when the measure is calculated for only the enrollees with the specified SRF(s) (that is, the SRFs included in the HEI). For Part D measures, this criterion is assessed separately for MA-PDs and cost contracts, and PDPs. We are proposing to exclude any measures from the HEI that less than 25 percent of contracts can have reliably calculated because scores would be missing for most contracts.

As proposed at §§ 422.166(f)(3)(iii) and 423.186(f)(3)(iii), the measures being evaluated for inclusion in the HEI would be announced annually in the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. These announcements (of the measures being evaluated for inclusion in the HEI) will not include the final list of measures used in the HEI for the upcoming Star Ratings because the data to determine that final set would not yet be available. In general, measures from HEDIS, HOS, and CAHPS would be included unless they meet one of the exclusion criteria, as previously described. Additionally, medication adherence, MTM Program Completion for CMR, and Statin Use in Persons with Diabetes measures would be included as long as they meet the requirements for inclusion for more than 25 percent of contracts.

In this section of this rule, we propose each of the five steps that CMS would take to analyze the measure-level scores for each contract and to roll up to the HEI scores in order to assess when an adjustment is available for a contract's ratings.

Step 1: For each measure included in the HEI, measure-level scores calculated for each contract among enrollees with the included SRFs (that is, all enrollees who are DE, LIS, or disabled combined into one group) would be combined over the two most recent measurement years. CMS carefully considered the number of years of data needed for the proposed HEI. We believe that using 2 years of data allows for a balance between increasing measure-level reliability so that smaller contracts may still have enough data to have the HEI calculated and minimizing the number of years of data used. As outlined in our goals in designing the HEI, it is important to minimize the number of years of data used to avoid carrying forward very old data in the Star Ratings and to allow new measures and newer contracts to more quickly be included in the HEI.

As proposed at §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B), the scores for the subset of enrollees with SRFs of interest included in the HEI would be calculated using a modeling approach that includes year (that is, an indicator for whether the data are from year 1 or year 2)

as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Scores are adjusted for year to account for situations where mean scores were, for the average contract, different in the 2 years (for example, higher in year 2 than year 1, or vice versa) and for contracts that have measure sample sizes that differ across years. Data will be used for contracts that have data for only the most recent year of the 2 years, but data will not be used for contracts that have data for only the first of the 2 years in order to ensure use of the most current data possible.

Step 2: Measures that are case-mix adjusted in the Star Ratings would be adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest. The CAHPS measures included in the Star Ratings are currently adjusted for DE and LIS. For the proposed HEI, for the subset of enrollees who are DE, LIS, or disabled in Step 1, we would not include the case-mix adjustment for DE and LIS when calculating the scores over the 2-year period for the CAHPS measures. If the proposal to implement risk adjustment for the three Star Ratings medication adherence measures based on the PQA specifications in section V.D.2.c. of this proposed rule is finalized, then we would not include risk adjustment for DE, LIS, and disabled enrollees when calculating the scores over the 2-year period as described in Step 1.

Step 3: For a measure to be included in the HEI for a specific contract, both of the following inclusion criteria in proposed §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv) would need to be met: (1) reliability of at least 0.7 when the measure is calculated for the combined subset of enrollees with the specified SRFs across 2 years of data, and (2) measure-specific denominator criterion (for example, HEDIS measures require a minimum denominator of at least 30) is met when the measure is calculated for the combined subset of enrollees with the specified SRFs across 2 years of data. We are proposing at paragraph (f)(3)(vi) that contracts would also need to have at least 500 total enrollees at the contract level in the most recent measurement year used in

the HEI. We are proposing a minimum in order to have reliable measure-level scores. For many of the Star Ratings measures (for example, HEDIS and HOS measures) at least 500 enrollees are needed to have a sufficient number of enrollees to reliably measure the performance of the contract.

Step 4: As we propose in §§ 422.166(f)(3)(v) and 423.186(f)(3)(v), to calculate the HEI score assigned to a contract, the distribution of contract performance on each eligible measure among enrollees with the specified SRFs (that is, all enrollees who are DE, LIS, or disabled combined into one group) would be calculated and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point for each measure. For example, for the Breast Cancer Screening measure, we would calculate performance for all contracts for the enrollees with one or more of the specified SRFs (that is, for the enrollees who are DE, qualify for LIS, and/or are disabled) using the two most recent measurement years. We would then look at the distribution of scores for this measure for all contracts that have at least 0.7 reliability and meet the minimum denominator size for the measure. Contracts that score in the top third of all contracts would receive 1 point for this measure, the middle third of contracts would receive 0 points for this measure, and the bottom third of contracts would receive 1 negative point for this measure. The same analysis would be repeated for each measure included in the HEI.

Step 5: For each contract, the HEI would then be calculated as the weighted average of these points using the Star Ratings measure weights and including only measures for which the contract met all of the inclusion criteria specified at §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv). The weighted average would be the weighted sum of points across all included measures divided by the weighted sum of the number of included measures. We propose to use the weight for the measure in the current Star Ratings year. For example, if the HEI were being calculated using data from the 2026 and 2027 Star Ratings year, the measure weight used would be the weight for the 2027 Star Ratings. To ensure that the HEI is not driven by a very small number of measures

for some contracts, we are proposing at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) that a contract must meet the reliability and denominator criteria for at least half of the measures included in the HEI in order to have the HEI calculated for the contract. Contract performance on the HEI would vary from -1.0 (performance was in the bottom third for each included measure) to 1.0 (performance was in the top third for each included measure).

Table 5 is a high-level summary of the steps CMS is proposing to take to calculate the HEI.

TABLE 5: STEPS TO CALCULATE THE HEI

Steps	High-Level Description of Steps to Calculate the HEI
Step 1	Measure-level scores for each measure included in the HEI are calculated for each contract using data from the two most recent measurement years based on enrollees with the specified SRFs using a modeling approach that accounts for year.
Step 2	Measures that are case-mix adjusted in the Star Ratings would employ all standard case-mix adjustors except for adjusters that are the same as the SRFs included in the HEI, are strongly correlated with the included SRFs, or are conceptually similar to the included SRFs.
Step 3	A contract would need to meet the reliability and minimum denominator criteria for at least half of the measures included in the HEI based on data from the two most recent measurement years and have at least 500 enrollees at the contract level in the most recent measurement year to have the HEI calculated.
Step 4	For each measure using all contract-level scores calculated in Step 1/Step 2 that have at least 0.7 reliability and meet the minimum denominator criteria, points would be assigned as follows: 1 point to those contracts that score in the top third of all contracts, 0 points to those that score in the middle third of all contracts, and 1 negative point to those that score in the bottom third of all contracts.
Step 5	For each contract, the HEI would be calculated as the weighted average of the points assigned in Step 4 using the Star Ratings measure weights and including only measures for which the contract met all inclusion criteria.

The HEI would be calculated separately for the overall and summary ratings, as proposed at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi), since the set of included measures differs for the overall, Part C summary, and Part D summary ratings. Four types of health equity indices would be calculated, with up to three health equity indices for each contract, as applicable, one for the

overall rating for MA-PDs; the Part C summary rating for MA-only, MA-PD, and cost contracts; the Part D summary rating for MA-PD and cost contracts; and the Part D summary rating for PDP (that is standalone Part D) contracts. The HEI calculated for the overall rating would be based on all of the Part C and Part D measures that meet the inclusion criteria for the HEI for each MA-PD contract. The HEI for the Part C summary rating would include all of the Part C measures that meet the inclusion criteria for the HEI for the contract. The HEI for the Part D summary rating would be calculated separately for MA-PD (including cost) and PDP contracts and would include all of the Part D measures that meet the inclusion criteria for the HEI for the contract.

In order to qualify for an HEI reward, we propose at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) that contracts must have a minimum rating-specific HEI score of greater than zero. We also propose a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified SRFs. Requiring both a minimum HEI score and a minimum percentage of enrollees in a contract with the specified SRFs is intended to avoid rewarding contracts that serve very few enrollees with the specified SRFs or do not perform well among enrollees with the specified SRFs relative to other contracts. This proposed HEI reward structure supports our goals for the HEI reward in that it avoids rewarding contracts that do not serve many enrollees with SRFs included in the HEI, making it easier for them to do well, and encourages MA, cost, and PDP contracts to enroll individuals with SRFs.

We propose that contracts that have percentages of enrollees with any of the specified SRFs in a given year that are greater than or equal to one-half of the contract-level median percentage of enrollees with the specified SRFs up to, but not including, the contract-level median would qualify for one-half of the HEI reward. Contracts that have percentages of enrollees with any of the specified SRFs greater than or equal to the contract-level median would qualify for the full HEI reward. Table 6 is a high-level summary of how the HEI score is converted into the HEI reward.

TABLE 6: CONVERTING HEI SCORE INTO HEI REWARD

Percentage of Enrollees with Specified SRFs Threshold	**Amount of Reward**
% of enrollees in a contract with the specified SRFs $<$ 0.5 of the median for all contracts.	Zero Reward.
% of enrollees in a contract with the specified SRFs $\geq$ 0.5 of the median for all contracts and $<$ the median for all contracts.	HEI reward would vary from 0 to 0.2 on a linear scale for contracts that have an HEI score > 0.
% of enrollees in a contract with the specified SRFs $\geq$ the median for all contracts.	HEI reward would vary from 0 to 0.4 on a linear scale for contracts that have an HEI score > 0.

We are also considering an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRF greater than or equal to one-half of the contract-level median would qualify for the full HEI reward. Both the tiered and non-tiered HEI reward structures align with our goals of promoting enrollment of enrollees with SRFs and not rewarding contracts that may do well among enrollees with SRFs but serve very few enrollees in this population, although the tiered HEI reward structure goes further in aligning with these goals. The non-tiered HEI reward structure aligns better with the goal of ease of use and understanding for contracts and other stakeholders.

We propose at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) that the contract percentages of enrollees with SRFs included in the HEI would be based on enrollment in the most recent of the 2 years of data used to calculate the HEI. For example, if the HEI includes data from measurement years 2024 and 2025, enrollment would be from 2025. We recognize D-SNP only contracts would meet the enrollment thresholds under either the tiered or non-tiered HEI reward structure; however, other plans that do not initially meet the thresholds can also work to increase enrollment of people with SRFs to meet the enrollment thresholds, which aligns with the goal of promoting enrollment of enrollees with SRFs. D-SNP only contracts would also need to perform sufficiently well among enrollees with the specified SRFs to qualify for a reward based on the HEI. One consideration in developing the proposed thresholds for the minimum percentages of

enrollees with SRFs included in the HEI needed to qualify for an HEI reward is that higher thresholds could potentially create geographic barriers in certain parts of the country to qualifying for the HEI reward because there is variation by State in the percent of enrollees who are LIS/DE or disabled. Both the tiered HEI reward and non-tiered HEI reward structures account for this as all states have percentages of LIS/DE/disabled enrollees that are greater than one-half the contract-level median based on 2019 data, although the non-tiered structure goes further in addressing this concern, as many states do not have percentages of LIS/DE/disabled enrollees that are greater than the contract-level median. As specified at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) the contract-level median and half of the contract-level median would be calculated and assessed separately for MA and standalone Part D (that is, PDP) contracts.

Because enrollees in Puerto Rico are not eligible for LIS, we believe that a different approach is necessary for contracts with services areas wholly located in Puerto Rico. We propose at §§ 422.166(f)(3)(vii)(A) and (B) and 423.186(f)(3)(vii)(A) and (B) to use a modified calculation to determine the percentage of enrollees with SRFs included in the HEI for contracts with service areas wholly located in Puerto Rico. We propose to limit this treatment to contracts with service areas wholly in Puerto Rico because our analysis indicates that for plans with services areas that include Puerto Rico and other locations, only a small portion of the enrollment is in Puerto Rico. We propose to estimate the number of enrollees with the specified SRFs in these contracts differently. We would start with the percentage of DE/disabled enrollees calculated from administrative data, and then add the estimated percentage LIS by taking the LIS/DE percentage calculated for the CAI for contracts with service areas wholly in Puerto Rico at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees. We need to estimate the number of LIS enrollees because LIS is not available in Puerto Rico; we are using the estimated LIS/DE information from the CAI calculations since these are the only data available on the estimated percentage of enrollees in Puerto Rico contracts that would qualify for LIS. We would then add the estimated LIS percentage to the

DE/disabled percentage calculated from administrative data to get the LIS/DE/disabled percentage of enrollees in Puerto Rico. This calculation could result in a slight overestimate since some disabled enrollees may also be captured in the estimated LIS percentage; therefore, contracts with service areas wholly in Puerto Rico would be excluded from our calculations to determine one-half of the contract-level median and the contract-level median of enrollees with SRFs included in the HEI. We believe that this approach would ensure equitable treatment of contracts with service areas outside of Puerto Rico. In our simulations of the HEI, we found that the slight overestimate had little impact on whether contracts with service areas wholly in Puerto Rico met the one-half of the contract-level median or contract-level median thresholds.

We also propose that contracts would need to have an HEI score greater than zero on the HEI calculated for the given rating (overall or summary rating) to qualify for a reward for that rating. As specified at proposed §§ 422.166(f)(3)(i) and 423.186(f)(3)(i), the HEI score for the overall rating would include the applicable Part C and D measures, the HEI score for the Part C summary rating would include only the applicable Part C measures, and the HEI score for the Part D summary rating would include only the applicable Part D measures. An HEI score of greater than zero means that the contract on average scored in the middle third or better across measures included in the HEI for enrollees with the SRF(s). HEI scores closer to 1.0 indicate better performance for enrollees with the SRFs included in the HEI. While we are initially proposing to require a minimum HEI score of greater than zero for contracts to receive an HEI reward, we may consider increasing this minimum score over time to continue to encourage improved contract performance for enrollees with SRFs included in the HEI. Any such increase to the minimum HEI score would be proposed through subsequent notice-and-comment rulemaking.

We propose at §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii) that the HEI reward would vary from 0 to 0.4 on a linear scale for contracts that meet the threshold for the median percentage of enrollees with SRFs included in the HEI, with a contract receiving 0 reward if the

contract received a score of 0 or less on the HEI and a 0.4 reward if the contract received a score of 1 on the HEI. Similarly, the HEI reward would vary from 0 to 0.2 on a linear scale for contracts that meet the threshold for one-half of the contract-level median percentage of enrollees with SRFs included in the HEI, but do not meet or exceed the contract-level median percentage of enrollees with SRFs included in the HEI. Contracts that cannot have an HEI score calculated (that is, contracts that do not have reliable measure scores or do not meet the denominator criteria for at least half of the measures included in the HEI or contracts that do not have at least 500 enrollees) would not receive an HEI reward.

As an example, if a contract meets the contract-level median percentage of LIS/DE/disabled enrollees and receives an HEI score of 0.722325, this would translate on a linear scale to a reward of 0.288930. That is, the size of the HEI reward would equal 0.4 times the difference between the HEI score and the threshold, divided by the difference between the maximum HEI score and the threshold (0.4*(0.722325-0)/(1-0), which equals 0.288930). As another example, if a contract meets one-half the contract-level median percentage of LIS/DE/disabled enrollees but does not meet the contract-level median percentage of LIS/DE/disabled enrollees and receives an HEI score of 0.722325, this would translate on a linear scale to a reward of 0.144465. That is, the size of the HEI reward would equal 0.2 times the difference between the HEI score and the threshold, divided by the difference between the maximum HEI score and the threshold (0.2*(0.722325-0)/(1-0), which equals 0.144465). The HEI reward would be rounded and displayed with 6 decimal places similar to how the CAI values are displayed.

As proposed at §§ 422.166(f)(3)(ix) and 423.186(f)(3)(ix), once each of the HEI rewards are calculated, the applicable HEI reward would be added to the unrounded overall and Part C and D summary ratings after the addition of the CAI and the application of the improvement measures described in §§ 422.166(g)(1) and 423.186(g)(1) and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star. For example, if the

HEI reward was 0.288930, as previously described in the example, and the unrounded overall rating was 4.234210 after the addition of the CAI and the application of the improvement measure hold harmless rule, the unrounded overall rating would be 4.523140 (4.234210 + 0.288930) resulting in a final, rounded overall rating of 4.5.

We also propose changes in the following sections to revise references to the existing reward factor or to limit application of the current reward factor to the Star Ratings through the 2026 Star Ratings: §§ 422.166(c)(1), 422.166(d)(1) 422.166(f)(1), 422.166(f)(2)(i), 422.166(g)(1), 423.186(c)(1), 423.186(d)(1) 423.186(f)(1), 423.186(f)(2)(i), and 423.186(g)(1). The new HEI reward would be implemented for the 2027 Star Ratings covering primarily the 2024 and 2025 measurement years. The existing reward factor would continue to be calculated through the 2026 Star Ratings.

We simulated the impact of removing the current reward factor and adding the proposed HEI reward. In simulations using data from the 2020 and 2021 Star Ratings,[199] the median percentage of LIS, DE, and disabled enrollees was 41.645 percent and one-half the median was 20.822 percent for MA and cost contracts. Half of MA and cost contracts were at or above the median, 33 percent were at or above one-half the median up to but not including the median, and 17 percent were below one-half the median. In the simulations, 88 percent of MA-PD contracts that received an overall rating received an HEI score, 42 percent received an HEI score greater than zero, and 34 percent received an HEI reward. The range of HEI scores among MA-PD contracts for the overall rating was -0.888889 to 1.000000. The average reward for the overall rating among MA-PD contracts with an HEI score greater than zero was 0.109. When simulating the removal of the current reward factor and addition of the proposed new HEI reward, 7 (1.7 percent) MA-PD contracts gained one-half star on the overall rating and 54 (13.4 percent) MA-PD contracts lost one-half star on the overall rating compared to the 2021 Star Ratings. Among

[199]Since data collections for HEDIS and CAHPS were curtailed for the 2021 Star Ratings due to the COVID-19 pandemic (CMS-1755-IFC), these simulations used HEDIS and CAHPS measure data from the 2019 and 2020 Star Ratings.

PDP contracts, the median percentage of LIS, DE, and disabled enrollees was 13.848 percent and one-half the median was 6.924 percent. Fifty-one percent of PDP contracts were at or above the median, 39 percent were at or above one-half the median up to but not including the median, and eleven percent were below one-half the median. Among PDP contracts that received a Part D Summary Star Rating, 91 percent received an HEI score, 47 percent received an HEI score greater than zero, and 40 percent received an HEI reward. The range of HEI scores among PDP contracts was -1.000000 to 1.000000. The average reward among PDP contracts with an HEI score greater than zero was 0.160. Compared to the 2021 Star Ratings, 3 (5.3 percent) PDP contracts gained one-half star on the Part D Summary Rating and 7 (12.3 percent) PDP contracts lost one-half star on the Part D Summary Rating.

We solicit comment on these proposals.

H. Improvement Measure Hold Harmless (§§ 422.166(g)(1) and 423.186(g)(1))

In the April 2018 final rule, we discussed that one of the goals of the Part C and Part D Star Ratings program is to drive quality improvement for plans and providers (83 FR 16521). In that final rule, CMS adopted, at §§ 422.166(g)(1) and 423.186(g)(1), a hold harmless provision for the inclusion of the Part C and/or Part D improvement measures for contracts with 4 or more stars for the highest rating. Under this provision, the highest rating is calculated both with and without the improvement measures; contracts with 4 or more stars without including the improvement measures are held harmless from having the highest rating reduced by the addition of the improvement measures. The original intent of this hold harmless provision was to recognize that higher performing contracts have less room to improve (83 FR 16578).

Our experience with the Part C and Part D Star Ratings program since this policy was finalized suggests that contracts with 4 or 4.5 stars for their highest rating still have room for improvement. For example, based on a review of data from the 2020 Star Ratings, MA-PD contracts with 4 stars for the overall rating received 5 stars on 42 percent of measures on average, those with 4.5 stars for the overall rating received 5 stars on 55 percent of measures on

average, and those with 5 stars for the overall rating received 5 stars on 79 percent of measures on average. PDP contracts with 4 stars for the Part D summary rating received 5 stars on 26 percent of measures on average, those with 4.5 stars for the Part D summary rating received 5 stars on 28 percent of measures on average, and those with 5 stars for the Part D summary rating received 5 stars on 57 percent of measures on average.

We believe that the hold harmless provision for the highest rating is not needed for 4 and 4.5 star contracts because they still have the potential to increase scores across measures and thus their Star Ratings. In order to encourage continued improvement across all measures for contracts with 4 and 4.5 stars for their highest rating, we propose to modify § 422.166 at paragraphs (g)(1)(i) and (ii) and § 423.186 at paragraphs (g)(1)(i) and (ii) to apply the improvement measure hold harmless provision to only contracts with 5 stars for their highest rating beginning with the 2026 Star Ratings.

We welcome feedback on this proposal.

I. Extreme and Uncontrollable Circumstances (§§ 422.166(i) and 423.186(i))

1. 60 Percent Rule

Currently, the Star Rating for each non-CAHPS measure score is determined by applying a clustering algorithm to the numeric value scores from all contracts required to submit the measure. The cut points for non-CAHPS measures are derived from this clustering algorithm. As discussed in the April 2019 final rule and described at §§ 422.166(i)(9), 422.166(i)(10), 423.186(i)(7), and 423.186(i)(8), we exclude from this clustering algorithm and from the reward factor calculations (under §§ 422.166(f)(1) and 423.186(f)(1)) the numeric values for affected contracts with 60 percent or more of their enrollees in Federal Emergency Management Agency (FEMA) designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance (84 FR 15776-15777). Affected contracts are contracts that meet all of the criteria in §§ 422.166(i)(1) and 423.166(i)(1). We generally call this the "60 percent rule" to distinguish it from the adjustments provided under §§ 422.166(i) and 423.186(i) for affected contracts with

25 percent of their enrollment residing in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

This exclusion ensures that any impact of the extreme and uncontrollable circumstance on certain affected contracts' measure-level scores does not have an impact on the cut points or reward factor for other contracts. When this rule was first implemented, the concern was that a contract impacted by an extreme and uncontrollable circumstance would have significantly different scores than other contracts and that these significantly different scores would shift the cut points and/or reward factor thresholds for non-affected contracts. Our analyses since the rule was implemented show the measure scores for affected contracts do not tend to be outliers and that this 60 percent rule can have adverse effects when extreme and uncontrollable circumstances affect nearly all contracts, as we saw with the COVID-19 PHE.

We are proposing to limit to the 2025 and earlier Star Ratings, application of the rule at §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) that excludes numeric values for affected contracts with 60 percent of their enrollees residing in FEMA-designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance from cut point calculations and reward factor determinations. During the COVID-19 pandemic, we adopted a change to remove these rules temporarily since all contracts qualified for the extreme and uncontrollable circumstances policy as a result of COVID-19 in 2020; this change was adopted in the interim final rule titled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" which appeared in the **Federal Register** and effective on September 2, 2020, and the final rule titled "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; etc." which appeared in the

Federal Register on May 9, 2022 and effective on June 28, 2022 (hereinafter referred to as the May 2022 final rule). The removal of the 60 percent rule was necessary to calculate measure stars for most measures for the 2022 Star Ratings and for HEDIS measures that are based on the Health Outcomes Survey (HOS) (HEDIS-HOS measures) for the 2023 Star Ratings. Without the removal of the rule, CMS would not have been able to calculate stars for most measures for 2022 Star Ratings and for the HEDIS-HOS measures for the 2023 Star Ratings because all contracts qualified for the extreme and uncontrollable circumstances policy as a result of COVID-19 in 2020.

Beginning with the 2024 Star Ratings, measure scores that are extreme outliers will be removed through Tukey outlier deletion, a standard statistical method to remove extreme outliers, as codified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), prior to applying the clustering methodology to determine the cut points. The combination of mean resampling (implemented with the 2022 Star Ratings and described at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i)) and Tukey outlier deletion will alleviate the impact of any extreme outliers. Thus, if a contract is impacted by an extreme and uncontrollable circumstance and as a result has a significantly lower score on a measure, the score would be removed if it is an extreme outlier. Removing extreme outliers will eliminate the concern that other contracts are inappropriately impacted by changes in scores for contracts impacted by disasters. By removing the 60 percent rule, we will also simplify the Star Ratings calculations and continue to allow measure-level Star Ratings to be calculated if all or most contracts qualify for an extreme or uncontrollable circumstance in the future.

We are proposing to amend sections §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) to remove the 60 percent rule beginning with the 2026 Star Ratings for non-CAHPS measures, including the Health Outcomes Survey measures even though the measurement period is slightly different for these measures. We welcome comments on this proposal.

2. Health Outcomes Survey (HOS) Measures

We adopted regulations for how Star Ratings would be calculated in the event of extreme and uncontrollable circumstances in the April 2019 final rule. We explained in the April 2019 final rule (CMS-4185-F) that for most measures, the extreme and uncontrollable circumstance adjustment applies for disasters from 2 years prior to the Star Ratings year (that is, a disaster that begins[200] during the 2020 measurement period results in a disaster adjustment for the 2022 Star Ratings). For Part C measures derived from HOS, the disaster adjustment is delayed an additional year due to the timing of the survey and 1 year recall period. That is, for measures derived from the HOS, the disaster policy adjustment is for 3 years after the extreme and uncontrollable circumstance. For example, we noted at 84 FR 15772-15773 that the 2023 Star Ratings would adjust measures derived from the HOS for 2020 extreme and uncontrollable circumstances. We are proposing to clarify in § 422.166(i)(3)(iv) the timing for HOS measure adjustments for extreme and uncontrollable circumstances. We welcome comments on this proposal.

J. Quality Bonus Payment Rules (§ 422.260)

Sections 1853(n) and 1853(o) of the Act require CMS to make QBPs to MA organizations that achieve at least 4 stars in a 5-star quality rating system. In addition, section 1854(b)(1)(C) of the Act ties the share of savings that MA organizations must provide to enrollees as the beneficiary rebate to the level of an MA organization's QBP rating. The administrative review process for a MA contract to appeal their 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

[200]We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

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. Historically, every November CMS has released the preliminary QBP ratings for MA contracts to review their ratings and to submit an appeal request under § 422.260(c) if they believe there is a calculation error or incorrect data are used. We propose to clarify in § 422.260(c)(3)(iii) some additional aspects of that administrative review process for appeals of QBP status determinations. These clarifications are how we have historically administered the appeals process so we are not proposing changes to how the appeals process has previously been administered.

When an MA organization requests an administrative review of its QBP status, permissible bases for these requests include a calculation error (miscalculation) or a data inaccuracy (incorrect data). A calculation error could impact an individual measure's value or the overall Star Rating. Historically, if an MA organization believes the wrong set of data was used in a measure (that is, following a different timeframe than the one in the measure specifications as adopted in the applicable final rule), this is considered a calculation error.

Currently, § 422.260(c)(3)(i) provides that CMS may limit the measures or bases for which an MA organization may request an administrative review. As described in 76 FR 21490, the appeals process is limited to data sets that have not been previously subject to independent validation. We propose to add a new paragraph in § 422.260(c)(3)(iii) to clarify that certain data sources would not be eligible for requesting an administrative review. We are proposing to clarify at § 422.260(c)(3)(iii) that an administrative review cannot be requested based on data accuracy for the following data sources: HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, MARx system, and other Federal data sources. The listed data sources have either already been validated or audited or come from the CMS system of record for that type of data such as enrollment data, which make it inappropriate to use the QBP appeal

process to challenge the accuracy of the data. For example, HEDIS measures and measures collected through the Part C and D reporting requirements have previously been audited or validated for accuracy; NCQA has a formal audit process for all HEDIS measures to check for accuracy, and MA plans sign off on the accuracy of the data following the audit and prior to the data being submitted to CMS. Similarly, data from the Part C and D reporting requirements are validated through an independent contractor (see 42 CFR § 422.516(g) and § 423.514(j)) before the data are submitted by MA organizations and Part D plan sponsors to CMS and used for Star Ratings measures. (With regard to Part D data and measures, the MA organization offering an MA-PD must comply with the applicable Part D regulations under § 422.500.) Because the MA organization bears the responsibility of data accuracy as well as signs off on audit findings in these situations, it is inappropriate to use the QBP appeal process to challenge the accuracy of these data. Organizations would have ample opportunity to raise any concerns about these data prior to submission to CMS for use in the Star Ratings.

We are also proposing that MA organizations cannot appeal measures that are based on feedback or surveys that come directly from plan enrollees. Measures derived from CAHPS and HOS data are not appealable because plans cannot challenge the validity of an enrollee's response since that is the enrollee's perspective. MA and PDP contracts contract with the CMS-approved vendor of their choice to conduct CAHPS and HOS, and these independent survey vendors conduct the surveys for contracts using detailed specifications provided by CMS and in some cases contract-specific information such as telephone numbers and language preference information provided directly by the MA and PDP contract. There are detailed specifications for data collection[201] for vendors to follow; CMS conducts oversight of the data collection efforts of the approved survey vendors.

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[201] MA and PDP CAHPS Survey administration protocols are contained in the *MA & PDP CAHPS Survey Quality Assurance Protocols & Technical Specifications* and are available at https://ma-pdpcahps.org/en/quality-assurance/. The *HOS Quality Assurance Guidelines and Technical Specifications* manual details the requirements, protocols, and procedures for the HOS administration and are available at https://www.hosonline.org/en/program-overview/survey-administration/.

Measures derived from Prescription Drug Event (PDE) data, Medicare Beneficiary Database Suite of Systems, enrollment data from Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources (for example, FEMA disaster designations) also cannot be appealed for data accuracy because we are pulling data from the system of record or authoritative data source. Part D sponsors submit PDE to CMS via the Drug Data Processing Systems (DDPS), which processes and validates the data. Sponsors must meet the PDE submission deadline to be included in the annual Part D payment reconciliation, and sponsors must certify the claims data (42 CFR 423.505(k)(3)). As another example, enrollment data used in the Star Ratings are also used for the monthly payment of contracts and any discrepancies would have been resolved through retroactive adjustments as needed. Similarly, Medicare Plan Finder (MPF) pricing files cannot be appealed. Plans use the Health Plan Management System (HPMS) Part D Pricing File Submission (PDPFS) module to submit their drug pricing and pharmacy data for posting on the MPF. After the data are submitted, CMS performs a multi-step validation. Validation results are provided to sponsors to correct their data or to attest to the accuracy of the data prior to display on MPF. Part D sponsors are required to perform their own quality assurance checks before submission to ensure that the files are complete and accurate.[202]

Further, in conducting the reconsideration under § 422.260(c), the reconsideration official reviews the QBP determination, the evidence and findings upon which it was based, and any other written evidence submitted by the organization or by CMS before the reconsideration determination is made. Currently, § 422.260(c)(1)(i) provides that the request for reconsideration must specify the given measure(s) in question and the basis for the MA organization's reconsideration request; the alleged error could impact a measure-level score or Star Rating, or the overall Star Rating. The request must include the specific findings or issues with which the MA organization disagrees and the reason for the disagreement, as well as any additional

[202]See May 28, 2021 HPMS memorandum, Contract Year (CY) 2022 Part D Pricing Data Submission Guidance. https://www.cms.gov/files/document/cy2022drugpricingsubmissionguidelines05282021final.pdf

evidence that the MA organization would like the reconsideration official to consider, as the basis for reconsideration. Currently, § 422.260(c)(2)(v) provides that the MA organization must provide clear and convincing evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect; in other words, the burden is on the MA organization to prove an error was made in the calculation of their QBP rating. We are proposing to revise this standard to require the MA organization to prove by a preponderance of evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect and to add additional language at § 422.260(c)(2)(v) clarifying that the burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status. We believe that the appropriate standard of proof is the preponderance of the evidence.

If the hearing officer's decision is in favor of the MA organization, the MA organization's QBP status is recalculated using the corrected data and applying the rules at §§ 422.160 through 422.166. Under our current implementation of § 422.260, recalculation could cause the requesting MA organization's QBP rating to go higher or lower. In some instances, the recalculation may not result in the Star Rating rising above the cut-off for the higher QBP rating. We are proposing additional language at § 422.260(c)(1)(i) to clarify that ratings can go up, stay the same, or go down based on an appeal of the QBP determination.

Under § 422.260(d), CMS may revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year on the basis of any credible information, including information provided during the administrative review process, requested by a different MA organization, that demonstrates that the initial QBP determination was incorrect. CMS issues annual guidance to MA organizations about the QBP appeal process available under § 422.260 each November titled, for example, "Quality Bonus Payment Determinations and Administrative Review Process for Quality Bonus Payments and Rebate Retention Allowances." We interpret and implement § 422.260 through this guidance and our administration of the annual administrative review process.

When the reconsideration official or hearing officer's decision for a particular appeal or other credible information suggests that there was a systematic error impacting all or a subset of contracts, the QBP status of all contracts is re-calculated using the corrected data and applying the rules at §§ 422.160 through 422.166. If the re-calculated QBP rating for a contract other than the appealing contract results in a lower rating, the original preliminary QBP rating will be used. Thus, a contract's QBP rating will not be decreased by CMS as a result of a systematic re-calculation for the current Star Ratings and associated QBP year to correct a systematic calculation error; however, the issue identified will be addressed in the next year's Star Ratings. However, if the QBP rating is higher for a contract after the systematic re-calculation, the new rating will be used. For example, if CMS has to do a systematic re-calculation for the 2023 Star Ratings following the release of the preliminary 2024 QBP ratings, a contract's 2023 Star Ratings used for the 2024 QBP ratings will not be decreased but the change that caused a systematic recalculation will be addressed when the 2024 Star Ratings are calculated. If the re-calculation of the 2023 Star Ratings results in a higher rating for a contract, the higher rating will be used. We propose to add language at § 422.260(d) to clarify that a reopening of a QBP determination to address a systemic calculation issue that impacts more than the MA organization that submitted an appeal would only be updated if it results in a higher QBP rating for other MA organizations that did not appeal. This is how we have historically noted how we would handle this type of systemic calculation error as described in our annual HPMS memo released in November each year.

We welcome comments on this proposal.

K. Calculation of Star Ratings (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the June 2020 final rule, we finalized use of Tukey outlier deletion effective for the Star Ratings issued in October 2023 and subsequent years. (85 FR 33833-36) In the rulemakings since that time, we have not proposed to eliminate the Tukey outlier deletion aspect of the Star Ratings methodology. As we stated in May 2022 final rule (87 FR 27766), we will implement

Tukey outlier deletion beginning with the 2024 Star Ratings to help improve stability of cut points and prevent cut points from being influenced by outliers. We further stated that with Tukey outlier deletion, extreme outliers will be removed from measure scores prior to clustering to prevent outliers from impacting cut points for all contracts. However, it appears that the sentence in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) ("Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed.") was inadvertently removed from the codified regulation text. We are proposing a technical amendment to fix this codification error from the May 2022 final rule. In addition, although the provision regarding application of the Tukey outlier deletion policy was originally at the end of paragraph (a)(2)(i) in each regulation, we are also proposing a non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) since Tukey outlier deletion is applied prior to the other steps. We believe that this makes the regulation text clearer.

We welcome comment on this proposal.

VI. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy

A. Contract Year Definition (§ 460.6)

Sections 1894(a)(9) and 1934(a)(9) of the Act define the trial period for PACE organizations as the first 3 contract years operating a PACE program under a PACE program agreement. Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency, to conduct a comprehensive annual review of the PACE organization's operation of the PACE program during the trial period to assure compliance with all significant requirements. The rule titled "Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)", which appeared in the November 24, 1999 issue of the **Federal Register** (64 FR 66234) (hereinafter referred to as the 1999 PACE interim final rule) defined a contract year at § 460.6 as the term of the PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS. This enables CMS to adjust the length of the initial contract year so that it always ends on December 31 and subsequent contract years align with a standard annual calendar year consisting of 12 months (64 FR 66236). For example, for a PACE organization that signs a program agreement in March 2022, CMS would extend the organization's initial contract year through December 31, 2023, so that all future contract years would align with calendar years.

As previously stated, CMS is required to conduct comprehensive reviews during a PACE organization's trial period to assess all significant regulatory requirements, and these reviews must be conducted on an annual basis for the first 3 contract years. Currently the first trial period contract year may include up to 23 months, but the subsequent two trial period contract years are limited to 12 months, each beginning on January 1 and ending on December 31. CMS has developed audit protocols to comprehensively assess PACE organizations which require the availability of multiple months of program data and typically take 6 to 9 months to complete, including pre-audit data collection, audit fieldwork, and the corrective action period which

allows time for PACE organizations to correct deficiencies identified during audits. CMS must conduct the first trial period audit within the first contract year in order to comply with the statutory and regulatory requirements. However, our ability to schedule and conduct the first trial period audit is limited by when a PACE organization enters into a program agreement, the current contract year definition in § 460.6, and when the PACE organization begins enrolling participants during their first contract year. Depending on when the program agreement is signed, the first trial period audit may be required within 12 months from the contract start date which we believe is not a sufficient length of time for new PACE organizations to establish their operations before undergoing an audit.

In order to have enough data to conduct a comprehensive audit, CMS has found it necessary to allow a PACE organization to operate with enrollees for at least 6 months before conducting its first trial period audit, which may not occur until the latter half or end of their first contract year. However, unless the first trial period audit is scheduled early in the calendar year, we encounter significant operational challenges conducting subsequent audits for the second and third years of the trial period in accordance with statutory and regulatory requirements, while still giving PACE organizations sufficient time between audits to ensure they are able to fully correct the deficiencies identified during an audit before CMS collects data for the next audit. Specifically, delaying the first trial period audit until later in the calendar year to ensure adequate PACE organization operational experience, reduces the time between audits, which creates overlap between timeframes to correct deficiencies and the data collection period for subsequent trial period audits. For example, under the current contract year definition, a PACE organization that enters into a program agreement on January 1, 2023 must receive its first comprehensive trial period audit by December 31, 2023, its second trial period audit in 2024, and its third trial period audit in 2025. If CMS first audits the PACE organization in early 2023, we would not have enough data to conduct a comprehensive review. However, waiting to schedule the first audit until later in 2023 reduces the timeframe within which CMS can schedule the second and

third trial year audits required in 2024 and 2025. Given that a PACE organization may need 9 months to complete the first trial period audit initiated in 2023, and multiple months of data are required for each audit, it is operationally challenging for CMS to schedule and complete the next 2 annual audits within the trial period while still affording PACE organizations a sufficient amount of time between audits to correct identified deficiencies.

CMS therefore proposes to amend the definition of contract year at § 460.6 to state that a PACE organization's initial contract year may be 19 to 30 months, as determined by CMS, but in any event will end on December 31. Under the proposed contract year definition, although the duration of the initial contract year of the trial period would change, the initial contract year would continue to begin when the program agreement is signed and end on December 31 to ensure subsequent contract years follow the standard annual calendar year cycle. For PACE organizations with an initial contract year start date of January 1 through June 1, CMS would extend the initial contract year through the following year. For example, for a program agreement signed on January 1, 2024 or up until June 1, 2024, the initial contract year would end December 31, 2025. The second and third contract years would begin on January 1, 2026 and January 1, 2027, respectively. Additionally, for PACE organizations with an initial contract year start date of July 1 through December 1, CMS would extend the initial contract year through the second succeeding year. For example, for a program agreement signed on July 1, 2024, the initial contract year would end December 31, 2026. The second and third contract years would begin on January 1, 2027 and January 1, 2028, respectively. This would allow CMS to continue adjusting the length of the initial contract year so that subsequent contract years align with the calendar year, but it would provide greater flexibility around scheduling the first trial period audit. We believe that making the minimum length of time 19 months (as opposed to 12 months) would ensure organizations have sufficient time both to enroll participants and gain adequate program experience before their initial audit, while still allowing time to address deficiencies and implement improvements before engaging in another audit. In addition, this change would

enable CMS to conduct the first trial period audit early enough in a calendar year that it does not adversely impact the second and third trial period audits. While we anticipate that this modification would allow us more flexibility in scheduling the first trial period audit, we intend to maintain our commitment to conducting first contract year audits as expeditiously as possible. For example, if a contract were signed on January 1, 2024, the initial contact year would extend to December 31, 2025 and CMS could potentially schedule the first trial period audit early in the 2025 calendar year. This would ensure that the PACE organization has sufficient time to operate before the start of the data collection period for the first trial period audit, and it would still allow CMS operational flexibility in scheduling the next two audits in 2026 and 2027.

We solicit comment on whether CMS should consider a different timeframe for the initial contract year. Specifically, we are seeking feedback on whether CMS should consider defining the initial contract year as 25 to 36 months to allow organizations additional time to implement and operate a PACE program before undergoing their first audit.

Since the effect of the proposed change would be to provide CMS with more flexibility when scheduling initial trial period audits without placing new requirements on CMS 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.

B. Determining that a Substantially Incomplete Application is a Nonapplication (§§ 460.12 and 460.20)

Sections 1894(e)(8) and 1934(e)(8) of the Act established CMS' authority regarding PACE provider application requirements. Based on this authority, we are proposing to strengthen the PACE regulations at §§ 460.12(a) and (b) and 460.20(b), which pertain to application requirements, by further defining what constitutes a complete and valid application.

CMS accepts PACE applications from entities seeking to establish a PACE program (initial applicants) or to expand an existing PACE program's service area (including both

expansion of a PACE programs' geographic service area and/or the addition of a new PACE center), on designated quarterly submission dates.

In order to receive funds under Part D to provide prescription drug benefits, PACE organizations must qualify as Part D sponsors under § 423.502(c)(1) by submitting an application in the form and manner required by CMS. Therefore, as a matter of necessity, initial PACE applicants that provide the Part D benefit to eligible beneficiaries must submit a separate Part D application. Effective March 31, 2017, CMS requires organizations to submit all applications electronically via the Health Plan Management System (HPMS). The PACE application includes attestations and certain required documents to ensure compliance with established PACE regulations, including but not limited to: policies and procedures related to enrollment, disenrollment, grievances and appeals; information regarding the legal entity and organizational structure; and State-based documents, including a State assurances document. The State assurances document is a template that includes standard statements regarding the State's roles and responsibilities and includes the physical address of the proposed PACE center, geographic service area, or both, as applicable, depending on the type of application. This document must be signed by an official within the applicable State Administering Agency (SAA), the designated agency for the PACE program in the State in which the program is to be located, and serves as confirmation of the State's support for the application. It is imperative that the applicant demonstrate the State's support as part of the application since the State is a party to the PACE program agreement, which, once approved and finalized, is a 3-way contract between CMS, the State, and the PACE organization.

Section 460.12 sets forth the application requirements for an organization that wishes to qualify as a PACE organization, and for an active PACE organization that seeks to expand its geographic service area and/or add a new PACE center site. Paragraph (a) of § 460.12 states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area and/or add a new center site

must submit a complete application to CMS in the form and manner specified by CMS. Furthermore, § 460.12(b)(1) specifies that an entity's application to become a PACE organization must include an assurance from the SAA of the State in which the program is to be located indicating that the State considers the entity qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity. Similarly, an existing PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the SAA of the State in which the program is located indicating that the State is willing to amend the signed PACE program agreement to include the expanded service area and/or new center site (§ 460.12(b)(2)).

We indicated in the final rule titled "Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)", which appeared in the June 3, 2019 issue of the **Federal Register** (84 FR 25610) (hereinafter referred to as the June 2019 final rule) that applications received without the required State assurances document would not be considered a complete application and would therefore, not be reviewed (see 84 FR 25615 and 25671).

Section 460.20(a) provides that within 90 days, or 45 days in the case of an application to expand a service area or add a PACE center, after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS: (1) approves the application or (2) denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial. An application is considered complete only when CMS receives all information necessary to make a determination regarding approval or denial (§ 460.20(b)).

As part of annual training sessions and resources available at: https://www.cms.gov/Medicare/Health-Plans/PACE/Overview, CMS has stated that the only required application document that may not be available and submitted as part of the initial application submission on CMS' designated quarterly date is the State readiness review (SRR) of a center site, as applicable. The SRR is conducted by the State at the applicant's PACE center,

and the accompanying report certifies that the PACE center satisfies all applicable local, State and Federal requirements and is ready for operations. CMS has instructed PACE applicants that this document may be uploaded when responding to a CMS request for additional information.

The application is not considered complete and valid without the required documentation from the applicable SAA that provides clear evidence of the State's support. However, in our experience, some PACE organizations submit a State assurances document that is not signed by the State, is provided after the designated submission date, or has changed the location of the proposed PACE center or included the corporate address as a placeholder. Should any of the aforementioned occur, the applicant is instructed to withdraw the application.

Under this proposal, we would treat any PACE application that does not include a signed and dated State assurances document that includes accurate service area information and the physical address of the PACE center as incomplete and invalid and therefore not subject to review or reconsideration. Entities that submit an application without a complete and valid State assurances document would have their application withdrawn from HPMS. They would then have to wait until the next quarterly submission date to submit the application with the State assurances included. We propose to add paragraph § 460.12(b)(3) to specify that any PACE application that does not include the proper State assurances documentation associated with the application would be considered incomplete and invalid.

In the June 2019 final rule, we added the phrase "in the form and manner specified by CMS" to § 460.12(a) when describing the submission to CMS of a complete application, to allow for submission of applications and supporting information in formats other than paper, which was the required format at the time the proposed rule was issued (84 FR 25671). We propose to amend § 460.12(a), which states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area (through a geographic service area expansion and/or addition of a new center site) must submit a complete application to CMS "in the form and manner specified by CMS" by adding a

parenthetical with the words “including timeframes for submission” after “manner”, in order to make clear that CMS will only accept applications that are submitted within the timeframes established by CMS.

We propose to establish at § 460.20(c) that any application that, upon submission, is determined to be incomplete under proposed § 460.12(b)(3) because it does not include a signed and dated State assurances document with accurate service area information and the physical address of the PACE center, as applicable, would be withdrawn by CMS, and the applicant would be notified accordingly. Proposed § 460.20(b)(1) would further specify that the applicant would not be entitled to a hearing if the application is withdrawn based on that determination. Without the necessary evidence of support for the application by the SAA, the application would not be valid and therefore not subject to reconsideration. We note this proposal would be consistent with how CMS addresses MA or Part D applicants that submit substantially incomplete applications. Such applications are considered invalid applications and applicant organizations are not entitled to a hearing per § 422.660 or § 423.650.

Finally, we are proposing to establish at § 460.12(a)(2) that an individual authorized to act for an entity that seeks to become a PACE organization (initial PACE applicant) is required to submit a separate Part D application that complies with the applicable requirements under Part 423 Subpart K. This is consistent with our current practice, under which initial PACE applicants must submit a Part D application. By contrast, existing PACE organizations seeking to expand their service area are not required to complete a Part D application. Therefore, consistent with our existing practice, we are not proposing to establish Part D application requirements for PACE organizations seeking to expand their existing service area. We also intend to continue our current practice of following the timeframes for PACE applications, including submission deadlines and review periods, for Part D applications associated with PACE applications—that is, we will continue to accept Part D applications from initial PACE applicants on a quarterly

basis. We believe it is important to continue to align application and review and submission deadlines for PACE applicants to the extent practicable in order to promote consistency.

Consistent with current practice, we propose to treat an initial PACE application that does not include responsive materials for one or more sections of its Part D application as substantially incomplete, and those applications would not be reviewed or subject to reconsideration. Should this proposal be finalized, if the Part D application associated with an initial PACE application is deemed substantially incomplete, that would render the PACE application incomplete and therefore not subject to review or reconsideration.

C. PACE Past Performance (§§ 460.18 and 460.19)

Sections 1894(e)(4) and 1934(e)(4) of the Act establish CMS' authority to oversee the PACE program. To effectively oversee the PACE program, we are proposing to amend the PACE regulation at § 460.18 (CMS evaluation of applications) to incorporate an evaluation of past performance into the review of applications submitted by PACE organizations that seek to offer a PACE program or expand an approved program by adding a geographic service area and/or PACE center site or sites. Our evaluation of past performance would be a criterion CMS would use to review a PACE organization's application. The addition of this proposed evaluation criterion at § 460.18(c) would permit CMS to deny applications from PACE organizations based on the organization's past performance. Our past performance proposal takes into account any compliance letters received by an organization. We are also proposing to establish at § 460.18(d) that CMS may deny a PACE application if the PACE organization's agreement was terminated or not renewed during the 38 months preceding the date the application was first submitted to CMS.

The past performance of an organization is an important criterion for CMS to review when considering a PACE application because it provides valuable information about the ability of an organization to effectively operate a new program or expand an existing program. Organizations that have performed well are more likely to continue their high performance while

organizations that have not may have difficulty meeting regulatory requirements in operating a new or expanded PACE program. This could pose a risk to the health and safety of the PACE participants they enroll. It is important for CMS to ensure that the legal entities with whom we hold program agreements are able to appropriately provide services and benefits to PACE participants.

In the Medicare Advantage (MA) and Part D programs, CMS considers an organization's past performance during the evaluation of the application. We are modeling the PACE past performance proposal after the MA and Part D review regulations at 42 CFR Parts 422 and 423, using applicable evaluation criteria in our proposal. We believe modeling the PACE past performance review criteria after the criteria that appear in the MA and Part D regulations is appropriate given that consideration of past performance has been a long-standing part of application reviews under the MA and Part D programs, resulting in the denial of applications of poor performing plans. CMS' goal is the same for PACE as it is in MA and Part D, which is to prohibit poor performing organizations from entering into new agreements, or expanding their service areas in the program.

In addition, we believe modeling past performance reviews in PACE on past performance reviews in MA and Part D is appropriate since PACE organizations that provide Part D benefits are subject to the regulations at 42 CFR 423, with the exception of those regulations CMS has waived in accordance with § 423.458(d). In addition, modeling after MA and Part D reduces burden by not having a different set of criteria for the non-Part D PACE benefits. In keeping with this requirement, our proposal would ensure that all entities that submit PACE applications would be subject to past performance reviews, the same as other entities that submit Part D applications.

In the January 2021 final rule (86 FR 5864), CMS established in regulation the methodology and criteria used to decide to deny an MA or Part D application based on prior contract performance (§§ 422.502(b) and 423.503(b)). We noted in the final rule that we may

deny applications based on past contract performance in those instances where the level of previous non-compliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees (86 FR 5999). In the January 2021 final rule and through subsequent rulemaking, CMS adopted the following factors as the bases for denying an MA or Part D application: (A) the organization was subject to an intermediate sanction; (B) the organization failed to maintain a fiscally sound operation; (C) the organization filed for bankruptcy or is under bankruptcy proceedings; (D) the organization had low Star Ratings for two or more consecutive years; or (E) the organization exceeded CMS' threshold for compliance actions (*see* 86 FR 6000 and 87 FR 27704). Each of these factors, on its own, represents significant non-compliance with an MA or Part D contract; therefore, the presence of any of these factors in an applicant's record during the past performance review period could allow CMS to deny its MA or Part D application.

CMS is now proposing to apply a past performance methodology to entities that seek to offer a new PACE program or expand an existing program. Our proposal would modify the regulations at Part 460 to permit CMS to consider an entity's past performance in determining whether to approve or deny a new application or an application to expand a current program. The proposed methodology for this evaluation would be similar to the methodology CMS uses when deciding whether to deny MA and Part D applications based on past performance. As with our MA and Part D past performance reviews, the purpose of our proposed PACE past performance reviews is to prevent organizations from expanding their PACE operations where the organization's past conduct indicates that allowing the organization to expand would pose a high risk to the success and stability of PACE and PACE participants. Like MA organizations and Part D sponsors, PACE organizations that have been under sanction, failed to meet fiscal soundness requirements, or been issued compliance actions above a certain threshold have demonstrated that they have had significant failures in operating their program. Consistent with

the past performance standards for MA and Part D, and as we discuss in detail later in this proposed rule, we are proposing that CMS would deny an initial or service area expansion (SAE) application based on the same factors (other than low Star Ratings) that serve as the basis for denying an MA or Part D application. CMS does not propose to include Star Ratings in the past performance review for PACE because CMS does not calculate these measures for PACE organizations.

CMS accepts applications on designated quarterly submission dates from entities seeking to either establish a PACE program or expand an existing program. Similar to MA applications, and in accordance with § 460.18, CMS evaluates a PACE application based on information contained in the application itself, as well as information obtained by CMS (or the applicable State Administering Agency (SAA), which serves as the designated State agency for PACE), through on-site visits or any other means. If an organization meets all application requirements, CMS approves the application.

CMS is proposing to incorporate past performance reviews into the PACE application process to safeguard the program and ensure PACE participants are protected from the expansion of poorly performing organizations. The PACE program has seen significant growth in recent years, with increased numbers of both initial and expansion applications and steady increases in overall enrollment. This growth can be attributed in part to a legislative change that took effect in 2015 that allowed for-profit entities to operate PACE programs (see sections 1894(h) and 1934(h) of the Act). Prior to that change, only not-for-profit entities were eligible to offer PACE programs. At the end of calendar year 2016, a total of 121 approved PACE organizations were in operation, serving 37,584 predominantly dually-eligible participants. In calendar year 2021, CMS received 22 initial applications and 22 expansion applications. As of September 2022, there were 149 PACE organizations serving 54,643 participants in 32 states.

PACE participants are some of our most vulnerable beneficiaries. In order to enroll in a PACE program, the SAA must determine that the beneficiary needs the level of care required

under the State Medicaid plan for coverage of nursing facility services (§ 460.150(b)(2)). Beneficiaries who need this level of care are generally frail, may have multiple conditions, and require extensive assistance with activities of daily living. The PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year (§ 460.98(a)). Each PACE organization must have a center, which PACE participants can visit weekly or even daily, based on each participant's needs and preferences. The PACE center must provide primary care services, nursing services, social services, restorative therapies (including physical therapy and occupational therapy), personal care and supportive services, nutritional counseling, recreational therapy, and meals (§ 460.98(c)).

Given the recent and anticipated future growth in PACE and the vulnerable populations that PACE organizations serve, CMS believes that the past performance of a PACE organization should be reviewed as part of the application process. Past performance evaluations would enhance CMS' ability to ensure that initial PACE applications and applications for service area expansions from low performing organizations are denied. The ability to deny initial PACE applications or service area expansion applications submitted by organizations that we determine are poor performers helps to ensure that the organizations with which we have an agreement will be able to provide health care services to beneficiaries in a high-quality manner.

The PACE application review process is unique, and we have developed these proposals with that process in mind. Per the regulations at § 460.20(a) and (c), upon receipt of a complete PACE application, CMS must: 1) approve the application; 2) deny the application; or 3) issue a request for additional information (RAI) in the event there are deficiencies. CMS' deadline for these actions is within 90 days of submission of an initial application or for a service area expansion (SAE) application that includes both a proposed geographic expansion and a new center site, or within 45 days of submission of an SAE application that includes either a proposed geographic expansion or a new center site. If CMS issues an RAI, the applicant must respond to

the RAI only when ready and able to submit a complete response that addresses all deficiencies cited in the RAI, which includes a complete State readiness review (SRR) report, as applicable. If CMS issues an RAI, the first review clock ends and the second and final review clock does not begin until the applicant submits a complete RAI response, which starts the second and final 45- or 90-day review clock, as applicable. As part of the application process, the applicable SAA must conduct an SRR at the applicant's proposed PACE center site (if applicable) to ensure that the PACE center meets the State's regulatory requirements. Applicants are required to submit documentation of the completed SRR report to CMS for applications that include a new PACE center site (*see* § 460.12(b)(2)). Per application instructions, the SRR report is the only required document that may be uploaded after the initial application submission, in response to CMS' RAI. In our experience, a response to a RAI may take anywhere from a few weeks to more than a year to receive, often because of the renovation or construction of a center site, attainment of building permits, and/or the need for a readiness review to be completed. The MA and Part D past performance review currently has a 12-month look back period which is defined as the most recent 12 months preceding the application deadline (*see* § 422.502(b) and 423.503(b)). Since MA and Part D applications are generally due in February of each year, this review period results in a 12-month look back period that covers the previous March through February of the year the applications are due. Similar to MA and Part D, we propose to use a 12-month review period under this PACE proposal, resulting in a review of an organization's past performance for the 12 months preceding the deadline established by CMS for the submission of PACE applications but also propose to apply the 12-month look back review upon receipt of the applicant's response to CMS' RAI. A 12-month look back period provides recent information on the operations of a PACE organization, which we believe is the best indicator of the PACE organization's current and future performance.

We propose, at § 460.18(c)(1)(i), to evaluate the following components of an applicant organization's past performance starting with the March 2024 quarterly application submission

cycle: whether the organization was subject to an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40, even if the reasons for the sanction have been corrected and the sanction has been lifted; whether the organization failed to maintain fiscal soundness; whether the organization has filed for or is under State bankruptcy proceedings; and whether the organization has exceeded CMS' proposed 13-point threshold for compliance actions with respect to the PACE program agreement. We are proposing that, if any of those circumstances applies to the applicant organization, CMS may deny its initial or expansion application.

Specifically we propose at § 460.18(c)(1)(i)(A) to include the imposition of enrollment or payment sanctions under § 460.42 for one of the violations listed in § 460.40 as a reason for which CMS may deny a PACE application, as noted in the paragraph above. Currently, § 460.42 authorizes CMS to impose a suspension of enrollment or payment if a PACE organization commits one or more of the violations listed in § 460.40. Violations in § 460.40 include the failure of the PACE organization to provide medically-necessary services, discrimination in enrollment or disenrollment of individuals eligible to enroll in a PACE program based on health status or need for health services, and involuntary disenrollment of a PACE participant in violation of § 460.164. These violations are serious and egregious actions by the PACE organization. Organizations that have been sanctioned (enrollment or payment) based on their failure to comply with CMS' regulations have either admitted they failed to comply with PACE requirements or have appealed and a third party has upheld CMS' determination that the PACE organization has failed to comply with requirements. Because of the egregiousness of the actions that led to the PACE organizations' sanctions, we do not believe these organizations should be permitted to enter into new agreements, add new PACE sites, or expand their service area until the PACE organization corrects the issues that resulted in the sanction and ensures that such issues are not likely to recur.

We propose at § 460.18(c)(1)(i)(B) to include, as a basis for application denial, the failure to maintain a fiscally sound operation after the end of the trial period. For purposes of fiscal soundness, the trial period ends when CMS has reviewed independently audited annual financial statements covering three full 12-month financial reporting periods. The regulation at § 460.80(a) requires a PACE organization to have a fiscally sound operation. Under § 460.80(a)(1), a PACE organization must have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities. To monitor compliance with § 460.80(a)(1), CMS requires PACE organizations to submit certified financial statements on a quarterly basis during the trial period, and annually thereafter, unless CMS or the SAA determines that the organization requires more frequent monitoring and oversight due to concerns about fiscal soundness, in which case the organization may be required to submit certified financial statements on a monthly or quarterly basis (or both) (§ 460.208). Fiscal soundness is a key factor in CMS' evaluation of past performance because CMS has a responsibility to ensure the organizations that provide health care services to our beneficiaries have sufficient funds to allow them to pay providers and otherwise maintain operations. The failure of an organization to have a positive net worth puts PACE participants in jeopardy of not receiving necessary health care. In addition, organizations that are not fiscally sound may not be able to continue operations, causing the organization to close doors, leaving all their PACE participants without PACE coverage. Based on this, CMS believes it is in the best interest of the program to add failure to maintain a fiscally sound operation—specifically, failure to have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities—to the list of reasons CMS may deny a new application or an expansion application from a PACE organization.

We propose to establish at § 460.18(c)(1)(i)(C) that CMS may deny the application of an organization that has filed for or is currently in State bankruptcy proceedings. Similar to an organization that lacks fiscal soundness, an organization that has filed for or currently is in State bankruptcy proceedings is at great risk of not having sufficient funds to cover costs associated

with running a PACE program. In circumstances where an organization has filed for bankruptcy or is currently in State bankruptcy proceedings, the outcome often results in the closure of an organization's operations, putting beneficiaries at great risk. Examples of participants being at risk may include the inability to find adequate and timely care, care coordination issues, loss of providers (especially primary care providers who are employed by the PACE organization), as well as loss of the social and emotional support the PACE organization provides. Thus, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the PACE program and CMS should be able to deny an application from any organization that has filed for or is in State bankruptcy proceedings.

Finally, we propose to establish at § 460.18(c)(1)(i)(D) that CMS may deny an initial application or an expansion application for a PACE organization that exceeds the proposed 13-point threshold with respect to CMS-issued compliance actions. Proposed § 460.19(a) would specify that CMS may take compliance actions as described at proposed § 460.19(c) (discussed in this section of this proposed rule) if CMS determines that a PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and an SAA. PACE organizations are required to adhere to requirements in sections 1894 and 1934 of the Act and in CMS regulations at 42 CFR Part 460. Proposed § 460.19(a)(1) would provide that CMS may determine that a PACE organization is non-compliant with requirements if the PACE organization fails to meet set performance standards articulated in sections 1894 and 1934 of the Act, regulations at 42 CFR chapter IV, and guidance. In addition, proposed § 460.19(a)(2) would establish that if CMS has not previously articulated a measure for determining compliance, CMS may determine that a PACE organization is non-compliant if its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

Currently, CMS issues three types of compliance actions: Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).[203] These actions are CMS' formal way of recording an organization's failure to comply with statutory and regulatory requirements as well as providing notice to the organization to correct its deficiencies or risk further compliance and/or enforcement actions. They also serve to document the problem and, in some instances, request details on how the organization intends to address the problem.

CMS proposes to specify at new § 460.19(c) the types of compliance actions we currently issue. First, CMS proposes to specify that NONCs may be issued for any failure to comply with the requirements of the PACE organization's current or prior PACE program agreement. CMS typically uses NONCs to document small or isolated problems. They are the lowest form of a compliance action issued by CMS. CMS typically issues NONCs for the least egregious failures, such as a first-time offense, a failure that affects only a small number/percentage of participants, or issues that have no participant impact. An example of a failure that would lead to an NONC would be a failure to upload or correctly upload marketing materials.

Second, CMS proposes to specify that WLs may be issued for serious and/or continued noncompliance with the requirements of the PACE organization's current or prior program agreement. CMS typically issues WLs as an intermediate level of compliance action, between a NONC and a CAP. They are issued either when an organization has already received a NONC, yet the problem persists, or for a first offense for larger or more concerning problems, such as failure to provide medically necessary services. Unlike NONCs, these letters contain warning language about the potential consequences to the organization should the non-compliant performance continue. Similar to CAPs, WLs are issued for more egregious instances of non-compliance or continued non-compliance. However, they are issued when the egregiousness or

[203]The CAPs CMS proposes to issue for purposes of compliance and take into account during past performance evaluations to determine whether to deny PACE organizations' applications would be separate and distinct from CAPs issued under § 460.194(a)(2), which are corrective action plans that are requested and received in the course of audits.

continued non-compliance may not warrant a CAP. For example, a WL might be issued when a PACE organization has failed to have the full interdisciplinary team (IDT) involved in the review of participant care plans, which may have or did result in participants not receiving necessary care. CMS might determine, based on a review of factors such as the types of care not received, that the PACE organization's non-compliance does not warrant a CAP, and issue a WL instead.

Third, CMS proposes to specify that the last type of compliance action, the CAP, is the most serious type of compliance action and may be issued for particularly egregious or continued noncompliance. CMS may determine that the PACE organization has repeated, not corrected, or has a new deficiency which substantially impacts beneficiaries. In these cases, CMS requires the PACE organization to implement a CAP.

The CAPs described in this proposed provision are not the same as corrective actions issued under § 460.194(a)(2). CAPs issued under § 460.194(a)(2) require PACE organizations to take action to correct deficiencies identified by CMS or the State administering agency through reviews and audits of the PACE organization (§ 460.194(a)(2)). CMS has a formal audit process, which identifies non-compliance. CMS issues CAPs under 460.194(a)(2) as a result of reviews or audits. These CAPs are routinely requested and PACE organizations submit them to CMS as a means of addressing deficiencies identified during reviews or audits. CMS expects to continue to request CAPs as necessary under 460.194(a)(2) in response to deficiencies identified through reviews or audits; nothing about this proposal would change that process.

Consistent with the past performance methodology applicable to MA, we propose to assign points to each type of compliance action taken by CMS against PACE organizations. We then propose to apply a compliance action threshold to determine if the PACE organization that submitted the application exceeds the threshold and should be denied. The following points would be assigned: CAP—6 points, WL—3 points, NONC—1 point. CMS will then total the points accrued by the applicant organization, and if the total meets or exceeds 13 points during

the 12-month review period, CMS may deny the organization's new or expansion application on the basis of past performance.

With the proposed addition of compliance actions as a basis for the denial of applications, CMS is also proposing to specify at new § 460.19(b)the factors we currently use to determine whether to issue a compliance action and the level of compliance action that should be issued.

At § 460.19(b)(1) through (6), we propose to put in regulations the factors we currently use when determining whether to issue a compliance action and what level of compliance action to issue. As discussed in the paragraphs that follow, CMS considers the following factors: the nature of the conduct, the degree of culpability of the PACE organization, the actual or potential adverse effect on participants which resulted or could have resulted from the conduct of the PACE organization, the history of prior offenses by the PACE organization or PACE organization's contractors or subcontractors, whether the non-compliance was self-reported, and other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

Proposed § 460.19(b)(1) would establish that CMS considers the nature of the PACE organization's non-compliant conduct. The nature of the conduct is relevant to CMS' determination of whether to issue a compliance action and the level of compliance action to take because failure to comply can range from an administrative issue to failure to provide necessary health care. Compliance issues that are less egregious in nature generally result in lower-level compliance actions.

Proposed § 460.19(b)(2) would provide that CMS considers the degree of culpability of the PACE organization. This factor is relevant because the PACE organization's failure may have been avoided if the PACE organization had performed differently. For example, if the PACE organization failed to properly train or failed to hire properly trained staff to assist participants in activities of daily living, such as bathing, and a participant fell and injured themself in the shower, the PACE organization would be more culpable than if staff were

properly trained and the participant still injured themself. The PACE organization has a responsibility to do everything possible to ensure the safety of the participants, and its failure, either intentional or unintentional (for example, lack of training, lack of oversight, lack of staff) would be a factor in CMS' decision about the type of compliance action to take.

Proposed § 460.19(b)(3) would provide that CMS considers the effects or potential effect of a PACE organization's conduct on PACE participants. This factor is relevant because a PACE organization's failure to comply may have very different effects (or potential effects) on PACE participants and may affect varying numbers of participants. For example, an organization's failure to timely arrange for primary care could affect the vast majority of participants enrolled with that organization. However, an organization's failure to timely arrange for a very specific type of specialty care may affect only a few participants.

Proposed § 460.19(b)(4) would specify that CMS considers the history of prior offenses of a PACE organization or its related entities. A PACE organization's (or its related entity's) failure to comply is relevant because the PACE organization should have ongoing processes in place to correct deficiencies as they occur and ensure that deficiencies are not likely to recur. As mentioned later in this section, organizations that have had recurrent compliance issues may be subject to a higher level of compliance action. For example, a PACE organization that failed to provide transportation to participants one year ago may have received a NONC at that time. If the organization fails to correct this deficiency after first being cited with a NONC for the deficiency, CMS may escalate the continued failure to comply by issuing a WL, based on the PACE organization's past history and continued failure to correct the deficiency.

Proposed § 460.19(b)(5) would provide that CMS considers whether an organization self-reported a compliance failure. A PACE organization that self-reports that the organization has found the deficiency, such as through an internal audit, generally indicates that the organization is actively engaged in identifying and correcting compliance issues, and likely has initiated the corrective action to address the deficiency prior to CMS being made aware of the matter. CMS

considers issues that are identified through specific requests made by CMS, the review of data CMS either has or has requested, or complaints that have come into CMS through sources such as 1-800-Medicare that or complaints that CMS has asked the PACE organization to provide as issues that are not self-reported. If an organization has self-reported a compliance issue, CMS may decide to lower the level of noncompliance (for example, issuing a NONC instead of a WL) because of the organization's transparency with respect to the non-compliant behavior, since it is possible CMS would not have found the deficiency if not for the self-reporting. However, even if the organization did self-report the issue, CMS may decide against lowering the level of compliance action if, depending on the factors identified above, to warrant a higher-level compliance action.

Finally, proposed § 460.19(b)(6) would provide that CMS considers the PACE organization's failure to adequately oversee its operations. For instance, if an organization fails to properly pay claims, is aware of the issue, and fails to correct it (for example, by processing the claims accurately), or if the organization fails to do any monitoring or auditing of its own systems to ensure proper claims payment is occurring, CMS could take that into account in determining whether to issue a compliance action and, if so, the level of compliance action.

As previously mentioned, CMS proposes in a new § 460.18(c)(1)(i)(D) that CMS would have authority to deny a new application or an expansion application if a PACE organization accumulates 13 or more compliance action points during the applicable proposed 12-month look back period. This would be the equivalent of just over two CAPs. Any organization whose performance results in issuance of two CAPs and a NONC, or whose performance results in any combination of compliance actions that add up to 13 points, should not be permitted to expand.

CMS is proposing at § 460.18(c)(1)(ii) that CMS could also deny an application from an organization that does not hold a PACE program agreement at the time of the submission, if the applicant's parent organization or another subsidiary of the same parent organization meets the past performance criteria for denial proposed in § 460.18(c)(1)(i). Specifically, if an initial

applicant is a legal entity under a parent organization that has a PACE program agreement, or if there are other organizations under the same parent that have a PACE program agreement, and the parent's PACE application or the other related organizations' PACE applications would be denied based on any of the factors proposed in § 460.18(c)(1)(i), we would also deny the new entity's application based on the past performance of other members of its corporate family. It is likely that similar structures, policies, and procedures are used across legal entities that are part of the same parent organization, increasing the likelihood that any part of a parent organization that has at least one poorly performing legal entity may be at increased risk of poor performance. In addition, using other legal entities' performance when the new applicant has no history would also prevent organizations from manipulating CMS'past performance methodology by establishing new legal entities and using those to submit PACE applications in order to avoid having CMS take into account the troubled performance history of the parent organization or its subsidiaries when reviewing the new legal entity's PACE application.

It would be especially important, when CMS reviews a new application from a legal entity that does not have activity that would constitute the past performance of that legal entity as a PACE organization, for CMS to be able to consider information from the current or prior PACE program agreements of the parent organization of the applicant, and from members of the same parent organization as the applicant. We are more frequently seeing initial PACE applications that represent unique and distinct legal entities that are part of a broader parent organization. In one recent instance, we reviewed an initial PACE application for a new legal entity under a parent organization that already had created a number of separate and unique legal sub-entities. In this case, in accordance with § 460.18(a) and (b), CMS considered the known adverse audit findings of other legal entities that were under the same parent organization, and which resulted in formal enrollment sanctions for the other legal entities. In the review of the new legal entity's application, we determined that the new legal entity was under the same "umbrella" as the legal entities that had been sanctioned, because many of the key members of

the executive leadership team were served in similar roles for both the sanctioned entities and the new applicant. CMS denied the application due to the nature of the deficiencies that led to formal sanctions for the related organizations.

We are also proposing one exception to this policy. A PACE organization that acquires an organization that would have an application denied based on any of the factors in § 460.18(c)(i) would have a 24 month "grace" period that would extend only to the acquiring parent organization. This means that the acquiring organization would still be able to enter into new agreements or expand its programs under other agreements for which there are no performance issues for 24 months following the acquisition. It is in the best interest of the PACE program to allow PACE organizations that are meeting CMS' requirements to acquire poor performing PACE organizations without being penalized based solely on their acquisition. As stated in proposed § 460.18(c)(ii), this "grace" period would be limited to 24 months from the date of acquisition. We believe this 24-month grace period would give an acquiring PACE organization sufficient time to "turn around" a poor performing organization.

Finally, we propose to add a new paragraph § 460.18(d) to provide CMS the explicit authority to consider prior termination history as part of the evaluation of an initial PACE or expansion application. Specifically, we propose that if CMS has terminated a PACE organization's program agreement under § 460.50(a), or did not renew the program agreement, and that termination or non-renewal took effect within the 38 months prior to the submission of an application by the PACE organization, CMS would be able to deny the PACE organization's application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant satisfies all other application requirements. The 38-month period is consistent with the Part D regulations at 42 CFR Part 423. Because PACE organizations that offer Part D are subject to 42 CFR Parts 423 and 460, we believe a 38 month period is appropriate. This ensures PACE applicants are not unduly burdened by having two different sets of past performance requirements, resulting in two different timeframes. CMS does not

unilaterally terminate PACE organizations' program agreements without significant failures, which are often failures affecting the furnishing or quality of care provided to PACE participants. Furthermore, a PACE organization whose program agreement has been terminated may appeal. If the PACE organization chooses to appeal and the termination is subsequently upheld through the appeals process, the organization has been found to have committed an action or actions that are egregious enough to warrant a termination. If the organization does not appeal, then the organization is acknowledging CMS' ability to terminate its PACE program agreement. Allowing organizations to come back into the PACE program when they have failed to adequately implement a prior agreement would be contrary to CMS' purpose of ensuring that high quality care is provided to PACE participants. However, we believe that an organization, after a 38-month period, may have improved its operations sufficiently for us to consider its submission of an initial application.

D. Clarification of PACE Enforcement Authority for Civil Money Penalties and Intermediate Sanctions (§ 460.40(b))

In the final rule titled "Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)" (84 FR 25610), which appeared in the June 3, 2019 issue of the **Federal Register,** CMS amended § 460.40 by adding paragraph (b), which establishes that CMS has the discretion to take alternative enforcement actions in the form of civil money penalties (CMP) or a suspension of enrollment of Medicare beneficiaries by, or payment to, a PACE organization if CMS makes a determination that could lead to a termination of a PACE program agreement under § 460.50. In order to terminate a contract under paragraph (b) of § 460.50, CMS or the State administering agency must determine that both of the following circumstances exist: (1) there are significant deficiencies in the quality of care furnished to participants; or the PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2; and

(2) within 30 days of the date of the receipt of written notice of a determination made under paragraph § 460.50(b)(1), the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies, or failed to continue implementation of the plan of correction.

In circumstances where CMS has made a determination under § 460.50 that could lead to termination, CMS would likely impose a CMP or suspension of enrollment and/or payment on a PACE organization prior to terminating the PACE organization, as authorized by § 460.40(b) (unless there was imminent risk to a PACE participant). This is because CMS views CMPs and suspensions of enrollment and/or payment as corrective in nature, since they are imposed when the PACE organization has been found noncompliant, and they provide time for the PACE organization to correct the issue(s) that led to the noncompliance with the ultimate goal of mitigating any actual or potential harm for PACE participants.

As previously stated, in order for CMS to take any enforcement action (CMP, suspension of enrollment or payment, termination) on a PACE organization based on the grounds for termination set forth in § 460.50(b), the PACE organization must fail to develop and successfully initiate a plan to correct the deficiencies, or fail to continue implementation of the plan of correction within 30 days of receiving notice. Given that CMPs and suspensions of enrollment and/or payment are corrective in nature and imposed prior to termination, CMS believes that providing PACE organizations an opportunity to correct prior to imposing a CMP or suspensions of enrollment and/or payment is unnecessary and most importantly an impediment to CMS' ability to protect PACE participants from potential harm.

For these reasons, CMS proposes to revise § 460.40(b) by adding the following: "If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administrating agency has to determine that the circumstances in 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension."

E. Personnel Medical Clearance (§§ 460.64 and 460.71)

Sections 1894(f)(4) and 1934(f)(4) of the Act grant CMS broad authority to issue regulations to ensure the health and safety of individuals enrolled in PACE. The PACE regulations at §§ 460.64 and 460.71 protect participants' health and safety by requiring PACE staff to be medically cleared of communicable diseases before engaging in direct participant contact.

In the 1999 PACE interim final rule (64 FR 66242), CMS added § 460.64, which sets forth certain personnel qualification requirements for PACE staff. When drafting these regulations, CMS reviewed the personnel requirements of other Medicare and Medicaid providers that serve populations similar to PACE participants (for example, home health agencies, nursing facilities, intermediate care facilities) (*Id.*). CMS also explained that in drafting these provisions we took a flexible approach that relied on State requirements as much as possible (*Id.*).

In the 2002 interim final rule, titled "Medicare and Medicaid Programs; Programs of All-inclusive Care for the Elderly (PACE); Program Revisions", which appeared in the **Federal Register** October 1, 2002 (67 FR 61496), CMS added § 460.71, which sets forth oversight requirements for PACE employees and contractors with direct patient care responsibilities. CMS noted the importance of adding this new section due to the vulnerable frail population served by the PACE program and the increased opportunity for a PACE organization to contract out participant care services due to the amendment in the 2002 interim final rule which allowed PACE organizations to provide PACE Center services through contractual arrangements (67 FR 61499). One of the new requirements that the 2002 interim final rule adopted was the requirement at § 460.71(b)(4) for PACE organizations to develop a program to ensure that all staff furnishing direct participant care services be "free of communicable diseases." In the rule titled "Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions", which appeared in the **Federal Register** on December 8, 2006 (71 FR 71243), herein after referred to as the 2006 PACE final rule, CMS amended § 460.64 to align

with § 460.71(b)(4) by adding the requirement at § 460.64(a)(5) that employees and contractors with direct participant contact "[b]e medically cleared for communicable diseases and have all vaccinations up-to-date before engaging in direct participant contact." When adding this requirement at § 460.64(a)(5), CMS noted, "It is standard practice in the health care industry that an individual must be cleared as free of communicable disease prior to employment" and "this is even more important with a frail elderly population considering their complex medical conditions and increased susceptibility" (71 FR 71267). CMS also indicated in the 2006 PACE final rule that we were amending § 460.71 "to be consistent with the general personnel qualifications" (71 FR 71328); as amended, § 460.71(b)(4) specified that all direct participant care staff and contractors must be "free of communicable diseases and have all immunizations up to date before performing direct participant care." In the June 2019 final rule, CMS amended the language in § 460.71(b)(4), which referred to staff being "free of communicable disease" so that it instead referred to staff being "medically cleared for communicable disease", which is the phrasing used in § 460.64(a)(5) (84 FR 25636). CMS explained that this inconsistency in language had caused confusion among PACE organizations about whether to attach the same meaning to "medically cleared for communicable diseases" and "free of communicable diseases." CMS amended § 460.71(b)(4) to use the phrase "medically cleared for communicable disease" that appears in § 460.64(a)(5) so that the two provisions would be consistent and contain the same language (84 FR 25636).

Based on our audit and oversight experience, we have found that PACE organizations have many varied interpretations of what it means for staff to be "medically cleared for communicable disease." As a result, PACE organizations do not implement consistent methods for assessing or detecting communicable diseases. For example, some organizations require individuals to have a physical examination by a physician, physician assistant, or nurse practitioner, whereas others allow for an assessment to be conducted by staff who are not licensed to evaluate individuals' medical conditions, and still other organizations only require a

self-assessment completed by the individual seeking employment. While a physical examination by a physician, physician assistant, or nurse practitioner is sufficient for clearing an individual of a communicable disease, CMS does not believe that assessments conducted by unlicensed staff or self-assessments are sufficient to meet the requirement.

For the last 2 years, the COVID-19 pandemic has demonstrated a need for a more comprehensive approach to infectious disease management and prevention. The elderly population was hit particularly hard by the pandemic, which highlighted the insufficiency of existing safeguards in nursing homes and similar care environments. While PACE participants live independently unless care is needed in a specific setting, they still require nursing home-equivalent levels of care. That care is typically provided in participants' homes and in the PACE centers, and participants interact with many different types of staff in those settings. We believe that the inconsistent approach to medical clearance that has been noted on audit has led to insufficient medical clearance, which places PACE participants at risk of exposure to communicable diseases including, but not limited to, COVID-19. Therefore, we are proposing to amend §§ 460.64 and 460.71 to require all PACE organizations to develop and implement a comprehensive medical clearance process with minimum conditions that CMS deems acceptable to meet the requirement of medical clearance and to better protect the frail and vulnerable population served by PACE.

We are proposing several modifications to the requirement at § 460.64(a)(5). Currently, the language states that staff must "be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact." First, we propose to separate the requirement to be medically cleared for communicable diseases from the requirement to have all immunizations up to date. We believe these are two separate and distinct requirements, and each serves a unique and important purpose. Specifically, we propose to create a new paragraph (a)(6) that would specify that each member of the PACE organization's staff (employee or contractor) who has direct contact with participants must have all

immunizations up to date before engaging in direct participant contact. Proposed paragraph (a)(6) would include language specifying that, at a minimum, vaccinations identified in § 460.74 must be up to date. In response to the COVID-19 pandemic, we amended § 460.74 by adding paragraph (d), which requires PACE organizations to develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19 (see 86 FR 61555 at 61618). We believe citing back to this immunization requirement in new § 460.64(a)(6) would help ensure that PACE organizations are considering COVID-19 vaccination status when ensuring staff have received all immunizations. Currently, while the regulation requires that "all immunizations are up to date", CMS has not defined what those immunizations must include, other than the COVID vaccination referenced in § 460.74. Rather, PACE organizations have historically set their own requirements for what vaccinations should be considered as "required" for their staff with direct participant contact. We considered defining all immunizations as including those recommended by the Advisory Committee on Immunizations Practices (ACIP) for health care workers, including when they are applicable based on individual criteria such as age or past infection.[204] However, based on the PACE population we are considering limiting the required vaccinations for PACE staff with direct participant contact to the Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B.[205] We solicit comment on whether any specific vaccinations other than the COVID-19 vaccination should be required for each member of a PACE organization's staff (employee or contractor) that has direct participant contact. We are particularly interested in commenters' views on the vaccinations recommended by ACIP and whether they should be included among the immunizations required for PACE staff with direct participant contact. We would also solicit comment on whether we should use the ACIP list without modifications, or whether we should

[204]Vaccines Indicated for Adults Based on Medical Indications | CDC

[205]Meningococcal vaccination is also a recommended immunization by ACIP; however, this immunization is recommended for microbiologists who are routinely exposed to Neisseria meningitidis, which we do not believe is relevant to the PACE population or PACE staff.

only require this subset of vaccines; Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B.

At § 460.64(a)(5), we propose to require that each member of a PACE organization's staff (employee or contractor) who has direct participant contact be medically cleared of communicable diseases both before engaging in direct participant contact and on an annual basis. Requiring staff to be medically cleared of communicable diseases annually will ensure that medical clearance is not a one-time requirement, but rather an ongoing responsibility. In our review of State requirements, we noted numerous states have some requirement for an ongoing or annual screening, and therefore it is reasonable to also propose that for PACE organizations. We are soliciting comment on adding this annual requirement into the medical clearance provision.

We also propose adding requirements to define what would constitute an acceptable medical clearance process. When considering what to require for medical clearance we considered many different provider types, including hospital systems, and what different states require for medical clearance. We also considered the PACE population, and its vulnerability to communicable diseases. Based on these factors, we believe the best practice for PACE organizations is to have each individual with direct participant contact on a PACE organization's staff (employee or contractor) undergo a physical examination by a provider acting within the scope of their authority to practice. A physical examination requirement would ensure that staff are appropriately medically cleared prior to engaging in direct participant contact. We therefore propose at § 460.64(a)(5)(i) to require that staff who engage in direct participant contact must be medically cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of the practitioner's authority to practice. This exam could be done at the PACE center by the primary care provider already employed by the PACE organization, and therefore, it would not be difficult to operationalize. We also propose at § 460.64(a)(5)(ii) that as part of the initial

physical examination, staff with direct participant contact must be determined to be free of active Tuberculosis (TB) disease. It is important for organizations to screen for TB because it is a deadly disease and baseline testing is recommended by the CDC for all health care professionals[206]. Testing for TB is widely available and relatively simple and we believe that a TB test should be conducted as part of any initial physical examination that is screening for communicable disease. We are proposing to add "initial" into this regulation text, because annual TB testing is not recommended by the CDC unless a risk assessment is performed which indicates it is necessary.[207]

However, we also understand that not all individuals who have direct participant contact have the same level of risk of having communicable diseases (through previous exposures), and requiring a physical examination may be overly burdensome. Therefore, we propose that, as an alternative to medically clearing all staff with direct participant contact for communicable diseases based on a physical examination, the PACE organization could opt to conduct an individual risk assessment as allowed under proposed § 460.64(a)(5)(iii). If the results of the risk assessment indicate the individual does not require a physical examination in order to be medically cleared, then a physical examination would not be required. This proposal would allow organizations to medically clear staff with direct participant contact by either conducting a physical examination, or by conducting a risk assessment of the individual and determining based on the results that no physical exam is needed.

Proposed § 460.64(a)(5)(iii) would identify the minimum requirements that the PACE organization must satisfy if it chooses to conduct a risk assessment for medical clearance. First, we propose to specify at § 460.64(a)(5)(iii)(A) that the PACE organization must develop and implement policies and procedures for conducting a risk assessment on each individual with direct participant contact based on accepted professional standards of care, for example,

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[206]https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm
[207]https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm

standards of care for screening influenza. For example, a risk assessment may include questions about an individual's current symptoms (if any), past diagnoses (specifically in regard to communicable diseases), and/or recent travel to determine whether the individual is at risk of being infected with a communicable disease. While each organization should have the operational latitude to develop its own policies and procedures, consistent with these proposed requirements, to assess if an individual needs a physical examination, when drafting and implementing these policies and procedures, organizations should consider any applicable professional standards of care and/or any applicable State guidelines on medical clearance.

Proposed § 460.64(a)(5)(iii)(B) would specify that the purpose of the risk assessment is to determine if, based on the assessment, a physical examination is necessary for an individual. As previously mentioned, we believe that the best practice for medical clearance is a physical examination by a physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice. However, by allowing PACE organizations to conduct a risk assessment to determine if some individuals on a PACE organization's staff who engage in direct participant contact (employee or contractor) may not need a full physical exam would provide some administrative flexibility for organizations.

Proposed § 460.64(a)(5)(iii)(C) would require that the results of the risk assessment be reviewed by a registered nurse, physician, nurse practitioner or physician assistant. We initially considered limiting these professions to primary care providers. However, we believe that because this risk assessment is used to screen staff to determine whether a physical exam is needed but is not itself a physical exam meant to diagnose an individual, it would be appropriate for a registered nurse to review those results and help triage staff that may need a more thorough exam. However, because registered nurses are not permitted to diagnose individuals, it would be inappropriate for a registered nurse to perform the physical examination.

Finally, we propose to identify at § 460.64(a)(5)(iii)(D) the minimum requirements we would expect to be included in a PACE organization's risk assessment. First, we propose to

require that any risk assessment developed by a PACE organization would assess whether staff have been exposed to or have symptoms of the following diseases: COVID-19, Diphtheria,[208] Influenza,[209] Measles,[210] Meningitis,[211] Meningococcal Disease,[212] Mumps,[213] Pertussis,[214] Pneumococcal Disease,[215] Rubella,[216] Streptococcal Infection,[217] and Varicella Zoster Virus.[218] When considering what communicable diseases to include in the risk assessment, we considered several resources, including State resources for reportable diseases, and we also considered information from the CDC on communicable diseases. We are proposing to include the aforementioned diseases in the risk assessment because they are commonly reportable and transmissible via air or through droplets. In addition to the aforementioned specific diseases, we are also proposing to include any other infectious disease noted as a potential threat to public health by the CDC in order to allow for situations such as the recent COVID-19 pandemic where a new communicable disease creates a situation that poses a threat to public health, and is significant enough that the CDC notes the threat. We would expect in those situations for a PACE organization to update its risk assessment to include that new public threat in the screening process. While we would want to account for new threats to public health, we recognize that the proposed language is more open to interpretation than listing specific diseases that may arise in the future. When developing this proposal, we considered CDC's Health Alert Network, the agency's primary method of sharing cleared information about urgent public health incidents with public information officers; Federal, State, territorial, Tribal, and local public health practitioners; clinicians; and public health laboratories.[219] It is likely that any threat to

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[208]https://www.cdc.gov/diphtheria/
[209]https://www.cdc.gov/flu/
[210]https://www.cdc.gov/measles/
[211]https://www.cdc.gov/meningitis/
[212]https://www.cdc.gov/meningococcal/index.html
[213]https://www.cdc.gov/mumps/
[214]https://www.cdc.gov/pertussis/
[215]https://www.cdc.gov/pneumococcal/
[216]https://www.cdc.gov/rubella/
[217]https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/selected-infections/group-a-strep.html
[218]https://www.cdc.gov/chickenpox/hcp/
[219]https://emergency.cdc.gov/han/index.asp

public health related to communicable diseases would be shared through this mechanism, but we solicit comment on whether this would be an appropriate source to consider, or whether there are other sources that CMS and PACE organizations should use. Because we recognize these sources may change over time, we are not inclined to add a specific source into regulation, but we solicit comment on that as well.

We also propose to require that a PACE organization's initial risk assessment must determine whether staff are free of active TB disease. We considered adding TB into the list of diseases in § 460.64(a)(5)(iii)(D)(1), however, we believe screening for this disease through a series of questions about exposure or symptomatology would not be sufficient to rule out this condition when conducting an initial evaluation of an individual. As aforementioned, the availability of testing for TB is wide spread, and all staff should be determined to be free of active TB prior to having direct participant contact. In order to ensure staff are free from active TB, a PACE organization should conduct either a skin test (with a chest x-ray when indicated) and/or blood test, as well as a physical examination if indicated, during the initial risk assessment process.

While we have proposed an alternative to requiring a physical examination for every employee or contractor with direct participant contact (that is, by allowing PACE organizations to conduct a risk assessment), we are soliciting comment on whether we should eliminate the risk assessment from this proposal, and require all staff who engage in direct participant contact (employee or contractor) to undergo a physical examination by a physician in order to be medically cleared. As indicated earlier in our discussion, we believe a physician, nurse practitioner, or physician assistant is best qualified to determine if an individual is medically cleared from communicable diseases.

We discuss and account for the burden of updating the policies and procedures in the collection of information requirements section of this proposed rule.

As we previously discussed, the requirement for medical clearance with respect to communicable diseases resides both in §§ 460.64(a)(5) and 460.71(b)(4). In section § 460.71(b)(4), we propose to amend the current language to state that all employees and contracted staff furnishing care directly to participants must be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis as required under § 460.64(a)(5). We also propose to add language to a newly designated § 460.71(b)(5) to require all employees and contracted staff to have all immunizations up-to-date before engaging in direct participant contact, including, at a minimum, the vaccine requirements identified in § 460.74. Under our proposal, current paragraphs (b)(5) and (b)(6) would be redesignated as paragraphs (b)(6) and (b)(7). We believe that by modifying this provision as proposed we would not be increasing the burden on PACE organizations as they are already required to ensure employees and contractors have all immunizations up-to-date.

F. PACE Contracted Services (§ 460.70)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations based upon those required under the PACE protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities.

The 1999 PACE interim final rule (64 FR 66234) was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment,

participant rights, and quality assurance. As we noted in that rule, that rulemaking implemented the directive in sections 1894(f)(2) and 1934(f)(2) of the Act to incorporate into regulation the requirements applied to PACE demonstration programs under the Protocol,[220] to the extent consistent with provisions of sections 1894 and 1934 of the Act. Among the required services included in the original PACE Protocol and the 1999 PACE interim final rule were medical specialty services. Specifically, the PACE Protocol identified a minimum subset of services that a PACE organization must provide, which was used to create the regulation at § 460.92. These medical specialty services included, but were not limited to, anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, general surgery, thoracic and vascular surgery, and urology.

In the 2006 PACE final rule (71 FR 71244), CMS reviewed and addressed comments concerning the list of required services in § 460.92. Some commenters had expressed the view that the list was too extensive and noted that it was longer than the list of required services for nursing facilities, which the commenters suggested presented a potential dilemma for states to establish the cost effectiveness of PACE compared to the cost for nursing facilities. Other commenters recommended that CMS reevaluate the list to ensure it included the minimum requirements necessary to protect the health, safety, welfare, and rights of consumers in the PACE program (71 FR 71280).

In response to these comments, CMS reiterated that the scope of benefits identified in sections 1894(b) and 1934(b) of the Act, and the requirement that PACE cover, at a minimum, all Medicare covered services, all Medicaid covered services, and any other services determined necessary by the IDT (71 FR 71280). However, following review of the comments, CMS

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[220] The Protocol references the PACE protocol published by On Lok, Inc. A copy of the original PACE protocol is included as an attachment to the 1999 PACE interim final rule (see 64 FR 66298). This Protocol was later replaced by the PACE program agreement.

determined it was not possible to provide a complete list of all inpatient, outpatient, physician specialty, care planning, and social support services that must be furnished to participants if ordered by the IDT (71 FR 71281). For this reason, CMS removed the listing of required services in § 460.92, including medical specialties; not because those services are not required in PACE, but because the PACE benefit covers even more services than the ones that had been initially listed under § 460.92, and we believed including an incomplete listing of specialties might be misunderstood to mean that specialties we did not list were not required services. Instead, CMS revised § 460.92 to state that PACE organizations are required to cover all Medicare covered services, all Medicaid covered services included in the State plan, and any other services determined necessary by the IDT.

While the list of specialties was removed from § 460.92, CMS did not remove § 460.112(c) which establishes that PACE participants have a right to a choice of providers, within the PACE organization's network, that is sufficient to ensure access to appropriate, high-quality health care. Specifically, CMS stated that each participant has the right to choose both their primary care provider and specialists within the PACE network (71 FR 71296). CMS stressed that "consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers" (*Id*.). CMS noted in that discussion that we expect the PACE organization to have contractual arrangements with primary care physicians (PCPs) and specialists to meet the needs of their participants, and that CMS and the SAA would determine compliance with the requirement as part of the application process and through ongoing monitoring. (*Id.*).

Since making these changes, we have seen through our monitoring and oversight efforts that some PACE organizations are not providing timely access to medical specialists. For example, based on data collected during 2021 audits (the most recent complete year of audit data), approximately 70% of organizations that were cited for a failure to provide necessary services were cited, at least in part, based on not providing necessary access to medical

specialists. These delays in access have, in some instances, contributed to adverse impacts to participants including injuries, hospitalizations and death. Based on our experience, we have found that delays in accessing medical specialists sometimes occur as a result of PACE organizations not having contracts in effect for the medical specialties commonly utilized by PACE participants, such as the types of medical specialties enumerated in the 1999 PACE interim final rule. Therefore, we are proposing to add back into the regulation the list of medical specialty services identified in the original PACE protocol that the PACE organizations must ensure access to as a minimum requirement. Specifically, we propose to amend by adding language to § 460.70(a)(1) that specifies that PACE organizations are required to execute and maintain a contract with the following medical specialties: anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, general surgery, thoracic and vascular surgery, and urology. We considered adding the medical specialties to § 460.92, where it was originally located; however, the requirement is better suited in § 460.70(a)(1) for several reasons. First, most, if not all, medical specialists do not work directly for the PACE organization, and rather are contracted providers that would need to adhere to the other requirements in § 460.70. Second, by adding this requirement into the contracted services provision of the regulation, we believe it will allow CMS and State agencies to better assess PACE organizations' readiness to enroll by ensuring these contracts are in place prior to participants enrolling in the organization.

While we are proposing to add a list of medical specialty services back into the PACE regulations, we continue to maintain that this is not an exhaustive list of all medical specialists that the PACE organization may be required to provide access to. For example, if the IDT determines that a participant needs to see a hematologist, the PACE organization would be required to provide access to that specialist in a timely manner. The specialties we are proposing

to add in § 460.70(a)(1) would represent a minimum requirement for all PACE organizations; each PACE organizations should consider the needs of its participants to determine what additional medical specialists may be necessary for its network to be sufficient. While we are proposing to add back into regulation the 25 medical specialty services identified in the original PACE protocol, we solicit comment on whether CMS should include the following additional specialty services in the list of minimum required services: endocrinology, hematology, immunology, neurology, colorectal surgery, palliative medicine, infectious disease, physical medicine and rehabilitation. Additionally, while we consider psychiatry to be an important behavioral health specialist since they write prescriptions for psychiatric medicines, we are soliciting comment on whether there should be other behavior health specialists required in this list, such as psychologists or licensed clinical social workers. When submitting comments on this proposal, we ask that commenters indicate whether they have any concerns with CMS adding any or all of the, previously discussed, specialty services to the list. For commenters who do have such concerns, we ask that you describe your concerns with specificity, so that we can more fully understand the nature and basis of your concerns. We believe a PACE organization must be able to access all these specialty services when a participant needs them, and based on our oversight experience, that these additional specialty services are often necessary for the PACE population.

We also propose at new § 460.70(a)(2) to require a PACE organization to execute these contracts with specialists prior to enrollment of participants, and to require the PACE organization to maintain such contracts on an ongoing basis to ensure participants receive appropriate and timely access to all necessary care and services. We clarify that we are not requiring PACE organizations to contract with individual specialists in situations where the PACE organization has contracted with a provider or practice that offers multiple specialties. In an instance of a medical provider or practice offering multiple specialties, the contract between the practice or provider, such as a hospital group, and the PACE organization would meet the

requirement to contract with whatever specialties were included in the practice or provider group. We believe it is appropriate for organizations to be able to demonstrate that they have sufficient and direct access to these commonly needed specialists prior to participants enrolling in the organization. Through our auditing and oversight efforts, we have seen lengthy delays in specialist referrals when an organization has to contract with a new specialist, and waiting until a participant enrolls or has need of the specialist may create unreasonable delays in the participant being able to access that specialist. Additionally, as we noted in the 2006 PACE final rule (71 FR 71296), PACE organizations are financially responsible for all of their participants' health care needs, and delays in referrals for specialist services may have a significant impact on the PACE organization's financial viability. Failure to provide timely specialist referrals may lead to more expensive care, including the need for institutionalization, which can drive up operating costs for a PACE organization.

At proposed § 460.70(a)(3), we would establish that a PACE organization must make reasonable and timely attempts to contract with medical specialists. PACE organizations are responsible for ensuring that participants have reasonable and timely access to medical specialty services, and that PACE organizations are responsible for taking appropriate steps in ensuring that they have suitable contracts in place in order to facilitate timely access to medical specialty services. We are not proposing to establish specific criteria for determining whether "reasonable" attempts have been made for purposes of proposed § 460.70(a)(3), as what is reasonable would depend on the facts and circumstances of the case. For example, in an area with multiple providers in a specific medical specialty, it would not be reasonable to only attempt to contract with a single provider, if that provider indicated they were unwilling to contract with the PACE organization.

We further propose to establish at § 460.70(a)(3)(i) that if at any time a PACE organization is unable to directly contract with a specific entity to provide specialist services to participants, the PACE organization must still ensure ongoing access to necessary care and

services that would otherwise be provided to participants by a contracted specialist, and that the participant's needs are met, through a different mechanism which may include hospitalization. As noted in the 2006 PACE final rule (71 FR 71296), we understand that in certain circumstances executing multiple contracts for a specific specialty may be difficult due, in part, to a limited number of specialists in certain geographic areas; however, we stress that PACE organizations continue to be responsible for meeting all of the participant's needs, even if there is not a direct contract in place. Additionally, under our proposal at § 460.70(a)(3)(ii) we would expect an organization to promptly report any contracting problems to CMS and the State Administering Agency (SAA), and include information on what attempts were made, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary services. This reporting may be initiated by the PACE organization when reasonable attempts to contract have been made, and were unsuccessful; or it may be done in response to CMS or the SAA inquiring as to the status of the contracts. For example, during the State readiness review, the SAA may inquire as to the status of the PACE organization's contracts with medical specialists. When reporting these contracting issues to CMS or the SAA, the PACE organization should be prepared to describe its attempts to contract with medical specialists, why a contract was not able to be effectuated, and how the PACE organization plans to ensure participants' needs are met. For example, if there is only one specialist in a service area, and they are not accepting new participants, the PACE organization must show its attempts to contract and how it will ensure participants are able to receive the care that the specialist would have provided. In other words, in this example, the PACE organization must show that they reached out to the one specialist in the area, attempted to contract with that specialist, and were unsuccessful in those attempts.

Finally, in order to account for PACE organizations that may choose to employ some medical specialists directly, such as dentists and podiatrists, proposed § 460.70(a)(4) would exempt a PACE organization from the contract requirements in § 460.70(a)(1) and (2) with

respect to a particular medical specialty if a PACE organization employs one or more individuals prior to contracting who are legally authorized and, if applicable, board certified, in the particular medical specialty. While we expect that most of the specialists in this list would be contracted by the organization, we understand that there are times when a PACE organization may directly employ one of these specialty providers. In those instances, assuming the participants have sufficient access to that type of specialist through that employment, the PACE organization would not be required to contract with additional providers in that specialty. However, the organization must have the specialist actively employed prior to enrollment of participants in order for the exception to be met and cannot rely on future employment to satisfy this requirement. We believe that by modifying this provision as proposed we would not be increasing the burden on PACE organizations as they are already required to either obtain and maintain contracts with or employ medical specialists.

G. Timeframes for Coordinating Necessary Care (§ 460.98(b)(4) and (c))

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act specify that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE Protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Additionally, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary

covered items and services 24 hours per day, every day of the year. This includes the full range of services required under the PACE statute and regulations.

We have implemented these requirements in several sections of the PACE regulations. For example, at § 460.98(a), we require a PACE organization to be responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. In order to meet participants' needs, PACE organizations must provide necessary services as expeditiously as the participant's condition requires; however, there is no specific timeframe on the delivery of services in PACE. The creation of a specific timeframe for delivery of services has been contemplated since the 1999 PACE interim final rule, where we noted that it was critical that care not be delayed and that the participant receive comprehensive care that maintains his or her functional status (64 FR 66251). However, we also noted that we recognize that some changes in the participant's plan of care (for example, installing a wheelchair ramp at the participant's home) may require more time to accomplish, and therefore CMS did not specify a timeframe for delivering services (*Id.*). Although we chose not to specify a timeframe for delivering services in the 1999 PACE interim final rule, we solicited comment on the necessity of requiring a specific timeframe (64 FR 66251). In the 2006 PACE final rule, we noted that commenters were split on the topic of timeframes and indicated that further consideration of this issue was needed before CMS would propose to adopt a specific timeframe (71 FR 71292). We discussed this issue again in 2020 when publishing a proposed rule (85 FR 9138) and when finalizing the January 2021 final rule (86 FR 6034). We stated at that time that we did not believe we could implement a specific timeframe given the vast array of service that PACE organizations provide (*Id.*). We also noted that determining how quickly a service must be provided would depend on more than just the physical health of the participant, and PACE organizations should consider all aspects of the participant's condition, including their social, emotional, and medical needs when determining the provision of services (*Id.*). Therefore, we finalized § 460.98(b)(4), which requires that all services must be provided as expeditiously as the

participant's health condition requires, taking into account the participant's overall medical, physical, emotional and social needs.

Despite the difficulty in creating a specific timeframe for the delivery of services, we continue to identify through monitoring and oversight situations where PACE organizations are jeopardizing participant health and safety by not promptly providing necessary services and that the cause for these delays is sometimes related to organizations failing to promptly schedule or arrange a service following approval from the IDT. Based on data collected through audits, in the past 4 years, over 80% of audited PACE organizations have been cited for a failure to provide services in a way that is necessary to meet participant needs. To address these concerns, we propose to establish timeframes for arranging the provision of IDT approved services for PACE participants. Requiring PACE organizations to promptly act to arrange or schedule necessary services creates accountability for expeditious service delivery while offering flexibility for wide ranges of services and variation in urgency. These timeframes would allow the IDT to determine how quickly a service is needed based on the participant's condition, but would ensure that the services were quickly arranged and scheduled to ensure that they are not forgotten or neglected in the course of other business. In drafting this proposal, we considered both the MA regulations in Part 422 and Medicaid regulations in Part 438; however, because PACE is not only an insurer, but also a direct care provider, we do not believe that the timeframes in these programs are appropriate for use in PACE. We therefore also considered the long-term care regulations in Part 483. Under those regulations, skilled nursing facilities and nursing facilities are required to refer residents to a dentist within 3 calendar days when a resident has lost or damaged their dentures (see §§ 483.55(a)(5) and 483.25(b)(3)). This requirement to refer residents to a dentist has a similar intent of ensuring the facility is promptly arranging for the necessary services for a resident.

Presently, § 460.98 specifies PACE program service delivery requirements related to access to services, provision of services, minimum services furnished at each PACE center,

PACE center operation, and center attendance. We propose to amend § 460.98 by, first, redesignating current paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively. Next, we propose to add a new paragraph (c) with the heading "Timeframes for Arranging and Providing Services." In addition, we propose to move the requirement in current paragraph § 460.98(b)(4) to provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs to new paragraph (c)(4). We also propose to redesignate paragraph (b)(5) as (b)(4).

We propose that the new section § 460.98(c) would have four subparagraphs related to the timeframes for arranging and providing services. A "service" as defined in § 460.6 means all services that could be required under § 460.92, including items and drugs. Given the vast array and differing availability of services in PACE, we considered creating one uniform timeframe for arranging all services, but ultimately determined that was not appropriate. Regarding the MA and Part D programs, we note that there are significant differences in the timeframes for approving and providing services under each program. In Part D, the timeframes for approving and providing coverage of medications are much shorter than the timeframes for approving and providing services in MA. Therefore, we believe it is appropriate in PACE to also create a distinct timeframe for medications.

We propose at new § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after the primary care provider orders the medication. We consider the use of the words "arrange and schedule" to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information for the pharmacy to fill the medication order and provide the participant with timely access to the medication. This timeframe would not require the medication to be delivered to the participant within that 24 hours, unless the participant's condition required delivery in that timeframe. Additionally, we believe that "no later than 24 hours after the primary care provider

orders the medication" is a fair timeframe and critical to meet the immediate care needs of participants, as lack of prompt access to many medications could result in deterioration of a participant's condition. Additionally, as pharmacies are usually open seven days a week, and prescriptions can often be submitted electronically, we believe that there is limited burden on the organization in meeting this timeframe. We solicit comment on this proposal, including whether CMS should consider other maximum timeframes for PACE organizations to arrange and schedule the dispensing of medications, or exceptions to this requirement. An example of the type of comment we hope to receive would be one that addressed whether over-the-counter medications should be included in this timeframe, as those medications may have different methods of being filled. We solicit comment on alternative maximum medication authorization timeframes less than or greater than 24 hours after the primary care provider orders the medication and request that such comments address how the alternative timeframes would ensure participant health and safety.

We propose to establish at new § 460.98(c)(2) the requirement that PACE organizations arrange or schedule the delivery of IDT approved services, other than medications, as identified in proposed § 460.98(c)(2)(i), as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or a member of the IDT first approves the service, except as identified in proposed § 460.98(c)(3). As previously noted, this requirement would apply to all services that are not medications. When developing this timeframe, we considered our experience with monitoring and auditing organizations, and feedback we have received from organizations in previous rules. In the 2006 PACE final rule (71 FR 71292), we noted that in comments that were submitted in response to a comment solicitation we had included in the 1999 PACE interim final rule, in which we sought input on whether to impose a timeframe under which PACE organizations would be required to initiate services after a revision to a participant's plan of care, some commenters indicated that they believe a maximum timeframe of 5 calendar days should apply to initiating service delivery following an approved

change in the plan of care. We considered, but decided not to propose a 5 calendar day timeframe, because a 5 calendar day timeframe may be operationally impractical for instances in which a PACE organization receives a request late in the business week that requires scheduling a service with a specialist or medical office closed on weekends and Federal holidays. We also considered whether other programs had timeframes we could draw from, but because PACE is both an insurer and provider and is required to provide such a broad range of services, we did not find a comparable program or provider directly applicable to PACE for purposes of scheduling services. We then considered the needs of the participant and the operational challenges of the organization when developing the timeframe. Based on all of these factors, we are proposing a 7-day timeframe, which we believe will balance the needs of the participant with the administrative responsibilities of a PACE organization. Based on our oversight efforts, we understand that some organizations already act to arrange services within a timeframe of 7 calendar days or sooner, as the participant's health condition requires. We are also proposing to describe the action that the PACE organization must take within the proposed 7-day timeframe in terms of when services are arranged or scheduled with the expectation that the delivery of the service would not need to occur within this timeframe; instead, the PACE organization would be expected to take affirmative steps to make sure the approved service was set up, scheduled, or arranged within this timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved. For example, if the IDT approved increasing a participant's physical therapy frequency from two to three times per week, we would expect the PACE organization to conduct outreach to the participant's physical therapist or the physical therapist's administrative support to set up a third weekly appointment within 7 calendar days of the IDT approval. If the IDT determines that the participant should see an ophthalmologist, the PACE organization would be required to schedule the appointment within 7 days of approval. We would not expect the delivery of the service (in this example, the actual appointment) to occur within 7 days, only that the appointment has been scheduled within that timeframe. Following the ophthalmologist

appointment, if the IDT determined that eyeglasses were necessary upon review of the provider's recommendation, the PACE organization would then be required to arrange for the provision of the eyeglasses within the timeframes proposed at § 460.98(c)(2), which may include a purchase order for eyeglasses. The 7-day timeframe begins once approval is made by the IDT or a member of the IDT. We would again stress that this is a maximum timeframe, and if a participant's condition required the service more quickly, the PACE organization would be expected to act to arrange the service more quickly. Our proposal would require that the timeframe of 7 calendar days begin after the date the IDT or a member of the IDT approves the service. We invite comment on alternative maximum timeframes for arranging or scheduling IDT-approved services. In particular, we are interested in knowing if PACE organizations continue to believe that 5 days is an appropriate timeframe to schedule and arrange services, and if not, whether commenters recommend a different maximum timeframe that is between 6 to 10 (that is, 6, 7, 8, 9 or 10) calendar days after the date the IDT or a member of the IDT approves the service. Additionally, we solicit comment on whether there are additional definitions of "arrange or schedule" that CMS should consider. We request that such comments address how the alternative timeframes would ensure participant health and safety, especially if commenters advocate for a timeframe longer than 7 calendar days.

We propose at § 460.98(c)(2)(i)(A) through (D) to define which services are included in the definition of interdisciplinary team approved services. We propose to specify at § 460.98(c)(2)(i)(A) that this includes services approved by the full IDT. These services would typically be the ones discussed and approved during the course of IDT meetings. This would be any service other than a medication. For example, if the IDT met and decided to approve physical therapy for six weeks, the date it made that approval would then trigger the timeframe of 7 calendar days. We propose to specify at § 460.98(c)(2)(i)(B) that IDT approved services also include services approved by a member of the IDT. We believe this is important to emphasize to ensure that service determination requests that are immediately approved by a

member of the IDT under § 460.121(e)(2) are subject to this new timeframe. Additionally, we have seen instances where a member of the IDT, in the course of their duties, may approve a service as necessary for a participant. For example, a physical therapist may approve extra therapy sessions during the course of their treatment. Or, following a recommendation from a cardiologist, the PCP may approve a Holter monitor for the participant. In these instances, when a service is approved by a member of the IDT, we would expect the PACE organization to promptly arrange and schedule the approved service within the 7 calendar days. We propose at § 460.98(c)(2)(i)(C) that IDT approved services include services ordered by a member of the IDT. We routinely see PCPs ordering necessary services as a part of managing the participant's condition, including but not limited to specialist consults, labs, and medications. We would consider an IDT member ordering a service as approving that service for purposes of proposed § 460.98(c)(2). For example, if a recommendation for a CT scan is made by an oncologist, and the PCP approves and orders the CT scan, we would expect the CT scan to be arranged within 7 calendar days from when the PCP approved/ordered the scan. We believe that it is important to specifically distinguish the types of approvals that could occur, as a part of the IDT's routine course of business, any one of which would trigger the timeframe of 7 calendar days to schedule or arrange for the delivery of services. We would also emphasize that under our proposal at § 460.98(c)(2), the timeframe begins when the IDT or a member of the IDT first approves a service. Therefore, when any one of these approvals occurs, on that first instance, the timeframe would be initiated. For example, if the IDT determined that labs were required for a participant in order to test their kidney function, the timeframe to arrange those labs would begin on that date, even if the PCP did not write an order for the labs until a later date or time. We solicit comment on this provision, including additional considerations that could improve the definition of IDT approved services.

We propose at the new § 460.98(c)(3) to exclude routine or preventative services from the timeframe to requirement in § 460.98(c)(2) when certain requirements are met. We

understand that PACE organizations may not be able to schedule every service within 7 calendar days, especially when the service is a routine service and not needed until much later in time. In order to satisfy this exception, we propose at § 460.98(c)(3)(i) through (iii) three requirements that would all need to be met in order for a PACE organization to be exempt from the timeframe included in § 460.98(c)(2). First, we propose at § 460.98(c)(3)(i) that the PACE organization must document that they were unable to schedule the appointment for the routine or preventative service due to circumstances beyond the control of the PACE organization. We believe that this is a reasonable exception, as we understand that for some routine appointments, for example, an annual eye exam, the specialist or contracted provider may limit how far out they are willing to schedule appointments. We would expect the PACE organization to document its efforts to arrange or schedule the appointment and that they were unable to schedule the appointment due to the specialist's availability. Second, we propose to establish at § 460.98(c)(3)(ii) that the PACE organization is exempt from the timeframe as long the participant does not have a change in status that requires the service to be provided more quickly. We recognize that a participant's condition may change, and a routine appointment may become more urgent as the participant's condition deteriorates. The exception to the timeframes in § 460.98(c)(2) only applies when a participant does not experience a change that would require the service to be provided more quickly. If the participant does experience a change in status that would warrant a faster appointment, the exception would no longer apply, and the PACE organization would be expected to schedule the service as necessary. Last, we propose at § 460.98(c)(3)(iii) that the PACE organization may be excepted from the timeframes to arrange a service if the PACE organization provides the service as expeditiously as the participant's condition requires. While we understand that there may be circumstances that prevent a PACE organization from scheduling some routine or preventative services, ultimately the PACE organization always remains responsible for ensuring the participant's needs are met. We believe it is in the best interest of participants and administratively reasonable to require all three of these factors in

order to exempt PACE organizations from the maximum timeframes proposed at § 460.98(c)(2) and to limit the exemption to services that are routine or preventative. We solicit comment on this provision, including suggestions of additional exceptions to the timeframes at § 460.98(c)(1) and (2).

We propose to redesignate § 460.98(b)(4) as § 460.98(c)(4) without further modification. Thus, the new § 460.98(c)(4) would maintain the requirement that PACE organizations provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical physical emotional, and social needs. The proposed timeframes in § 460.98(c)(1) through (c)(3) are maximum timeframes for arranging the provision of services. PACE organizations must continue to provide or deliver services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs, which may require the PACE organization to arrange or schedule services sooner than the timeframes proposed in § 460.98(c). Under redesignated § 460.98(c)(4), PACE organizations would continue to make determinations on how quickly to provide a service on a case-by-case basis, and we would expect PACE organizations to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require during monitoring efforts by CMS.

We estimate a one-time burden for PACE organizations to update their policies and procedures to reflect the proposed timeframes for arranging and providing services. We discuss and account for the one-time burden for their policies and procedures to reflect the proposed timeframes for arranging and providing services in the Collection of Information Requirements section and through an update to the CMS-R-244 PRA package.

We solicit comments on this proposal.

H. Care Coordination (§ 460.102)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require PACE organizations to provide comprehensive health care services to PACE participants in accordance with the PACE

program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24 hours per day, every day of the year. Additionally, sections 1894(b)(1)(C) and 1934(b)(1)(C) of the Act specify that PACE organizations must provide services to participants through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services in accordance to regulations, and specify the covered items and services that will not be provided directly by the entity, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations.

CMS has codified requirements pertaining to the interdisciplinary team (IDT) at § 460.102. Although the PACE organization is ultimately responsible for providing comprehensive, multidisciplinary care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, the IDT has a critical role in enabling the PACE organization to meet these responsibilities. As established in the 1999 PACE interim final rule (64 FR 66248), the IDT, then referred to as the multidisciplinary team, must comprehensively assess and meet the individual needs of each participant. In addition, the IDT is responsible for the initial assessment, periodic reassessments, the plan of care, and coordinating 24-hour care delivery (64 FR 66249). Through monitoring and oversight activities, CMS has determined that further specification of IDT responsibilities is necessary to ensure appropriate compliance with

the program requirements. While many IDTs appropriately apply the multidisciplinary approach to providing care, our monitoring efforts have shown that some organizations do not ensure the IDT is fully involved in coordination of care for participants across all care settings. We have also seen organizations interpret IDT responsibilities to coordinate care narrowly. For example, an IDT may order care, but then fail to ensure that the care has been provided in accordance with those orders and that the participant's needs were met.

Current § 460.102(d)(1)(i) specifies that the IDT has responsibility for the initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery. Section 460.102(d)(1)(ii) states that the IDT is responsible for documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b). We propose several amendments to § 460.102(d)(1). First, we propose to redesignate current paragraph (d)(1)(ii) as paragraph (d)(1)(iii), and to add a new paragraph (d)(1)(ii). We also propose to add a new paragraph (d)(1)(iv).

We propose to modify § 460.102(d)(1) to specify that the IDT is responsible for all activities as described at § 460.102(d)(1)(i) through § 460.102(d)(1)(iv) for each participant. The proposed regulation would include the words "for each participant" to emphasize that these responsibilities are not general requirements the IDT must fulfill, but rather specific responsibilities the IDT must fulfill for each participant. The 1999 PACE interim final rule (64 FR 66288) established basic requirements for the IDT at § 460.102(a), including that the IDT must comprehensively assess and meet the individual needs of each participant and that each participant be assigned an IDT at the PACE center that they attend. Since inception of PACE, CMS has considered the IDT responsibilities to apply to all participants at the individual level. CMS believes the current language in § 460.102(d)(1) does not preclude the proposed requirements at § 460.102(d)(1)(i) through § 460.102(d)(1)(iv) from applying at the individual

participant level. However, the addition of "each participant" more clearly emphasizes CMS' expectations.

We propose to modify the requirement at § 460.102(d)(1)(i) to include only the IDT's responsibility for the initial assessment, periodic assessment, and plan of care and to relocate the requirement pertaining to the IDT's responsibility to coordinate 24-hour care delivery to new § 460.102(d)(ii). We believe the responsibility to coordinate 24-hour care delivery is a separate and distinct requirement from the requirements to conduct assessments and create or revise a plan of care. Additionally, we propose to add a paragraph heading at § 460.102(d)(1)(i) to read "Assessments and Plan of Care" in order to reflect the proposed modified content of the paragraph.

We propose to move IDT coordination of care requirements from § 460.102(d)(1)(i) to new § 460.102(d)(1)(ii), because separating IDT coordination of care responsibilities at § 460.102(d)(1)(ii) from the assessment and care planning responsibilities at § 460.102(d)(1)(i) improves the provision's readability. We also propose to modify the language of § 460.102(d)(1)(ii) and to add 5 paragraphs at § 460.102(d)(1)(ii)(A) through (E) to further specify what coordination of 24-hour care delivery involves by defining what actions we consider care coordination to include.

We propose at new § 460.102(d)(1)(ii) to require that the IDT coordinate and implement 24-hour care delivery that meets participant needs across all care settings. We added language into this requirement about meeting the participant's needs across all care settings in order to clarify the scope of the IDT's care coordination for all participants, including, but not limited to, participants residing in long-term care facilities. We also added "implementation" into the requirement at § 460.102(d)(1)(ii) because we have seen through audits and monitoring efforts that PACE organizations are interpreting "coordination" narrowly, and they do not consider it to include all necessary components of care coordination, such as ensuring the implementation of care. As a result, we have seen problems with medication orders being implemented

appropriately, wound care not being done in accordance with orders, and other necessary services not being provided to the participant. This proposal will further emphasize CMS' expectations of IDT coordination of care responsibilities and lead to better care for participants, especially participants residing in acute and long-term care facilities.

This proposal is consistent with the current statutory and regulatory requirements for PACE organizations and the IDT. PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year (see § 460.98(a)). PACE organizations are also responsible for furnishing comprehensive medical, health, and social services that integrate acute and long-term care. We have received requests to explain the difference between the PACE organization's responsibility to furnish care, and the IDT's responsibility to coordinate care. As we explained in the January 2021 final rule (86 FR 6036), PACE organizations are responsible for furnishing comprehensive services to PACE participants. The IDT, which consists of a subset of PACE organization's employees or contractors, is responsible for certain activities, such as coordinating care, which includes services that are furnished by the IDT as well as services furnished by other employees and contractors of the PACE organization. The proposed requirement at § 460.102(d)(1)(ii) for the IDT coordinate and implement 24-hour care delivery that meets participant needs across all care settings aligns with this interpretation, as the IDT is not always responsible for directly furnishing or providing the care to participants, but it always maintains responsibility for coordinating care for participants.

As previously noted, we are proposing to add 5 subparagraphs at § 460.102(d)(1)(ii)(A) through (E) that further specify IDT coordination responsibilities across all care settings. We propose at § 460.102(d)(1)(ii)(A) that the IDT is responsible for ordering, approving, or authorizing all necessary care in order to clarify CMS expectations regarding one aspect of the IDT care coordination responsibilities. PACE is a program designed around the IDT being responsible for authorizing and ordering all care that is needed for PACE participants. In fact,

contractors, including medical specialty providers, must agree to furnish only those services authorized by the PACE IDT at § 460.70(d)(5)(i). We believe the proposed responsibilities at § 460.102(d)(1)(ii)(A) are important aspects of coordinating care that are inherent to the IDT's established and central role in care coordination.

We propose at § 460.102(d)(1)(ii)(B) to establish that the IDT is responsible for communicating all necessary care and relevant instructions for care. As discussed in connection with proposed § 460.102(d)(1)(ii)(A), the IDT is already responsible for authorizing all care the participant receives; however, in order for the participant to actually receive the care, the IDT must communicate the orders and relevant instructions to the appropriate individuals. For example, while a PCP may order a specialist consult, it is often scheduling or administrative staff that are responsible for actually arranging the appointment. As a part of coordinating care, the IDT must ensure that it communicates the necessary care and instructions to those individuals that need to know, for example, the individuals who will schedule, arrange, or provide the care and services. We contemplated adding further specificity in regulation about who those individuals may be, but we believe that it would encompass too many individuals for us to identify. For example, for a participant residing in a nursing facility, the IDT would need to ensure it communicated orders and instructions for care to the facility staff. For scheduling appointments, the IDT may need to communicate orders to administrative staff. We believe the IDT would be in the best position to identify the staff that need to know the information, and therefore we are leaving this proposed regulatory provision broad.

We propose to specify at § 460.102(d)(1)(ii)(C) that the IDT is responsible for ensuring care is implemented as it was ordered, approved, or authorized by the IDT. We have seen through oversight and monitoring efforts that while the IDT will order or authorize care, the team does not always follow through on ensuring that the care is provided in accordance with those orders. For example, a PCP may order wound care 3 times a week, but then the IDT will not follow through on ensuring that the wound care is actually done in accordance with those orders.

As previously discussed, the 1999 PACE interim final rule (64 FR 66279) established the IDT as instrumental in controlling the delivery, quality, and continuity of care. Part of controlling the delivery and quality of care is ensuring that the care that is ordered, approved or authorized is actually provided.

We propose at § 460.102(d)(1)(ii)(D) to establish that the IDT is responsible for monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs. The IDT cannot appropriately coordinate 24-hour care delivery without also ensuring that it remains alert to the participant's condition by monitoring and evaluating the participant's condition. While the IDT is responsible for making sure that care is implemented in accordance with the approved or authorized orders, the IDT also remains responsible for ensuring the participant's needs are met through that care. For example, if the PCP orders wound care 2 times a week but the wound continues to worsen, the PCP should consider whether a new order is necessary in order to meet the participant's needs.

We propose to specify at § 460.102(d)(1)(ii)(E) that the IDT is responsible for promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant. The IDT's responsibilities for a participant do not end when care is authorized or ordered. As we stated in the 2006 PACE final rule (71 FR 71289), it is important for the IDT to monitor and respond to any changes in a participant's condition. It is important that the IDT respond promptly and modify care when it is determined that the participant's needs are not currently being met. For example, if the PCP writes an order for blood pressure medication but then notes during a later assessment that the medication is not working, we would expect the PCP and the IDT to consider alternative medications or treatments that might better meet the participant's needs.

We propose to redesignate current § 460.102(d)(1)(ii) as § 460.102(d)(1)(iii) and add the title "Documenting Recommended Services" for improved readability. No further modifications are proposed for this provision.

We propose to add § 460.102(d)(1)(iv) to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists. As discussed earlier, the IDT is responsible for authorizing, approving and ordering all care, including care recommended from contracted providers. This means that a participant may not receive necessary care until the IDT considers and approves or authorizes those recommendations that were made by the provider or specialist. Through monitoring and oversight activities, we have identified instances where the IDT is not promptly reviewing recommendations from urgent and emergency care providers, as well as employees and contractors. Based on data collected during the 2021 audits, approximately 75 percent of audited PACE organizations were cited based on a failure to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. Delayed review of recommendations and action on recommendations can delay the provision of necessary care and services, and can jeopardize participant health and safety. To address these concerns, we propose timeframes for the IDT to review and take action on recommendations from urgent and emergency care providers, as well as employees and contractors. As we stated in the January 2021 final rule (86 FR 6132), we do not believe we could implement a specific timeframe for the provision of services, given the vast array of services that PACE organizations provide and variation in individual participant needs. However, we believe requiring the IDT to promptly act on recommendations from urgent and emergency care providers, as well as employees and contractors, creates accountability for expeditious service delivery while offering flexibility for wide ranges of services and variation in urgency.

The timeframes we propose at § 460.102(d)(1)(iv)(A) through (C) would be maximum timeframes within which the IDT must review, assess and determine whether service recommendations from urgent and emergency care providers, as well as employees and contractors, are necessary to meet the participant's medical, physical, social, or emotional needs,

and if so, promptly arrange and furnish the service in accordance with the timeframes at § 460.98(c). Under § 460.98(b)(4) (which we propose to redesignate as § 460.98(c)(4)), PACE organizations must continue to provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs. In order to meet the participant's needs, the IDT may need to review and act on recommendations sooner than the timeframes proposed in § 460.102(d)(1)(iv). Nothing in § 460.102(d)(1)(iv) would require the IDT to approve all recommendations; however, we would expect that the IDT review, assess, and act on the recommendation. That action would either be to either make a determination to approve or provide the recommended service or make a determination to not approve or provide the recommended service. If the IDT makes a determination to approve or provide a service, it must arrange and schedule the service in accordance with § 460.98(c). If the IDT makes a determination not to approve or provide a service, we would expect the IDT to document the reason(s) for not approving or providing the recommended care or services in accordance with current § 460.102(d)(1)(ii), which, as previously noted, we propose to redesignate as § 460.102(d)(1)(iii) and § 460.210(b).

We propose at § 460.102(d)(1)(iv)(A) to establish that the appropriate member(s) of the IDT must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs within 24 hours from the time of the participant's discharge. We considered multiple factors when proposing a 24-hour timeframe. We believe the 24-hour timeframe is necessary and reasonable due to the following considerations. First, this timeframe would be limited to only those recommendations made by hospitals, emergency departments and urgent care providers, and it would not apply to recommendations made by other providers or more routine appointments. Second, we considered that PACE is responsible for the needs of the participant 24 hours a day, every day of the year. When a participant is discharged from one of these settings there may be recommendations made or care needed, that

cannot wait until the next business day. For example, a participant who is discharged from the hospital on a Saturday with a recommendation for antibiotics should not have to wait until Monday to have their prescription ordered or approved by the IDT. Third, we are proposing to not require that the full IDT be involved in assessing and acting on these recommendations, but rather the appropriate member(s) of the team as determined by the IDT. We do not anticipate that the full IDT would need to be involved in all decisions relating to recommendations made by hospitals or urgent care centers. It would likely be 1 or 2 IDT members that would ultimately be responsible for these recommendations and therefore a shorter timeframe is reasonable. For example, for the post discharge recommendation for antibiotics previously described, the IDT PCP may be the only discipline required to review and act on the medication request, since the PCP is responsible for ordering care and medications. We invite comment on alternative maximum timeframes for IDT review of all recommendations from hospitals, emergency departments, and urgent care providers and to make a determination on the recommendation's necessity; we are particularly interested in commenter's perspectives on timeframes of 12 hours, 48 hours, and 72 hours from the time of the participant's discharge. We request that such comments address how the commenter's preferred/recommended timeframe would ensure participant health and safety.

We propose to require at § 460.102(d)(1)(iv)(B) that the appropriate member(s) of the IDT must review all recommendations from other employees and contractors and make a determination with respect to whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 5 calendar days from the date the recommendation was made. We have seen through monitoring and audits where recommendations have not been considered or acted upon for significant periods of time, which has contributed to delays in the provision of necessary care. While we do not believe that all recommendations made by all types of employees and contractors need to be responded to as quickly as recommendations from

hospitals, urgent care providers, or emergency departments, we do believe the IDT must act promptly to consider the recommendations made, and, when the IDT deems the recommended care necessary, it must authorize the care. The proposed 5-day timeframe would represent the maximum amount of time a PACE organization would have to determine whether a recommended service is necessary, and we would expect the IDT to consider the participant's condition in determining whether it is necessary to make a determination sooner than 5 days after the recommendation is made. Additionally, we propose that the timeframe would begin when the recommendation is made, not when the recommendation is received by the IDT. We have seen through monitoring instances of PACE organizations not making initial requests for consult notes from a participant's appointment with a specialist until months after the appointment has taken place, and only learning at that time that a recommendation was made during the appointment. It is important that the PACE organization promptly act on recommendations, and it is our expectation that they develop processes with their employees and contractors to ensure the IDT is receiving recommendations in a manner that allows the IDT to determine the necessity of the recommended services within the proposed timeframe. We invite comment on alternative maximum timeframes for IDT review of all recommendations from other employees and contractors and to make a determination on the recommendation's necessity. We are particularly interested in commenters' perspectives on whether we should adopt a 3 calendar day timeframe, a 7 calendar day timeframe, or a 10 calendar day timeframe. We request that commenters address how the alternative timeframes would ensure participant health and safety.

We propose to establish at § 460.102(d)(1)(iv)(C) that, if recommendations are authorized or approved by the IDT or a member of the IDT, the services must be promptly arranged and furnished under § 460.98(c), as proposed. As discussed in section VI.G. of this proposed rule, we are proposing timeframes for the IDT to promptly arrange and schedule services that are authorized, ordered or approved by the IDT or a member of the IDT. If a recommendation is made by a contractor or an employee, and the IDT or a member of the IDT

approves or orders that recommended service, we would expect the PACE organization to arrange and schedule the service in accordance with the proposed regulations at § 460.98(c). We are proposing distinct timeframes depending on the facts and circumstances of the situation and the service at issue. For example, if a hospital, at the time of discharge, makes a recommendation for a medication, the appropriate members of the IDT would have 24 hours to act on the recommendation, and if approved and ordered by the PCP, another 24 hours to arrange for the medication to be dispensed under proposed § 460.98(c)(1). In this scenario, because the recommendation is being made by a hospital, the timeframe to act on the recommendation is 24 hours under the proposal at § 460.102(d)(iv)(A), and because the recommended service is a medication, the timeframe to arrange the service is 24 hours from the date of the order under the proposal at § 460.98(c)(1). If a specialist recommends a medication, then the IDT would have 5 calendar days to make a determination with respect to the recommendation, and if it is approved and ordered, 24 hours to arrange for the medication to be dispensed. If a recommendation is made from a contractor such as a medical specialist for a service that is not a medication, the IDT would have 5 calendar days to consider and act on the recommendation, and then, if approved or authorized, the PACE organization would have 7 calendar days to arrange or schedule the approved or authorized service.

The timeframe to schedule the service would begin the day the IDT or a member of the IDT approves or authorizes the recommendation. We emphasize again that these timeframes are maximum timeframes that the IDT and PACE organization should consider when reviewing recommendations. For some recommendations, such as an MRI to be done in 3 months, these timeframes would be sufficient to ensure that the service is approved and arranged before the service is needed. However, there are other recommendations made where it would not be appropriate for the IDT to take a full 12 calendar days to assess and act on a recommendation, and then arrange and schedule it. For example, if a cardiologist indicated that the participant

needed an urgent coronary artery bypass graft, we would expect that the IDT and PACE organization act upon that information in a more expeditious manner.

We are not scoring this provision in the Regulatory Impact Analysis section because the IDT is already required to comprehensively assess and meet the individual needs of each participant, including ensuring the participant's access to all necessary covered items and services 24 hours per day, every day of the year. We believe that by modifying this provision as proposed we would not be increasing burden on PACE organizations, as they already consider these items on a routine basis. We are also not scoring this provision in the Collection of Information section since all information impacts of this provision have already been accounted for under OMB control number 0938-0790 (CMS-R-244).

I. Plan of Care (§ 460.106)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations based upon those required under the PACE protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities.

In the 1999 PACE interim final rule (64 FR 66251), CMS developed requirements for participant plans of care based on the requirements in Part IV, section B of the original PACE Protocol. Those requirements were finalized in the 2006 PACE final rule (71 FR 71292) and they included: prompt development of a comprehensive plan of care by the IDT that specified

the care needed to meet the participant's medical, physical, emotional, and social needs as identified in the initial comprehensive assessment; identification of measurable outcomes to be achieved; implementation, coordination, and monitoring of the plan of care whether the services were furnished by PACE employees or contractors; reevaluation of the plan of care on at least a semiannual basis; development, review, and reevaluation of the plan of care in collaboration with the participant or caregiver, or both; and documentation of the plan of care, and any changes made to it, in the participant's medical record.

In 2010, in response to questions from PACE organizations, CMS issued a subregulatory document titled, "Care Planning Guidance for PACE Organizations." This care planning document provided detailed guidance for developing, implementing, monitoring, reevaluating, and revising plans of care. The care planning document also provided guidance on interdisciplinary team involvement in the plan of care and what content or care should be included in the participant's plan of care. While this document stressed that care plans should be comprehensive and include the participants medical, physical, social and emotional needs; it also noted that not all care received by the participant would need to be included in the care plan, and instead, could be tracked and documented through discipline specific progress notes. The guidance stated that, "Each PACE organization must define what care is integrated into the participant's plan of care, and what discipline-specific care is appropriately documented and monitored by the respective discipline specialist in the progress notes."[221]

Since that time, CMS has seen through oversight and monitoring efforts that participant care plans are often sparse and may not fully detail the care received by a participant. We have noted that organizations are relying heavily on providing and documenting care through

[221]Centers for Medicare & Medicaid Services. (2022, April 15). *Care Planning Guidance for PACE Organizations.* Retrieved from Silo Tips: https://silo.tips/download/care-planning-guidance-for-pace-organizations (pg 11)

discipline-specific progress notes, rather than through incorporation into a more comprehensive and formal plan of care.

In the June 2019 final rule (84 FR 25675), CMS added additional requirements around the development of a comprehensive plan of care. As part of the modifications made during the June 2019 final rule, we added at § 460.104(b) the requirement that within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT. The June 2019 final rule also added § 460.104(b)(1), which provides that if, in developing the plan of care, the IDT determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care. CMS explained in the June 2019 final rule that if the IDT does not believe a PACE participant needs a certain service as it relates to the IDT care plan assessment findings and, therefore, does not authorize that service, the IDT must document the rationale for not including the service in the plan of care (84 FR 25643). CMS also noted that we would expect 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 the time (*Id.*).

In addition to the modifications at § 460.104(b), in the June 2019 final rule, CMS also amended § 460.106 in order to provide additional clarity with respect to the development and content of the plan of care process (84 FR 25646). Among other changes, CMS added at § 460.106(b) three new requirements related to the interventions that must be included in a participant's plan of care. Specifically, CMS added requirements for PACE organizations to utilize the most appropriate interventions for each care need that advance the participant toward a measurable goal and outcome (§ 460.106(b)(3)); identify each intervention and how it will be implemented (§ 460.106(b)(4)); and identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes (§ 460.106(b)(5)).

Despite the addition of these requirements in the June 2019 final rule, we continue to find that PACE organizations are struggling with developing, implementing, monitoring, reevaluating, and revising plans of care. While the addition of § 460.104(b)(1) has helped organizations create more robust initial care plans for participants, we have seen through our oversight and monitoring process that these care plans become more sparse over time, and care initially included in the plan of care will be omitted in subsequent revisions and handled through discipline-specific progress notes as the participant's enrollment continues. We acknowledge that documenting detailed information about participant care and services in discipline-specific progress notes is necessary and an accepted standard practice; however, this should not be done in lieu of a comprehensive plan of care that addresses the participant's needs. The purpose of a plan of care is to allow the different IDT disciplines to discuss a participant's needs and develop interventions and goals, as a team. The IDT approach to care management and service delivery is a statutory requirement, and is one of the requirements that is essential to the PACE program and cannot be waived (*see* section 1894(f)(2)(B)(iii) of the Act). As we explained in the 2006 PACE final rule (71 FR 71285), we believe a well-functioning IDT is critical to the success of the PACE program as the team is instrumental in controlling the delivery, quality, and continuity of care. Members of the IDT should be knowledgeable about the overall needs of the participant, not just the needs that relate to their individual disciplines. In order to meet all of the health, psychosocial, and functional needs of the participant, team members must view the participant in a holistic manner and focus on a comprehensive care approach. By handling care through discipline-specific progress notes, the team role in discussing and monitoring that care is removed, and individual team members provide care in a more isolated and individualized approach. The plan of care is a tool that allows the IDT to assess a participant holistically, and develop interventions and goals that may cross disciplines. We also believe that failing to develop comprehensive plans of care poses a risk to participants enrolled in PACE organizations by making it harder for the organization to track and monitor the provision of services. When

information is documented throughout a medical record in discipline-specific progress notes, instead of being consolidated in a single comprehensive plan of care, it prevents employees and contractors from quickly or easily locating necessary information and, as a result, may contribute to care not being provided as necessary or in a timely manner. Since the June 2019 final rule became effective, CMS has completed 40 PACE audits and we have identified a failure to provide services or delays in providing services in 37 of the 40 audits conducted. Although this non-compliance cannot be directly attributed to a failure to consolidate information into a comprehensive plan of care, our audit findings suggests that the coordination and delivery of necessary services is a challenge for PACE organizations.

Finally, in addition to seeing concerns related to the content of care plans, we have also seen on audit that participant and caregiver involvement in the care planning process tends to be minimal and primarily occurs after the development and/or revisions to the plan of care have been finalized and implemented by the IDT. In the 1999 PACE interim final rule (64 FR 66252), CMS specifically stated that plans of care must be developed, reviewed, and reevaluated in collaboration with the participants or caregivers. The purpose of participant/caregiver involvement is to ensure that they approve of the care plan and that participant concerns are addressed. Furthermore, in the 2006 PACE final rule (71 FR 71293), CMS reiterated that it is our expectation that the IDT will include the participant in the plan of care development when possible and include the participant's representative when it is not appropriate to include the participant or at the instruction of the participant. We continue to believe that participant and caregiver involvement in the development, review, and reevaluation of the plan of care is necessary to ensure participants' needs are fully met.

As a result of our experience overseeing PACE organizations, we believe it is prudent to implement additional requirements related to the minimum requirements for a participant's plan of care, including: further defining the timeframes for care plan development and reevaluation, defining the minimum content that should be reflected in a plan of care, emphasizing the ongoing

responsibilities of the IDT to monitor and revise the plan of care to determine its effectiveness, and defining the involvement of the participant and/or their caregiver in the plan of care before it is finalized. In developing these proposed requirements, we attempted to adopt language and requirements that are consistent with the long-term care facility regulation at § 483.21(b), when possible. The regulation at § 483.21(b) requires nursing facilities to develop comprehensive and person-centered care plans that meet residents' needs and identify the services necessary to meet those needs. Individuals who enroll in PACE must be deemed as nursing home eligible; therefore, individuals who enroll in PACE and individuals who receive services from nursing facilities have similar needs. Additionally, while PACE organizations are insurers, they are also direct care providers. Since nursing homes are also direct care providers, and serve a similar population, aligning care planning requirements across these programs is an important safeguard for participants, and will improve the PACE organization's ability to meet participants' needs and to deliver necessary services for this vulnerable population.

First, we propose to modify the requirement in § 460.106(a) to require that the members of the IDT specified in § 460.102(b) must develop, evaluate, and if necessary, revise a person-centered plan of care for each participant. This is consistent with the requirement at § 460.104(b) that states that within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT. Additionally, the IDT is required to reevaluate the plan of care on a semi-annual basis at the current § 460.106(d); however, we are proposing to remove that requirement as our proposal at § 460.106(a) would cover the role of the IDT in both the initial care plan development and also the subsequent reviews and reevaluations of the care plan. We are also proposing to add language into § 460.106(a) that would require each plan of care to take into consideration the most current assessment findings and identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being. As we will discuss in Section VI.J. of this proposed rule, since PACE is a direct care provider, serving

nursing home eligible participants, we also considered nursing home regulations as we drafted this proposal. The nursing home regulations require that care plans must describe "the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psych-social well-being" (§ 483.21(b)(1)(i)). This language should also apply to PACE care plans, since they serve the same nursing home eligible population.

Next, we propose to add a new section, § 460.106(b), which would define the specific timeframes for developing, evaluating, and revising care plans. For initial care plans, we intend to maintain the requirement for the IDT to finalize the development of the initial plan of care within 30 calendar days of the participant's enrollment that is located at current § 460.106(a), but we propose to move this requirement to new section § 460.106(b)(1).

The regulation at § 460.106(d) currently requires the IDT to reevaluate the plan of care, including defined outcomes, and make changes as necessary on at least a semi-annual basis. The interpretation of the semi-annual timeframe has posed issues for PACE organizations. We therefore propose at § 460.106(b)(2) to require that the IDT must complete a reevaluation of, and if necessary, revisions to each participant's plan of care at least once every 180 calendar days. We believe that creating a strict timeframe of 180 days would be less ambiguous and easier for organizations to track.

We propose at § 460.106(b)(3)(i) that the IDT must complete a reevaluation, and if necessary, revisions of the plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status or more expeditiously if the participant's condition requires. Currently, the members of the IDT specified in § 460.104(d)(1) must conduct reassessments when a participant experiences a change in participant status. Additionally, the IDT members that conduct a reassessment must also reevaluate the participant's plan of care (see § 460.104(e)(1)) and discuss any changes in the plan with the IDT (see § 460.104(e)(2)). However, there is no timeframe for how quickly the IDT members must conduct those reassessments or reevaluate the plan of care

to determine if changes are needed. We believe that a 14-calendar day timeframe is appropriate since it will ensure the IDT is promptly acting on changes to the participant's status. In considering an appropriate timeframe, we reviewed the nursing home requirements. The long-term care regulations at § 483.20(b)(2)(ii) require that the resident receive a comprehensive assessment within 14 calendar days after the date the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. The long-term care facility must then use the results of the assessments to develop, review and revise the resident's comprehensive plan of care (see § 483.20(d)). This is an appropriate standard to apply in PACE as well, since as we have previously discussed, participants in PACE are deemed nursing home eligible, and therefore their conditions are substantially similar to the conditions a nursing home resident experiences. As discussed later in this section of this proposed rule, we are also proposing to modify § 460.104(e) to emphasize that all required assessments must be completed prior to the plan of care being revised. Therefore, this 14-calendar day timeframe would include both the required assessments under § 460.104(d)(1) and the process of revising the plan of care under § 460.106.

We propose to specify at § 460.106(b)(3)(i) that the 14-calendar day timeframe starts when the PACE organization determines, or should have determined, that a change in the participant's condition occurs. This requirement would align with long-term care regulations for when the timeframe begins following a participant's (or resident's) change in condition. If a participant experiences a change in status that triggers this reassessment and reevaluation of the care plan, the PACE organization should not be able to delay the timeframe by not recognizing the change in status for a period of time. We also propose to define at § 460.106(b)(3)(i) what constitutes a change in status. While the PACE regulations require assessments when a change in participant status occurs, what constitutes a change in status has not been previously defined. Like other proposed changes in this proposed rule, we are proposing to adopt in PACE the requirement applicable to nursing homes at § 483.20(b)(2)(ii), but we have tailored the language

of the proposed regulation to be specific to PACE. For example, the proposed PACE regulation would refer to the "participant" as opposed to the "resident", which is the term used in the long-term care regulation, it would use the phrase "change in participant status" where the long-term care regulation uses the phrase "significant change". Therefore, the requirement as proposed would state that for purposes of this section, a "change in participant status" means a major decline or improvement in the participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status, and requires IDT review or revision of the care plan, or both. The proposed change would bring additional consistency between the PACE and nursing home requirements and ensure similarly situated beneficiaries are treated equally.

In conjunction with the proposed requirement that a PACE organization must reevaluate and, if necessary, revise the plan of care within 14 calendar days after a change in the participant's condition occurs, we propose at § 460.106(b)(3)(ii) that if a participant is hospitalized within 14 calendar days of the change in participant status, the IDT must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital. We recognize that when a participant is hospitalized, it is difficult for the IDT to assess the participant, and revise a plan of care, during the course of that hospitalization. Given this complexity, we propose that the timeframe for reevaluating the plan of care starts when the participant is discharged from the hospital. Despite this proposed exception, we would remind PACE organizations that their responsibilities toward the participant do not end or stop when a participant is hospitalized, and the IDT should remain alert to pertinent information in all care settings under § 460.102(d)(2)(ii).

We solicit comment on whether 14 calendar days is an appropriate timeframe to use. We also considered 21 or 30 calendar days, but were not persuaded to propose either, given the

14-day requirement in the nursing home regulations. However, are interested in commenters' feedback on whether 21 or 30 days would be more appropriate and, if so, why the timeframes for PACE and nursing homes should be different.

We propose at § 460.106(c) to make certain modifications related to the content of a plan of care. Currently, the content of a plan of care is specified at § 460.106(b), which requires the care plan to include the care needed to meet the participant's medical, physical, emotional and social needs; identify measurable outcomes to be achieved; utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal; identify each intervention and how it will be implemented; and identify how each intervention will be evaluated to determine progress. We have seen as part of our audit and oversight activities where treatments for participants' medical conditions are included in discipline-specific notes, but not in the comprehensive care plan. This has resulted in members of the IDT being unaware of what treatments or recommendations the participant has received from different members of the IDT or from outside contracted specialists. As a result, we have seen participants experience delays in receiving the recommended treatment or service, the treatment or service not being provided at all, and in some situations, duplicate orders for a service or treatment due to the IDT being unaware the service or treatment was previously provided. Therefore, in addition to proposing to move the content of plan of care requirements from § 460.106(b) to § 460.106(c), we propose to add language to the section to create minimum requirements for what each plan of care must include. When determining the minimum content a plan of care should include, we considered the care plans that nursing homes are required to create. Specifically, we considered the regulations at § 483.21(b) which specify the requirements for a comprehensive plan of care. Additionally, § 483.21(b) makes reference to § 483.24 (Quality of Life), § 483.25 (Quality of Care), and § 483.40 (Behavior Health), so we considered those sections as well. Given the similarities between PACE participants and nursing home participants, our proposal aligns with the nursing home requirements to the extent we believe those requirements are applicable.

Therefore, at § 460.106(c), we propose modifying the language to state at a minimum, each plan of care must meet certain requirements, which would be set forth in the regulations at proposed § 460.106(c)(1)(i) through (xiii). At § 460.106(c)(1), we propose to add language that requires PACE organizations to identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring, and that at a minimum, the care plan must address specific factors we will discuss in the next paragraph. Care plans are currently required at § 460.106(b)(1) to include the care needed to meet the participant's medical, physical, emotional and social needs, as identified in the initial comprehensive assessment. However, we are proposing to further specify that the plan of care should address all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring. This is consistent with nursing home requirements since nursing homes must assess a resident's disease diagnoses and health conditions as part of the comprehensive assessment (see § 483.20(b)(1)(x)) and use those assessments in developing, reviewing and revising the plan of care (see § 483.20(d)). We believe our proposal related to chronic behavioral and psychiatric disorders is consistent with long-term care requirements in § 483.40, which require that each resident must receive and the facility must provide the necessary behavioral health care and services. As we mentioned earlier, the nursing home care plan requirements at § 483.21(b) reference the behavior health requirements at § 483.40. Therefore, we propose that chronic behavioral and psychiatric disorders that require treatment or routine monitoring also be included in PACE plans of care.

While the nursing home assessment criteria require consideration and assessment of all disease diagnoses and health conditions, we are proposing in PACE to limit what diseases must be included in the plan of care to those that are chronic and require treatment or routine monitoring. For example, if a participant had Hepatitis C but was treated and cured, that disease may not need to be included in the plan of care. On the other hand, if a participant has coronary

artery disease and requires ongoing monitoring by a cardiologist, we would expect that disease to be included in the plan of care. When considering how organizations would define "chronic" we believe that most organizations would consider the guidance issued by the CDC, which defines chronic diseases as conditions that last 1 year or more, and require ongoing medical attention or limit activities of daily living or both.[222] We also considered whether it would be appropriate for the plan of care to address acute conditions, but decided that including acute conditions could make the care plan subject to more modifications than what is feasible for the IDT. For example, if the care plan needed to be updated for every infection, the care plan may be under a constant state of revision. However, we solicit comment on whether acute conditions should be included in the minimum content that a care plan must address.

We propose to specify at § 460.106(c)(1)(i) that the PACE participant's plan of care must address the participant's vision needs. This is consistent with the long-term care provisions at §§ 483.20(b)(1)(v) and 483.25(a). Given the age of the PACE population, and the co-morbidities that may impact this population (such as diabetes), addressing a participant's vision needs is an important part of any plan of care. We similarly propose at § 460.106(c)(1)(ii) that a PACE participant's plan of care must address the participant's hearing needs. This is consistent with the long-term care regulations at § 483.25(a). We propose at § 460.106(c)(1)(iii) that a participant's plan of care must address the participant's dentition. This would be consistent with the requirement at § 483.20(b)(1)(xi). We propose at § 460.106(c)(1)(iv) that a plan of care must address the participant's skin integrity. This requirement would be consistent with the requirements at §§ 483.20(b)(1)(xii) and 483.25(b). We propose at § 460.106(c)(1)(v) that the participant's plan of care must address the participant's mobility. This requirement would be consistent with the requirement at § 483.25(c). We propose at § 460.106(c)(1)(vi) that the participant's plan of care must address the participant's physical functioning (including activities

[222]Centers for Disease Control and Prevention. (2022, May 6). About Chronic Diseases. Retrieved from: https://www.cdc.gov/chronicdisease/about/index.htm

of daily living). This would be consistent with the requirements at §§ 483.20(b)(1)(viii) and 483.24(b). We propose at § 460.106(c)(1)(vii) that the plan of care must address the participant's pain management needs. This would be consistent with the requirement at § 483.25(k).

The next few proposed requirements deviate from the nursing home requirements and are tailored specifically to the PACE program. We propose to require at § 460.106(c)(1)(viii) that the plan of care address the participant's nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs. This proposed language is based on the long-term care regulations at §§ 483.20(b)(1)(xi), 483.24(b)(4), and 483.25(g), but it is tailored to be more specific to PACE. In a nursing facility, the facility is responsible for providing three meals a day in the actual facility, and therefore the access to meals is not as much of an issue. However, in PACE, participants live in a variety of settings. While the PACE organization is responsible for ensuring that participants' nutritional needs are met per the regulations at § 460.78, the exact manner in which the organization meets that requirement may be different for each participant. As we stated in the 2006 PACE final rule (71 FR 71281), the PACE organization is responsible for a participant's health and safety including his or her nutritional needs 24 hours a day, 7 days a week. The IDT must assess the participant's needs as well as his or her access to adequate nutrition. The participant's nutritional requirements and dietary needs should be included in the plan of care, whether it is providing tube feedings, arranging for Meals on Wheels, sending meals home with the participant, or documenting that appropriate meals are provided by the family/caregiver. For this reason, we are including in proposed § 460.106(c)(1)(viii) language that would specify that the plan of care address not only nutrition, but also how a participant accesses meals that meet their nutritional and special dietary needs.

We propose at § 460.106(c)(1)(ix) to establish the requirement that the plan of care address the participant's ability to live safely in the community, including the safety of their home environment. This proposal also deviates from the nursing home requirements, as the goal

of PACE is to keep nursing home eligible individuals out of a facility and living in the community. In order to accomplish that goal, the IDT must assess the participant's environment and living situation for potential factors that may make it not safe for the participant. For example, if the PACE organization recognizes the participant does not have a means of contacting either the PACE organization or emergency services, the PACE organization should address that concern as part of the plan of care, and provide the participant with a method of contacting those individuals or entities. As we noted in the 2006 PACE final rule (71 FR 71275), PACE organizations are at risk for all health care services the participant receives and; therefore, we expect PACE organizations will be involved in assuring the health and safety of participants at all times, including when they are at home. We propose at § 460.106(c)(1)(x) that the plan of care must address the participant's home care needs. This proposal would also deviate from nursing home guidance; however, we believe it to be important in the PACE model. The nursing home is responsible for 24-hour care similar to PACE, but inherently provides all care as part of the resident living at the facility. PACE often provides similar care, for example medication administration, through home care services. Therefore, we believe a participant's home care needs must be addressed through the plan of care. We propose to establish at § 460.106(c)(1)(xi) that the participant's center attendance must be included in the plan of care. Again, while not a requirement in nursing homes, center attendance is an integral part of the PACE program, and we believe it is appropriate to include it in a participant's plan of care. We propose at § 460.106(c)(1)(xii) to require that a participant's transportation needs be incorporated into the plan of care. Transportation is an essential part of the PACE benefit, as often it is the PACE transportation that ensures participants have access to their necessary medical appointments and specialist visits. In addition, we propose to require at § 460.106(c)(1)(xiii) that a participant's communication needs (including any identified language barriers) be incorporated into the plan of care. For participants who are not English speaking, or have some other difficulty communicating, addressing and resolving these needs preemptively

can mean the difference between quality of care and participant's not receiving the care they need.

We are soliciting comment on all items identified in the proposed § 460.106(c)(1) and whether they should be required content in a plan of care for PACE participants. Along with any general comments that are submitted, we are specifically requesting comment on whether to include acute diseases and/or acute behavioral and psychiatric disorders in the plan of care. We contemplated adding acute diseases as part of the minimum criteria for the plan of care, but ultimately, we believe it might be hard to operationalize. When submitting comments on whether acute diseases should be included in the plan of care, we ask that commenters also indicate whether they believe the term "acute diseases" should be defined in the PACE regulations, and if so, how. We also solicit comment on whether there is other content that is required to be in a nursing home care plan that should also be included in a PACE plan of care. We are particularly interested in feedback that addresses whether we should include incontinence care and dialysis care as required content for PACE plans of care. (Both incontinence care and dialysis care are required in nursing home care plans, per the regulations at § 483.25(e) and (l)).

We propose at § 460.106(c)(2) to require that the plan of care must identify each intervention (the care or service) needed to meet the participant's medical, physical, emotional, and social needs. In addition to identifying the needs of the participant as they relate to the proposed criteria in § 460.106(c)(1), the PACE organization must also identify any service that will be provided in response to those needs. PACE organizations are currently required at § 460.106(b)(4) to identify each intervention, so this provision is consistent with the current requirement, but further emphasizes that it's any intervention needed to meet the participant's medical, physical, social or emotional needs. For example, if the participant has poor vision, the IDT may deem it necessary to provide glasses and routine trips to the optometrist or ophthalmologist. The IDT would need to identify these services in the plan of care. We propose to include at § 460.106(c)(2) an exception to the interventions that need to be included in the

plan of care; specifically, proposed § 460.106(c)(2) would provide that the plan of care does not need to identify the medications needed to meet a participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record. As we define services at § 460.6 to include medications, we strongly believe that medications are an important part of the PACE benefit, and may be the most applicable service for a particular diagnosis or condition. However, we also understand that medications may change frequently, especially when a participant is first beginning a medication routine, and are typically documented in the medical record in way that would allow the IDT to understand all current, pending and discontinued medications; therefore, we are not inclined to require medications to be included in the plan of care. However, while we are not proposing to require that all medications be identified in the plan of care, nothing would prohibit an organization from choosing to include medications in the care plan. We are soliciting comment on this proposal and whether the plan of care should include a comprehensive list of active medications.

We propose to redesignate current § 460.106(b)(3), which requires the care plan to utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome, as § 460.106(c)(3).

We propose at § 460.106(c)(4) to specify that the plan of care must identify how each service will be implemented, including a timeframe for implementation. The IDT is already required to identify how each intervention will be implemented in § 460.106(b)(4), however we are proposing to modify the language to specify that as part of identifying how the intervention will be implemented, the PACE organization should specify a timeframe for that implementation. As part of the plan of care process, the IDT should determine the parameters of a service, specifically how it will be provided to the participant in order to meet their needs. For example, it is not enough for the IDT to decide that the participant needs physical therapy. They should also discuss how often the participant should receive physical therapy, when it should be provided, and by whom.

We propose at § 460.106(c)(5) to require that the plan of care must identify a measurable goal for each intervention. The current care plan regulations require that the plan identify measurable outcomes (§ 460.106(b)(2)), and utilize appropriate interventions that advance the participant toward a measurable goal (§ 460.106(b)(3)). Our proposal at § 460.106(c)(5) is consistent with the intention of the current requirement; however, we believe the specificity of identifying measurable goals for each service are necessary. We believe that it is important when identifying a service to also identify the measurable goal for that service. Using the aforementioned example of physical therapy, we believe the IDT must determine what measurable goal the participant should achieve as a result of attending physical therapy. For example, the goal may be the participant's increased mobility demonstrated by the participant ambulating a specific distance either determined by an actual measurement (for example, 100 feet) or from one area of a room to another (for example. the participant will ambulate from the bed to the toilet without falling).

We propose at § 460.106(c)(6) to require that the care plan identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified. The IDT is currently required at § 460.106(b)(5) to identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes. While our proposal is similar in intent, it would reduce ambiguity by specifying that the evaluation by the IDT should be focused on whether the goal was met for determining whether the intervention needs to be continued, discontinued or modified. For example, the IDT determines that the PACE participant should receive physical therapy 3 times a week. The goal may be that the participant is able to ambulate independently 100 feet. The IDT may determine the appropriate timeframe for that goal is 6 weeks. At the time the PACE organization identifies the measurable goal, it must determine how it will evaluate the participant's success in meeting the goal. In this example, at the end of the 6-week timeframe, the PACE organization should have a mechanism to determine if the participant has met the goal of ambulating 100 feet. If the

participant met the goal, the IDT may determine the intervention can be discontinued. If the participant has not met the goal, the IDT may determine whether the intervention needs to be modified or if it should be continued for another set period of time, at which point the IDT will need to determine a new measurable goal and how it will be evaluated.

Finally, we propose at § 460.106(c)(7) to require that the plan of care must identify the participant's preferences and goals of care. It is important for the PACE organization to document the participant's goals and wishes for treatment and to consider them not only when developing and reevaluating the plan of care, but during implementation of the services that were added to the plan of care.

Currently, § 460.106(c) includes requirements for the implementation of the plan of care. We propose to move these requirements to § 460.106(d) and make modifications to the existing requirements. Currently, § 460.106(c)(1) requires the team to implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or contractors. We propose to move this language to § 460.106(d)(1) and to modify it to read that the IDT must continuously implement, coordinate, and monitor the plan of care, regardless of whether the services are furnished by PACE employees or contractors, across all care settings. Through our audit and oversight activities, we have seen where PACE organizations met the minimum requirement of reassessing participants semiannually and updating the plan of care accordingly, but then took no further action with respect to the plan of care until the next semiannual assessment period. We want to reemphasize that the intent of the plan of care is to create a comprehensive, living document that is updated per the participant's current status at any given point; we are proposing to add the word "continuously" to emphasize that the team must continue to be responsible for implementing, coordinating and monitoring the plan of care. We are proposing to include language specifying that this implementation, coordination and monitoring of the plan of care must be done across all care settings, to reiterate the responsibilities of the IDT in ensuring that care is appropriately coordinated and furnished,

regardless of where a participant resides. For example, if a participant is living in a nursing home, that does not absolve the IDT of its responsibility to ensure that the care is implemented appropriately and that the participant's needs are met.

Currently, § 460.106(c)(2) requires the IDT to continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT. We propose to move the current requirements at § 460.106(c)(2) to § 460.106(d)(2) and to modify § 460.106(d)(2) to specify that the IDT must continuously evaluate and monitor the participant's medical, physical, emotional, and social needs, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT and other employees or contractors. The proposed modification to change the language from "participant's health and psychosocial status" to "participant's medical, physical, emotional, and social needs" is intended to align more closely with the regulation on required services at § 460.92(b).

We propose to add § 460.106(d)(3) to state that all services must be arranged and provided in accordance with § 460.98(c). The provision of care planned services is an important part of implementing the plan of care. As we discussed in section VI.G. of this rule, we have proposed additional criteria concerning the arranging and provision of services that are determined necessary by the IDT. When a service is care planned, the IDT has determined that the service is necessary for the participant, and we would expect it to be arranged and provided in accordance with the rules governing other approved or necessary services.

Currently, § 460.106(e) requires that the team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed. We have seen as part of our audit and oversight activities where participants and/or caregivers are unaware of

the contents of their plan of care or what services they should be receiving. We have also seen that the involvement of the participant and/or caregiver in the plan of care is often limited, and often reflects no direct involvement or input in that decision-making process. Instead, we often see that the plan of care is finalized by the team and then provided or reviewed with the participant after the fact as a means of "collaboration." Therefore, we propose to split the existing language into two new paragraphs § 460.106(e)(1) and (e)(2). We propose at § 460.106(e)(1) that the IDT must develop, evaluate, and revise each plan of care in collaboration with the participant or caregiver, or both. We are proposing to amend the language to refer to "each" plan of care in order to emphasize that this collaboration must be performed for every new plan of care, including the initial, semi-annual, and a revised plan of care as a result of a change in status. We also propose at § 460.106(e)(2) that the IDT must review and discuss each plan of care with the participant and/or caregiver before the plan of care is completed to ensure that there is agreement with the plan of care and the participant's concerns are addressed. We want to ensure the participant and/or caregiver has an opportunity to voice concerns and ensure that any concerns are addressed in the proposed plan of care; therefore, our proposal addresses the expectation that the IDT discuss the plan of care with the participant prior to it being finalized. We believe a discussion about the plan of care, with the participant and/or caregiver, is the best way for the IDT to explain the care they believe is necessary, and receive input from the participant and/or caregiver about their wishes and concerns related to their care.

Currently, § 460.106(f) requires that the team must document the plan of care, and any changes made to it, in the participant's medical record. As part of our audit and oversight activities, we have seen organizations have insufficient documentation related to participant plans of care. We often see minimum documentation related to whether a participant has met the goals set at the last assessment and any changes in the participant's status, but we do not see documentation of the conversations with the participant in the plan of care, including whether the participant disagreed with any part of the plan of care and whether those concerns were

addressed. Therefore, we propose to modify the language in § 460.106(f) to state that the team must establish and implement a process to document and maintain records related to all requirements for the plan of care in the participant's medical record, and ensure that the most recent care plan is available to all employees and contractors within the organization as needed. This proposal is consistent with the current requirement, but ensures that the PACE organization understands that it must document all care planning requirements. Therefore, we would expect to see documentation that the appropriate members of the IDT were involved in care planning in accordance with § 460.106(a), the IDT met the timeframes for finalizing care plans in § 460.106(b), that the care plans included all required content in § 460.106(c), that the IDT implemented and monitored the plan of care in accordance with § 460.106(d), and that the participant and caregiver were appropriately involved in the care planning process in accordance with § 460.106(e).

We also propose certain modifications to § 460.104 to align with our proposed amendment to § 460.106. Currently, § 460.104(e) requires that the team member who conducts a reassessment must reevaluate the participant's plan of care, discuss any changes in the plan with the IDT, obtain approval of the revised plan from the IDT and the participant (or designated representative), and furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires. We propose to remove most of the language currently in section § 460.104(e), and add the requirement that when the IDT conducts semiannual or unscheduled reassessments, the IDT must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments. We believe this will eliminate any unnecessary duplication and ensure there is no confusion as it relates to care plans.

As both the development of and updates to the care plan are a typical responsibility for the IDT, any burden associated with this would be incurred by persons in their normal course of business. Therefore, the burden associated with the development of and updates to the care plan

are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a usual and customary business practice.

J. Specific Rights to Which a Participant is Entitled (§ 460.112)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify in part that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including a patient bill of rights. Previously, we established in § 460.112 certain rights to which a participant is entitled. This includes the participant's right to considerate, respectful care and the right not to be discriminated against (§ 460.112(a)); the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions (§ 460.112(b)); the right to access emergency services without prior authorization (§ 460.112(d)); and the right to participate fully in decisions related to his or her treatment (§ 460.112(e)).

In this proposed rule, CMS is proposing to amend § 460.112 to incorporate the following participant rights: the right to appropriate and timely treatment for health conditions including the right to receive all care and services needed to improve or maintain the participant's health condition and to attain the highest practicable physical, emotional and social well-being; the right to have the PACE organization explain all treatment options; the right to be fully informed, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services; the right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services; and the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121.

Sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act establish that PACE organizations shall provide enrollees access to necessary covered items and services 24 hours per day, every day of the year. CMS codified these required services at § 460.92, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all

Medicare covered services, all Medicaid covered services as specified in the State's approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant's overall health status. At § 460.98(a), CMS established the requirement for PACE organizations to provide care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. However, through our audit and oversight activities, we have identified some PACE organizations that do not provide care meant to improve or maintain the participant's condition, and instead provide a palliative-like benefit, where the services provided to participants are geared more toward ensuring the participant's comfort even when that is not in line with the participant's wishes or needs. We have also seen organizations, in care plans and notes from discussions with participants, use terms such as palliative care and comfort care without clearly defining those terms for the participants and/or their designated representatives, leaving participants and families confused as to what level of care they are receiving. Based on what we have seen through audits, we believe that not all participants understand that they are entitled to all care and services deemed necessary to improve or maintain their health status, and are not limited to services related to palliative, comfort or end-of-life care. As we stated in the January 2021 final rule (86 FR 6041), enrollment in the PACE program continues until the participant's death, regardless of changes in health status, unless the participant voluntarily disenrolls or is involuntarily disenrolled. Therefore, it is reasonable that a PACE participant may transition from receiving treatment meant to cure or maintain health conditions at the time of enrollment, to receiving end-of-life care by the time they approach their death. However, it is essential that PACE participants understand their right to receive all treatments in the PACE benefit package that are necessary and appropriate at the time of enrollment and on an ongoing basis, and that they clearly understand their rights as they transition from receiving treatment focused on curing a condition or improving or maintaining their health status, to treatment meant solely to provide comfort.

For the foregoing reasons, we are proposing certain modifications to § 460.112. First, we propose to redesignate current paragraphs (a) through (c) as paragraphs (b) through (d) to allow for the addition of proposed new paragraph (a). Proposed new paragraph (a)(1) would state that participants have a right to appropriate and timely treatment for their health conditions, which includes the right to receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being. We are proposing to add this language in new paragraph (a)(1) of § 460.112 because the right to treatment is a separate and distinct right that should be assigned its own paragraph in the participant rights section. By creating a new paragraph (a) and titling it the right to treatment, we aim to emphasize the participant's right to receive care and services, which many of the other participant rights relate to or build upon. In drafting proposed new § 460.112(a)(1), we considered the language in § 460.92 related to services meant to improve or maintain the participant's health condition. Additionally, since a PACE organization is a direct care provider that serves nursing home eligible participants, we also considered nursing home regulations as we drafted this proposal. The nursing home regulations require that care plans must describe "the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being" (§ 483.21(b)(1)(i)). We adapted this language to align with existing PACE regulations. We believe this modification will ensure that PACE participants are made aware of their right to receive any care and services that are necessary to improve their condition to the highest practicable level, or maintain their condition to the highest practicable level, depending on the participant's health condition.

In addition, we propose to add to § 460.112 a new paragraph (a)(2), which would state that participants have the right to appropriate and timely treatment for their health conditions, including the right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team. The right to access emergency care services currently appears at § 460.112(d); however, we believe that it relates to the right to

treatment, and therefore, we propose to move the text of current § 460.112(d) to new § 460.112(a)(2). It is appropriate that both of the proposed provisions concerning the right to treatment (that is, proposed paragraph (a)(1) regarding standard treatments and proposed paragraph (a)(2) regarding emergency treatments) appear in the same paragraph of § 460.112.

In the 1999 PACE interim final rule, CMS codified at § 460.112(a) (which we propose to redesignate as § 460.112(b)) that all participants have the right to considerate respectful care, and each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment (64 FR 66253). CMS also codified at § 460.112(e) the right of participants to participate fully in all treatment decisions. As part of that right, participants have the right to have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions (§ 460.112(e)(1)). This right has two specific parts; the right to have all treatment options explained in a culturally competent manner, and the right to make health care decisions. We believe the first right, the right to have all treatment options explained in a culturally competent manner, relates more to the rights under redesignated § 460.112(b) ("Respect and nondiscrimination"). Therefore, we propose to add a new paragraph at § 460.112(b)(8) which states that participants have the right to have all information regarding PACE services and treatment options explained in a culturally competent manner. Culturally competent care respects diversity in the patient population and cultural factors that can affect health and health care, and can contribute to the elimination of racial and ethnic health disparities. By moving the provision establishing the right to have treatment options explained in a culturally competent manner from § 460.112(e)(1) to new § 460.112(b)(8), as proposed, we would emphasize that receiving materials about all PACE services, not just treatment options, in a culturally competent manner is an inherent right.

In the 1999 PACE interim final rule (64 FR 66254), CMS codified the participant's rights to receive accurate and easily understood information at current § 460.112(b) (which we propose to redesignate as § 460.112(c)). In the 2006 PACE final rule, CMS further stated that this information was necessary for participants to "comprehensively assess differences in their health care options" (71 FR 71295). CMS also codified at § 460.112(e) that "a participant who is unable to participate fully in treatment decisions has the right to designate a representative" (64 FR 66290). For the participant's designated representative to be able to act on behalf of the participant in the event the participant is unable to make informed decisions, the designated representative should receive the same accurate, easily understood information the participant receives. Therefore, we are proposing to add language to the newly designated § 460.112(c) that would provide that a participant has the right to have all information in this section shared with their designated representative. As previously mentioned, participants may be enrolled with a PACE organization until their death, and therefore the PACE benefit adapts as the participant's needs change. Because PACE is designed to meet a participant's needs, regardless of what those needs are, PACE organizations are permitted to provide participants similar benefits to hospice or end-of-life care while allowing participants to remain in PACE, assuming that is in line with the participant's wishes for treatment. However, we have seen as part of our audit and oversight activities that certain types of care offered by PACE organizations are not well-defined. For instance, through audits we have seen organizations use terms such as palliative care, comfort care, and end-of-life care, with little or no information on what those terms mean or how they are defined or implemented across PACE organizations. We have also seen that the lack of a clear, comprehensive definition of palliative care, comfort care, or end-of-life care has caused confusion to participants and/or their caregivers related to what care they are and are not getting when this type of care is provided. While CMS does not seek to define these terms, we believe it is important for PACE organizations to define the terms within their respective programs, and provide clear information to participants and their designated representatives on what the terms

mean. Participants and their representatives have the right to understand how their choices to pursue these different types of treatment options will impact their ability to continue pursuing care and services meant to improve or maintain their health conditions. Therefore, we are proposing to add language to newly designated § 460.112(c)(5) that would provide that participants have the right to be fully informed, in writing, of several factors before the PACE organization implements palliative care, comfort care, or end-of-life care. We propose that the written notification to participants must explain four different aspects of the treatment options, which we outline in proposed § 460.112(c)(5)(i) through (iv).

First, we propose at § 460.112(c)(5)(i) that the written notification must include a description of the palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving to meet their individual needs. The explanation of the different types of care, and more importantly, how they differ from the care being currently received is important in ensuring that participants are fully informed of their options for treatment and are therefore able to make informed decisions on the care they wish to receive. A participant should have the right to fully understand the care they are agreeing to receive prior to that care being initiated.

Proposed § 460.112(c)(5)(ii) would require PACE organizations to explain, in writing, to participants or their designated representative whether palliative care, comfort care, or end-of-life care services (as applicable) will be provided in addition to or in lieu of the care the participant is currently receiving. We have seen through audit that some PACE participants receive palliative care and/or comfort care in addition to other services a participant may be receiving, including services meant to improve or maintain their health condition. We have also seen PACE participants receive palliative care and/or comfort care instead of providing services meant to improve or maintain the participant's health condition. In other words, for some participants, when they agree to receive palliative care or comfort care, they are also agreeing to no longer receive care meant to improve or maintain their health condition and are receiving, in

essence, end-of-life care. While this may be appropriate in some instances, given a participant's condition, it is important that participants fully understand what they are agreeing to when they enter into palliative or comfort care status. We believe that part of the appeal of PACE to participants is the person-centered nature of the benefit, which allows for the IDT to provide any and all services that are tailored around the participant's needs. This is true for end of life services too. One participant may want, and the IDT may approve, comfort measures in addition to treatment meant to maintain the participant's health condition. Another participant may be at the end of their life, and may only want treatment meant to reduce or control pain. CMS believes that the PACE organization is allowed to pursue either scenario, but that the participant must be able to understand the options and what care they will or will not receive in order to make an informed decision.

Proposed § 460.112(c)(5)(iii) would require PACE organizations to identify all services that would be impacted if the participant and/or their designated representative elects to initiate palliative care, comfort care, or end-of-life care. For example, one or more of the following types of services could be impacted and the PACE organization should include the impacted services in the detailed description: physician services (including specialist services), hospital services, long-term care services, nursing services, social services, dietary services, transportation, home care, therapy (including physical, occupational, and speech), behavioral health, diagnostic testing (including imaging and laboratory services), medications, preventative healthcare services, and PACE center attendance. Under this proposal, PACE organizations would be required to provide a detailed explanation of how specific services would be impacted by the addition of or transition to palliative care, comfort care, or end-of-life care. If the participant would be receiving palliative care or comfort care in addition to all the other services they are currently receiving, then the PACE organization may not have to provide a detailed analysis, and could simply include language that the designation of palliative care or comfort care will not impact any existing services. However, if moving a participant to palliative care,

comfort care, or end-of-life care would impact their services (for example a participant would no longer be sent to specialists, or they would no longer be sent to the hospital), then a PACE organization would be required to identify the services that would be impacted, and explain how those services would be impacted.

Proposed § 460.112(c)(5)(iv) would state that the participant has the right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason either verbally or in writing. We also propose to require PACE organizations to explain this right to participants both orally and in writing. A participant has the right to fully participate in treatment decisions, as established at current § 460.112(e). Part of that right is participating in the decision-making process of what care to receive, and a participant must not only understand what the proposed care or treatment decisions mean, but also that they can change their mind with regards to treatment decisions previously made. We have seen through audits and oversight activities that participants or their designated representatives may decide to pursue palliative care or comfort care, without fully understanding what those terms mean. We have also seen situations where participants or their designated representatives want to stop palliative care or comfort care when they realize they will no longer receive other services and do not know they have the right to revisit prior treatment decisions. Participants should be clearly informed, in writing, that they have the ability to change their mind on these important treatment decisions.

In the 1999 PACE interim final rule (64 FR 66255), CMS established at § 460.112(e) the right for each participant to fully participate in all decisions related to his or her care. Paragraph (e)(1) specifies that this includes the right "[t]o have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions." In this proposed rule, we are proposing to modify the language in § 460.112(e)(1) by removing the language regarding the participant's right to have all treatment options explained in a culturally competent manner. As we explained in the discussion around our proposed amendments to § 460.112(b), the right to

have treatment options explained in a culturally competent manner is better suited for inclusion in that paragraph, which, as amended, sets forth participant rights related to respect and non-discrimination. We also propose to restructure and modify § 460.112(e)(1) by separating the requirements into three subparts at § 460.112(e)(1)(i), (ii) and (iii). We propose at § 460.112(e)(1)(i) to establish that participants' right to make health care decisions includes the right to have all treatment options fully explained to them. Inherent in the right to participate in health care decisions is the right to understand all available options for treatment. A participant cannot make an informed health care decision without fully understanding the options available. Proposed § 460.112(e)(1)(ii) would provide that participants have the right to refuse any and all care and services. As we explained in the 2006 PACE final rule (71 FR 71298), the right to refuse treatment is a type of health care decision, and participants have the right to make those decisions. We propose at § 460.112(e)(1)(iii) to specify that participants have the right to be informed of the consequences their decisions may have on their health and/or psychosocial status. The language at current § 460.112(e)(1) refers to the participant's right to "be informed of the consequences of the decisions," but we propose to add additional specificity around that right and the obligation it creates for PACE organizations by modifying the regulatory language to refer to the participant's right to "be informed of the consequences their decisions may have on their health and/or psychosocial status." We believe this proposed revision would emphasize that the participant should be made aware of how their decision to refuse care may impact their health and/or psychosocial status. For example, if a physician was recommending the participant have a diagnostic cardiac catherization, and the participant refused, the participant has the right to be informed that, by not having the diagnostic testing done, they might be at increased risk for a cardiac event, including a heart attack.

We propose to further amend § 460.112(e) by redesignating current paragraphs (e)(2) through (e)(6) as (e)(3) through (e)(7), and by adding a new paragraph (e)(2), which would state that participants have a right to fully understand the PACE organization's palliative care, comfort

care, and end-of-life care services. Proposed paragraph (e)(2) would further require that PACE organizations take several steps, outlined at proposed § 460.112(e)(2)(i) through (iii), in order to ensure that participants understand this right. As we mentioned in our discussion of § 460.112(a), we have seen as part of our audit and oversight activities that participants and/or their representatives are not always fully aware of what treatments they will or will not receive if they opt to pursue palliative care, comfort care, or end-of-life care services. While palliative care, comfort care, and ultimately, end-of-life care are necessary components of the PACE benefit, PACE organizations must ensure that participants fully understand these terms and treatment options, prior to them being initiated.

At § 460.112(e)(2)(i), we propose to establish that the PACE organization must fully explain the applicable treatment options to the participant prior to initiating palliative care, comfort care, or end-of-life care services. This proposal would require the PACE organization to explain to the participant what these terms mean, and how choosing one of those options would impact the participant's health. We are also proposing at § 460.112(e)(2)(ii) to require that the PACE organization provide the participant with written information about their treatment options in accordance with § 460.112(c)(5). In the discussion around § 460.112(c)(5), we highlighted that we believe providing written information on these terms is important for the participant, and that the information must include details regarding the treatment and how the participant's current services may be impacted. We are proposing to add paragraphs (e)(2)(i) and (e)(2)(ii) as separate provisions because the organization should be responsible both for providing the written notification outlined in § 460.112(c)(5), and actually explaining the treatment options in a way that is understandable to the participant. A participant may be overwhelmed by receiving only written notification; therefore, both provisions are necessary to ensure the participant has a full understanding of their options. Finally, we are proposing at § 460.112(e)(2)(iii) that the PACE organization obtain written consent from the participant or their designated representative to change a treatment plan to include palliative care, comfort care, or end of life care. Because

some organizations stop treatments to improve or maintain a participant's condition when a participant enters palliative care or comfort care, it is especially important that participants or their designated representatives are in agreement with these treatment options, and consent to receiving this care. We believe ensuring that this consent is in writing is the most appropriate safeguard, not only for participants, but also for PACE organizations to ensure that they have adequate documentation to support providing these benefits. We propose to redesignate current paragraphs (e)(2) through (e)(6) of § 460.112 as (e)(3) through (e)(7) to allow for the addition of a new paragraph (e)(2) as discussed in this section. We want to emphasize that this proposed requirement would not take the place of any advanced directives a participant may have, and would not eliminate the requirement in current § 460.112(e)(2) (which would be redesignated as (e)(3) under our proposal) that requires a PACE organization to explain advance directives and to establish them, if the participant so desires. That directive is distinct from the notification proposed at new § 460.112(e)(2), which should explain the services under the PACE benefit that may be provided or not provided to the participant as a part of their care decisions.

In the 1999 PACE interim final rule (64 FR 66256, 66290), CMS codified at § 460.112(g) the participant's right to "a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review." In the January 2021 final rule (86 FR 5864), CMS added § 460.121 to clearly define service determination requests and specify the requirements for how those requests would be processed. As we explained in that rule, the service determination request process serves an important participant protection, as it allows a participant to advocate for services (86 FR 6008). We also explained that the service determination request process is the first step of the appeals process (86 FR 6008). At § 460.112(g)(1), the participant is provided the right to be encouraged and assisted to voice complaints to PACE staff and outside representatives; and § 460.112(g)(2) provides participants the right to appeal any treatment decision of the PACE organization, its employees, or contractors through the process described

in § 460.122. Because the participant rights in section § 460.112(g) discusses both the right to voice grievances and the right to appeal, it should also reference the right to request a service determination request, which is the first step in the appeals process. Therefore, we propose to add a new § 460.112(g)(2) to provide that a participant has the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121. We propose to redesignate current paragraph (g)(2) as (g)(3) to allow for the addition of a new paragraph (g)(2) as discussed in this section. We believe the burden associated with this provision is related to developing written templates regarding the PACE organization's palliative, comfort, and end-of-life care services and tailoring those templates to the participants. We discuss the burden in the collection of information section.

K. Grievance Process (§ 460.120)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. We have codified requirements around the processing of grievances at § 460.120. The grievance process serves as an important participant protection as it allows for participants and their family members to express complaints related to the quality of care a participant receives, or the delivery of services. Currently, § 460.120 defines a grievance as a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished. A PACE organization must have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, family members, or representatives (§ 460.120(a)). At a minimum, the PACE organization's grievance process must include written procedures for the following: (1) how a participant files a grievance; (2) documentation of a participant's grievance; (3) response to, and resolution of, grievances in a timely manner; and (4) maintenance of confidentiality of a participant's grievance (§ 460.120(c)).

A PACE organization must discuss with and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant's

grievance. The PACE organization must also maintain, aggregate, and analyze grievance data for use in its internal quality improvement operations (§ 460.120(f)).

Since the grievance regulations were codified in 1999, CMS has received feedback from PACE organizations requesting clarification and guidance on the grievance process. Additionally, we have discovered through audits that the current grievance process, which allows PACE organizations latitude to define their own grievance resolution timeframes and develop their own procedures for processing grievances, has created confusion and inconsistency in how grievances are handled from organization to organization. We are proposing certain modifications to the grievance requirements at § 460.120 to strengthen participant protections and provide more detailed processing requirements for grievances from PACE participants and their family members. We also propose certain adjustments that would align the requirements with the service determination process in § 460.121 for consistency.

Currently, the grievance requirements at § 460.120(a) require a PACE organization to have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, their family members, or representatives. We propose to modify paragraph (a) of § 460.120 to align more closely with paragraph (a) of § 460.121, which establishes the requirement to have certain written procedures in place for identifying and processing service determination requests. First, we propose to amend § 460.120(a) by removing the current paragraph header, which reads "Process to resolve grievances,", adding in its place a new paragraph header, which would read, "Written procedures." Specifically, we propose to modify the requirement to state that each PACE organization must have formal written procedures to promptly identify, document, investigate and resolve all medical and nonmedical grievances in accordance with the requirements in this part. It is important to ensure that PACE organizations develop internal processes and procedures to properly implement the grievance process. In addition, we propose to further amend § 460.120(a) by removing the list of individuals who can

file a grievance, as we are proposing to create a new paragraph that outlines who may file a grievance at § 460.120(d).

We propose to add to § 460.120 a new paragraph (b), which would define a grievance in PACE as a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested; and further that a grievance may be between a participant and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant. Currently, the term grievance is defined in the introductory paragraph of § 460.120 as a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished. We have heard from PACE organizations over the years that they would prefer that the term grievance be better defined in the regulations, and we have received requests from PACE organizations for the grievance definition to be narrowed to exclude complaints that may not rise to the level of a grievance. Based on this feedback, we considered how we might refine the definition of grievance for purposes of PACE. In doing so, we reviewed how grievances are defined in other managed care programs and care settings, specifically in MA and in nursing homes.

The MA regulations define a grievance as any complaint or dispute, other than one that constitutes as organization determination, expressing dissatisfaction with any aspect of an MA organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested (§ 422.561). While the long-term care regulations do not define "grievance", § 483.10(j)(1) provides that a resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Section 483.10(j)(1) further specifies that such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their long-term care facility stay. When considering these other approaches to defining what

constitutes a grievance, we concluded that the definition used in PACE is already tailored more narrowly than the MA or nursing home requirements. That being the case, we do not believe it would be appropriate to narrow the definition even more, and potentially limit a PACE participant's ability to complain about their care and have their complaints resolved through a formal process.

However, we recognize that there are aspects of the MA regulations' definition of grievance that would be helpful to include in the PACE definition at § 460.120, because it would further refine the grievance definition and offer clarity sought by PACE organizations in previous feedback. For example, in developing our proposal, we noted that the MA regulations specify that a grievance is any complaint that meets the definition at § 422.561 regardless of whether remedial action is requested. We have seen on audit where PACE organizations will not recognize or process complaints that fit within the definition of a grievance, because remedial action was not requested. However, we want to stress that a grievance must be identified and processed if it satisfies the definition, regardless of whether remedial action is requested. This is an important participant safeguard because grievances are required under the current § 460.120(f) to be maintained, aggregated and analyzed as part of the PACE organization's quality improvement program. Regardless of whether remedial action is requested, it is important for organizations to analyze all complaints received in order to ensure they are making necessary improvements in their quality program. For these reasons, we propose to include in our definition of a grievance that a request for remedial action is not required.

In further consideration of MA grievance regulations, and specifically MA grievance procedures at § 422.564, we propose that the definition of a grievance would provide that a grievance may be between a participant and the PACE organization, but it may also be between any other entity or individual through which the PACE organization provides services to the participant. This proposed change to the PACE grievance definition is based on the MA grievance definition, which provides at the current § 422.564(a) that each MA organization must

provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers. PACE provides a wide array of services through different home care agencies, medical specialists, and facilities such as nursing homes. It is important that a participant or their family have the ability to voice complaints related to any care they receive, even if that care is provided through a contracted entity or individual.

We are proposing the grievance definition at § 460.120(b) be: "For purposes of this part, a grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant." However, we would like to solicit comment on whether we should modify the PACE grievance definition to more closely resemble the definition of grievances in MA at § 422.561. Specifically, we solicit comment on whether we should consider use of the following definition for PACE grievances: A grievance means any complaint or dispute expressing dissatisfaction with any aspect of the PACE organization's or it's contractors' operations, activities, or behavior, regardless of whether remedial action is requested.

Currently, § 460.120(b) requires that upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process. We are proposing to redesignate § 460.120(b) as § 460.120(c), change the title, and amend the regulation text. Specifically, we propose to change the title from notification to participants to grievance process notification to participants, to differentiate from notifications related to grievance resolutions, and that the grievance process notification be written in understandable language. We propose to add new paragraphs (c)(1), (c)(2), and (c)(3) to § 460.120, which would set forth requirements for the grievance process notification. We solicit comment on whether the other individuals should receive the grievance process notification, in addition to the

participant, upon the participant's enrollment and annually thereafter. Specifically, we are soliciting comment on whether the other individuals specified in § 460.120(d) should receive the grievance process notification, or at a minimum, whether the participant's designated representative should receive the notification in addition to the participant.

First, we propose at § 460.120(c)(1) that the grievance process notification must include information on the right of the participant or other individual specified in § 460.120(d) to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal. In developing this proposal, we again considered the long-term care regulation at § 483.10(j)(1), and we believe that the language in the long-term care regulation that provides that a resident has the right to voice grievances without reprisal or discrimination and without the fear of reprisal or discrimination would also be relevant in PACE. PACE participants have the right to voice complaints to PACE staff without reprisal by the PACE staff under current § 460.112(g)(1), but we believe this right should be specifically called out in the PACE regulations, as written in the long-term care regulations, in the notification that goes to participants about the grievance process. By including it in the notification under proposed § 460.120(c), we would ensure that participants would be aware of this right to complain, and that they are assured in that notification that they and the other individuals specified in § 460.120(d) should not fear making complaints. When we have conducted interviews of PACE participants and their family members as part of our audit process, we have heard that some participants are afraid to voice grievances for fear that the PACE organization will take some punitive action against them. For example, some participants have expressed fears that the PACE organization will eliminate their center attendance, or discontinue other necessary services, if the participant complains about the care they receive. We believe it is important for the grievance process notification to participants to emphasize that a participant or other individual specified in § 460.120(d) has the right to voice grievances without the fear of reprisal or discrimination.

We propose at § 460.120(c)(2) that the grievance process notification must inform pariticipants that a Medicare participant as defined in § 460.6 or other individual specified in § 460.120(d) acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services, consistent with section 1154(a)(14) of the Act. Section 1154(a)(14) provides that the QIO "shall conduct an appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under title XVIII) not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such title (or a person acting on the individual's behalf)." Title XVIII of the Act is the Medicare statute, so this provision is specific to Medicare beneficiaries and Medicare-covered benefits. Since most PACE participants are Medicare beneficiaries, they are also eligible to submit quality of care grievances to a QIO. This right has not been formally provided to PACE participants before, and we are proposing to require it now in order to ensure that Medicare beneficiaries enrolled in PACE understand this additional right.

We propose at § 460.120(c)(3) to require that the grievance process notification include the grievance definition at § 460.120(b) and provide information on all grievance processing requirements in paragraphs (d) through (k) of § 460.120. In order for the grievance process to serve as a fair and efficient avenue for participants to express their dissatisfaction with service delivery or the quality of care furnished, and to resolve their differences with the PACE organization or any other entity or individual through which the PACE organization provides services to the participant, participants must understand how to submit a grievance to the organization, and how that grievance will be processed once submitted.

Currently, at § 460.120(c), PACE organizations are required to develop written procedures that, at a minimum, must address how a participant files a grievance, documentation of the participant's grievance, response to and resolution of a grievance in a timely manner, and maintenance of confidentiality of a participant's grievance. These requirements allow PACE

organizations to develop their own procedures for resolving grievances, including creating their own timeframes for doing so. Given the frail and vulnerable population in PACE, we believe that additional structure around how grievances should be processed is necessary. Therefore, we are proposing to remove the language that is currently at § 460.120(c) and create specific processing requirements in its place.

We propose to move the language regarding who can submit a grievance from current § 460.120(a) to a new paragraph at § 460.120(d), as we believe the details regarding who is eligible to file a grievance will be more easily understood if they are placed in a new paragraph and separated from the remainder of § 460.120(a), which, under our proposed amendments, would require PACE organizations to have a formal written process to promptly identify, document, investigate, and resolve all grievances. Current § 460.120(a) provides that grievances can be submitted by participants, family members or their representatives. We propose to amend the list of individuals who can submit a grievance to include the participant's caregiver. We believe the proposed addition would be in alignment with the service determination process requirements in § 460.121, which allow a participant's caregiver to request services (§ 460.121(c)(3)), and with the plan of care requirements at § 460.106, which allow the caregiver to be involved in the development and reevaluation of the care plan (§ 460.106(e)).

As we stated in the January 2021 final rule (86 FR 6018), given the fact that caregivers may provide some care to the participants, it is important that caregivers are able to advocate for services on the participant's behalf. Similarly, if caregivers are providing some care to the participant, they should be able to make complaints related to any aspect of the care that the participant receives from the PACE organization. Since the grievance regulation already allows for family members and representatives to submit a grievance, we believe the change to add the term caregivers will not create a substantial change or burden for PACE organizations, since we believe that most caregivers will fall into one of the categories of family member or representative. As we explained in the January 2021 final (86 FR 6018), we have not historically

considered “caregivers” to include employees or contractors of the organization. We know some organizations may use the term “caregiver” to describe an aide at a nursing home, but CMS would not generally consider these individuals to fall within this category. We also explained in that rule (86 FR 6018) that employees and contractors of the PACE organizations enter into a contractual relationship with the PACE organization and generally have a predominately financial incentive to provide care; and we have not considered these individuals to be “caregivers” under the regulations. While these paid individuals may have pertinent information related to the participant’s care, their feedback is captured under the requirements for the IDT to remain alert to pertinent information under current § 460.102(d)(2)(ii). We do not believe that these paid individuals would generally be entitled to file a grievance under § 460.120. We solicit comment on our proposal to amend the list of individuals who can submit a grievance to include a participant’s caregiver.

In order to provide more clarity regarding CMS’ expectations for recognizing and processing complaints as grievances, we believe it is appropriate that we add additional structure to the regulations concerning how a grievance may be submitted, similar to how the service determination regulations are structured. We propose to add these rules around the submission of grievances in new paragraph § 460.120(e).

Proposed § 460.120(e)(1) would provide that any individual permitted to file a grievance with a PACE organization under § 460.120(d) may do so either orally or in writing. Currently, the introductory text of § 460.120 allows for a grievance to be filed orally or in writing. The right to file a grievance orally or in writing is an important participant safeguard, especially in an aging population, and it should continue to appear in our regulations. However, we believe it is more appropriate that we codify this right in a separate provision (as opposed to folding it into the definition of the term grievance, as in current § 460.120) in new proposed paragraph (e), along with the other proposed requirements for the submission of grievances. Proposed § 460.120(e)(2) would establish that the PACE organization may not require a written grievance

to be submitted on a specific form. While we understand that some organizations may use forms to help them process and investigate the grievance, we do not believe that a PACE participant should be restricted in how they can submit the complaint. We have seen participants detail their complaints to PACE organizations in letters and email correspondence. Receipt of these written complaints should be considered grievances and accepted in their original form. If a PACE organization decides to create a grievance form on its own and summarize the original grievance, that would continue to be permitted under our proposal, as long as the PACE organization maintains the written communication in its original form as required by § 460.200(d)(2).

Proposed § 460.120(e)(3) would provide that a grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants. This language is similar to the method for filing a service determination request at § 460.121(d)(2). As we indicated in the January 2021 final rule (86 FR 6019), these are the settings where participants have the most frequent contact with employees or contractors of the PACE organization, and therefore are logical settings for service determination requests to occur. We believe the same logic can be applied to grievances, and as a result, we limited our proposal to employees and contractors working in these settings.

We propose at new § 460.120(f) to establish the requirement that the PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known. Investigating why the situation occurred is an important part of ensuring that appropriate action will be taken in response to a grievance. However, we also recognize there may be some situations where the cause for the complaint or a specific issue is already known and therefore an investigation is not needed. For example, if the PACE bus has a flat tire, and as a result is late to pick up a participant for their center attendance, the participant may complain to the PACE organization about the late pick-up. While this would constitute a grievance and would need to be identified and processed, an investigation would not be

necessary because the PACE organization was already aware of the cause of the complaint (that is, the flat tire). If there are multiple issues within a grievance that require investigation, proposed § 460.120(f) would require the PACE organization to conduct a thorough investigation into each distinct issue when the cause of an issue is not known. We have seen on audit that some complaints may contain different issues within the one grievance. For example, a participant may call to complain that their home care aide is routinely late and does not clean the kitchen as is care planned for that participant. These are 2 different issues and both may need to be investigated in order to appropriately resolve the grievance. The PACE organization as a result of its investigation may determine that while the aide was late due to poor time management skills, the kitchen was not being cleaned because the home care company did not have the most recent care plan for the participant. The results of the investigation would directly impact how the PACE organization would resolve these concerns.

We propose at new § 460.120(g) to establish resolution and notification timeframes that would apply to grievances. Specifically, we propose at § 460.120(g)(1) that the PACE organization must take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance. Again, we considered both the MA grievance regulations and also the long-term care regulations. While the long-term care regulations do not define a timeframe for resolving grievances, the MA regulation at § 422.564(e)(1) requires that an MA organization must notify an enrollee who submits a grievance of the organization's decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the organization receives the oral or written grievance. We believe this is a fair timeframe, and based on our oversight efforts, we believe that a majority of organizations currently utilize a similar timeframe for resolving grievances. In our proposal for the PACE grievance regulation, we propose to adopt a modified version of the requirement in the MA regulations, which would specify that the 30-day

timeframe is the maximum amount of time the PACE organization has to resolve the grievance, as opposed to the maximum amount of time to notify the participant. Proposed § 460.120(g) would maintain the language regarding ensuring that this timeframe is a maximum length of time, and that organizations may need to resolve grievances more quickly if the participant's case requires. We propose at § 460.120(g)(2) that the PACE organization must notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with § 460.120(g)(1). We contemplated combining both the notification and resolution of a grievance into a single timeframe, but ultimately decided against that. We believe that the act of resolving a grievance, and the act of notifying the submitter about the resolution, are two separate actions. Additionally, as we will discuss in this section of this proposed rule in relation to proposed new § 460.120(i), we believe this exception strengthens our rationale for having distinct resolution and notification timeframes since we would expect a timely resolution of the grievance even if the individual who submitted the grievance requested not to be notified of that resolution.

Proposed § 460.120(h) would establish requirements for the processing of expedited grievances. Specifically, we propose to require that the PACE organization must resolve and notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 24 hours after the time the PACE organization receives the oral or written grievance if the nature of the grievance could have an imminent and significant impact on the health or safety of the participant. Because PACE organizations are direct care providers, it is important that they have a system for recognizing and processing complaints quickly when those complaints could have both an imminent and significant impact on the health or safety of the participant. We have not chosen to define the words "imminent" and "significant", because we believe PACE determine how they will define those terms as a part of their development of their grievance procedures. PACE organizations should already have some

system in place to recognize similar situations as organization's are currently required as a part of their quality improvement program at § 460.136(a)(5) to immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant. It would be important for PACE organizations to have a procedures for quickly responding to those complaints that may have an imminent and significant impact on the participant's health or safety. For example, if a participant complains that a home care aide abused him or her, and the aide is due back in the home later that day, the PACE organization should be prepared to investigate and resolve that concern immediately.

We propose at new § 460.120(i) to create grievance resolution notification requirements for how the PACE organization must inform the individual who submitted the grievance of the resolution of that grievance. We propose at § 460.120(i)(1) that the PACE organization may inform the individual either orally or in writing, based on the individual's preference for notification, except for grievances identified in § 460.120(i)(3). We contemplated following the MA rule around notification in § 422.564(e)(3), which allows for oral grievances to be responded to orally or in writing, but requires written grievances to be responded to in writing. However, we understand that because PACE organizations are not only an insurer, but also a provider, they often have calls or other remote communications with participants, and likely talk with them more often than an MA organization would talk with one of their enrollees. We also understand that some PACE participants would prefer oral notification, even if they their grievance was submitted in writing. Likewise, some PACE participants may call with a grievance, but may want a formal written notice explaining the resolution. Therefore, we believe that PACE organizations should tailor the notification of the grievance resolution to what a PACE participant prefers.

We propose to establish at § 460.120(i)(2) that oral or written notification of grievance resolutions must include a minimum of three requirements. First, we propose at § 460.120(i)(2)(i) that the notification must include a summary statement of the participant's

grievance including all distinct issues. This is especially important when a grievance cannot be resolved immediately and requires additional investigation. When notifying a participant or other individual who submitted the complaint, it would be important to restate the distinct issues of the grievance so they understand what the organization was investigating and resolving. Second, we propose at § 460.120(i)(2)(ii) that for each distinct issue that requires an investigation, the notification must include the steps taken to investigate the issue and a summary of the pertinent findings or conclusions regarding the concerns for each issue. As we stated earlier, we do not believe that every grievance, or every issue within a grievance, will require an investigation, and some issues may require minimal investigation; however, we believe that to the extent it is applicable it would be important for the individual who submitted the grievance to understand what the organization did during their investigation. Third, we propose at § 460.120(i)(2)(iii) that for a grievance that requires corrective action, the grievance resolution notification must include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur. In the example we used earlier, we noted that during the investigation into the home care aide not cleaning the kitchen, the PACE organization discovered that the home care agency did not have the most current care plan for that participant. The correction that would likely result from that investigation would be to provide the updated care plan to the home care agency and ensure they have received and understand it. This action should be communicated to the participant in order for them to understand how their grievance has been handled and resolved.

Proposed § 460.120(i)(3) would set forth requirements related to how PACE organizations must provide notification when the complaint relates to a Medicare quality of care issue. Specifically, we propose that for Medicare participants, any grievance related to quality of care, regardless of how the grievance is filed, must be responded to in writing. This is consistent with the MA requirement in § 422.564(e)(3)(iii). As previously discussed, Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit

quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act. We propose at § 460.120(i)(3) that, when a grievance relates to a Medicare quality of care issue, the PACE organization must provide a written grievance resolution notification that describes the right of a Medicare participant or other individual specified in § 460.120(d) acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. The only exception to this requirement to provide a written resolution notice would be when the submitter specifically requests not to receive notification as specified in proposed § 460.120(i)(4), which is discussed in more detail in this section of this proposed rule. We also propose to specify that for any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint. This language is consistent with the language used in the MA program, and therefore we are proposing it be added to the PACE regulations as well. Because the QIO's statutory function related to review of quality of care concerns and responses to beneficiary complaints is only applicable to Medicare services and only available to Medicare beneficiaries, and because PACE organizations may have some participants who are not Medicare beneficiaries and may cover non-Medicare services, we expect PACE organizations to work with participants to help them understand whether their grievance relates to a Medicare quality of care issue.

We propose to establish at new § 460.120(i)(4) that the PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive notification of the grievance resolution, and the PACE organization has documented this request in writing. We have heard through our auditing experience that some participants may wish to remain anonymous and some may want to submit a complaint, but they may not wish to receive any notification of the resolution. In order to balance the need for an organization to track and process grievances, with respect for the preferences of participants who wish to not receive communications related to the resolution of a grievance after submitting the initial complaint, we propose to specify in new § 460.120(i)(4) that PACE participants must have

an option to request not to receive any further communication or notification of the grievance resolution following their initial complaint submission. In order for a PACE organization to withhold notification of the grievance resolution for participants who request to exercise this option, the PACE organization would be required to document the participant's request in writing. We propose to include in new § 460.120(i)(4) language that provides that the PACE organization would still be responsible for all other parts of this section.

Section 460.120(d) specifies that the PACE organization must continue to furnish all required services to the participant during the grievance process. We propose to redesignate current § 460.120(d) as § 460.120(j) to account for our other proposals.

Currently, § 460.120(e) requires a PACE organization to discuss with and provide to the participant in writing the specific steps, including the timeframes for response, that will be taken to resolve the participant's grievance. We believe our proposals at § 460.120(c) and § 460.120(i) would ensure that PACE participants receive sufficient notification regarding both the general grievance process and how a specific grievance was resolved. Therefore, we propose to remove current § 460.120(e).

We propose to add a new paragraph § 460.120(k) that would redesignate and modify the requirement that is currently included at § 460.120(c)(4). Specifically, we are proposing that the PACE organization must develop and implement procedures to ensure that they maintain the confidentiality of a grievance, including protecting the identity of any individuals involved in the grievance from other employees and contractors when appropriate. As we stated when discussing the proposed notification requirements at § 460.120(i)(4), we understand that some grievances may be sensitive and some participants or other submitters may wish for their complaint to be kept confidential. For example, if a participant has a complaint related to their physical therapist, that participant may not want the physical therapist to be aware of the complaint. We expect that organizations consider these situations, and have a method for participants that may want certain information to be kept confidential. There may be instances

where a person submitting the complaint may want their identity to be protected, or where the complaint involves a sensitive matter where the identity of all individuals may need to be protected, and we would expect the PACE organization to have a process for ensuring that there is a way to maintain the confidentiality of the identity of any individual involved in the grievance from other employees or contractors when it is appropriate. However, we would reiterate that accepting and processing a confidential grievance would not negate the PACE organization's responsibilities to investigating and resolving the grievance. It also would not negate the responsibilities to document, aggregate and analyze the grievance, as required under current § 460.120(f). Also, as we discussed earlier, we have heard from multiple PACE participants that sometimes participants or their family members are afraid to complain to the PACE organization for fear of reprisal. While we require a PACE organization to ensure that confidentiality of a grievance is maintained, we also want to remind PACE organizations that participants have the right to submit grievances without fear of reprisal. We have heard through oversight and monitoring activities that participants are afraid that they will lose necessary services, or not be approved for services, if they complain regarding the care received by an organization. PACE organizations should ensure that all participants understand that they are free to complain without any fear of reprisal, regardless of what their grievance is about.

We propose to add a new paragraph at § 460.120(l) that aligns with the record keeping requirements for service determination requests, which are set forth at § 460.121(m). Specifically, proposed § 460.120(l) would require that a PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of § 460.120(k), must be available to the IDT to ensure that all members remain alert to pertinent participant information. We expect that PACE organizations have appropriate mechanisms in place for documenting all complaints, including ensuring that oral complaints are documented appropriately, and that written complaints are

maintained as required in § 460.200(d)(2). We believe that proposed § 460.120(k), similar to the § 460.121(m) service determination request, would ensure that all relevant parts of the grievance process are documented, including details of the investigation, the findings, any corrective action that was taken, and the notification (oral and/or written) that was provided to the participant of the resolution.

Finally, current § 460.120(f) requires PACE organizations to maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the PACE organization's quality improvement program. We are proposing to redesignate this as paragraph (m) to account for our other proposals. We are also proposing to remove the word "maintain" that appears in the current regulation text, since the requirement to maintain records has been added to the proposed paragraph (l). Redesignated § 460.120(m), as revised under our proposal, would state that the PACE organization must aggregate and analyze the information collected under paragraph (l) of this section for purposes of its internal quality improvement program. We note that this requirement applies to all grievances; oral or written, including anonymous grievances. We have seen through audit that some organizations do not include all grievances as a part of their internal quality improvement analysis. It is important that PACE organizations consider all complaints that constitute a grievance in order for them to make adequate improvements to their program.

We estimate a one-time burden for PACE organizations to update their grievance materials to meet these proposed requirements. We do not believe there will be a change in annual burden as a PACE organization is already required to provide notification to participants on their grievance resolution, and may opt to do so orally or in writing. Therefore, we believe that the ongoing burden will not change with this proposal. We discuss and account for the one-time burden for PACE organizations to update their grievance materials to meet the proposed new requirements in the Collection of Information Requirements section. We will submit these

changes to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on December 31, 2023.

We solicit comments on this proposal.

L. Service Determination Request (§ 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 participant, 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.

A service determination request is defined at § 460.121(b)(1) as a request to initiate a service, to 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. Once a service determination request is received by the full IDT, the IDT must make a decision on the request and provide notification of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the IDT receives the request, except that the IDT may extend the timeframe for review and notification by up to 5 calendar days if the extension requirements as specified in § 460.121(i)(1) are met. When CMS proposed[223] to require service determination request extension notifications in § 460.121(i)(2), we based the requirement on the MA organization determination requirements in § 422.568, which require written notification when an extension is taken. Comments submitted by PACE organizations and industry advocacy groups regarding our proposal to require written notification of extensions recommended we allow either oral or written notification when the IDT extends the timeframe for a service determination request, rather than requiring written notification only. At the time, we did not finalize the change to allow oral or written notification for extension requests, and we explained that we believed written notification

[223]CMS included this proposal in the February 2020 proposed rule (85 FR 9002).

of the extension was important in order to ensure the participant received a full explanation. Additionally, we explained that providing written notification of the extension would allow the participant to share the information with family members or caregivers, if desired (86 FR 6022).

Since that rule was finalized, PACE organizations have had an opportunity to implement the provision and assess whether written notification is practical for all extensions. Additionally, since the rule was finalized, PACE organizations have been operating under a worldwide pandemic, which has required organizations to increase their ability to engage participants in new ways through the use of remote technology, and utilizing different means of communicating orally has become more prevalent and has proven an effective way to communicate important information quickly. For these reasons, we are now proposing to revise the requirement in § 460.121(i)(2) to allow the IDT to provide notification either orally or in writing to the participant or their designated representative when the IDT extends the timeframe for a service determination request, as permitted under § 460.121(i)(1). Allowing the IDT to provide either oral or written notice of service determination request extensions would increase operational flexibility for PACE organizations without compromising participant safeguards. In order to ensure participants are fully informed of the reason(s) for an extension, we expect oral notice of the service determination request extensions to meet the same requirements as written notice, including the expectations that notices will explain the reason(s) for the delay and be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe. We also expect that PACE organizations would document the content of oral notifications of service determination request extensions in accordance with § 460.121(m). An IDT may choose to provide the extension notification both orally and in writing if it believes that is necessary to ensure the participant's understanding.

We estimate ongoing burden reduction due to the expected decrease in written notifications of service determination request extensions in favor of oral notification. We discuss and account for the burden reduction resulting from the expected decrease in written notification

of service determination request extensions in the Collection of Information Requirements section. We will submit these changes to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on December 31, 2023.

We solicit comment on this new alternative.

M. Participant Notification Requirement for PACE Organizations with Performance Issues or Compliance Deficiencies (§ 460.198)

Sections 1894(f)(3) and 1934(f)(3) of the Act provides CMS the discretion to apply such requirements of Part C of title XVIII and sections 1903(m) and 1932 of the Act relating to protection of beneficiaries and program integrity as would apply to Medicare Advantage (MA) organizations under Part C and to Medicaid managed care organizations under prepaid capitation agreements under section 1903(m) of the Act. Some examples of where CMS has previously exercised this discretion include the development and implementation of requirements related to PACE compliance and oversight, PACE enforcement actions (CMPs, sanctions, and termination), and PACE participant rights and protections.

Under §§ 422.111(g) and 423.128(f), CMS may require an MA organization or Part D plan sponsor to disclose to its enrollees or potential enrollees, the MA organization or Part D sponsor's performance and contract compliance deficiencies in a manner specified by CMS. The purpose of these beneficiary protections is to provide beneficiaries with the information they need to assess the quality of care they are receiving and to make sponsoring organizations accountable for their performance deficiencies, which should improve compliance with the rules and requirements of the Medicare program. Further, in the final rule titled "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (75 FR 19677), which appeared in the April 15, 2010 issue of the **Federal Register**, CMS explained that "our intent is to invoke this disclosure authority when we become aware that a sponsoring organization has serious compliance or performance deficiencies such as

those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. One example of a situation where enrollees should be notified of performance or compliance deficiencies would be when a sponsoring organization fails to provide beneficiaries with the proper premium notices to collect premium amounts in arrears. Another example would be if a sponsoring organization failed to provide access to services and we instructed the sponsor to contact enrollees regarding this issue and assist them with obtaining needed services or medications. In each of these situations we would require a sponsoring organization to disclose the deficiency to its enrollees and take affirmative steps to alleviate any problems for enrollees, such as providing enrollees with options to fix the issue" (75 FR 19734-19735).

In contrast to the Part C and D regulations at Parts 422 and 423, respectively, the PACE regulations at Part 460 do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies. In addition, we note that although regulations at Part 423 generally apply to PACE organizations, § 423.128 was waived for PACE organizations in 2005 (*see* January Part D 2005 final rule (70 FR 4430, 4432-4433)). However, we believe the disclosure of this information would serve as an important protection for PACE participants, as it would help to ensure current and potential PACE participants and their caregivers have adequate information to make informed decisions about whether to enroll in or to continue their enrollment with a PACE organization. PACE participants that are enrolled in the organization and their caregivers should have notice of the PACE organization's performance and compliance deficiencies in order to assess whether they have experienced similar issues that must be addressed by the PACE organization. In addition, for participants that are looking to enroll in a PACE organization, it is important they understand any potential issues that they may experience if they proceed with their enrollment. Finally, it is important to ensure there is public transparency regarding a PACE organization that has, or has had, performance and contract compliance deficiencies.

Therefore, effective beginning in CY 2024, we propose to amend the regulations at Part 460 by adding § 460.198, which would require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS. As in the MA and Part D programs, we anticipate that we would invoke the disclosure requirement when we become aware that a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or requires immediate correction, and where we believe PACE participants and potential PACE participants should be specifically notified.

Consistent with § 423.128(d), CMS waives any provision of the Part D regulations to the extent that CMS determines that the provision is duplicative of, or conflicts with, a provision otherwise applicable to PACE organizations under sections 1894 or 1934 of the Act, or as necessary to promote coordination between Part D and PACE. Because sections 1894 and 1934 of the Act do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies, the regulation at § 423.128(f) does not duplicate, conflict with, or impede coordination between Part D and PACE. In addition, we note that, at the time CMS announced the waiver of § 423.128 in the January Part D 2005 final rule (*see* 70 FR 4432-4433), the disclosure requirement in paragraph (f) did not appear in § 423.128.[224] Therefore, we believe the 2005 waiver of the rest of § 423.128 does not apply to § 423.128(f), and the disclosure of information regarding performance and contract deficiencies concerning a PACE organization in its capacity as a Part D sponsor would serve as an important protection for PACE participants, as it would help to ensure current and potential PACE participants and their caregivers have adequate information to make informed decisions about whether to enroll in or to continue their enrollment with a PACE

[224]The April 2010 final rule (75 FR 19677) amended § 423.128 to include paragraph (f).

organization. This proposed rule does not impact the waiver of the remainder of § 423.128 for PACE organizations, as applicable.

N. PACE Maintenance of Records (§§ 460.200 and 460.210)

Under sections 1894(b) and 1934(b) of the Act, PACE organizations are required to provide all items and services covered under Medicare and Medicaid, and all additional items and services specified in regulations and determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status. Currently, PACE organizations are required to safeguard data and records in accordance with § 460.200(d). PACE organizations must also maintain a single comprehensive medical record for each participant in accordance with accepted professional standards (§ 460.210(a)(1)).

In the February 2020 proposed rule (85 FR 9002), CMS proposed to add a new requirement at § 460.200(d)(2) for PACE organizations to maintain in the medical record all written communications received from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6). We explained in the proposed rule that we had found through our monitoring of PACE organizations that they do not always maintain and safeguard important records such as communications related to a participant's care from family members, caregivers, and the participant's community (85 FR 9134). We stated that maintaining a comprehensive, complete, and accurate medical record allows a PACE organization to remain alert to all information that is relevant to a participant's care, health and safety, and to provide appropriate and timely care to the participant (85 FR 9140). Therefore, we also proposed a new requirement at § 460.210(b)(6) for PACE organizations to maintain in a participant's medical record original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to (i) communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a

participant's health or safety or both; and (ii) communications from an advocacy or governmental agency such as State-based Adult Protective Services.

In the January 2021 final rule, CMS summarized and responded to the comments received on these proposed record maintenance requirements (86 FR 6039 through 6040). We noted that some commenters recommended we allow PACE organizations to maintain original communications *outside* of the medical record systems, as they believed that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format *in* the medical record would compromise the usefulness of the medical record, due to the quantity of information that would be required to be stored (86 FR 6040). Based on these comments, we contemplated allowing original documentation of communications to be summarized in the medical record, so long as PACE organizations maintained the original documentation of the communication in a separate system. Ultimately, we chose not to modify our proposal with the contemplated change of permitting PACE organizations to summarize written communications relating to the care, health, or safety of a participant in the medical record. We did, however, modify our original proposal to allow PACE organizations to maintain in a participant's medical record original documentation, or an electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant. In finalizing this provision, we explained that we were not establishing specific requirements governing where affected communications must be stored within a participant's medical record. We also explained that PACE organizations may operationalize these requirements in accordance with the capabilities of their medical record systems (86 FR 6040).

Participants, their family members, and representatives have a longstanding right to file a grievance expressing dissatisfaction with the delivery of PACE services or the quality of care furnished as part of the PACE benefit package (see §§ 460.112(g)(1) and 460.120). A PACE organization must have a formal written process to evaluate and resolve medical and non-medical grievances by PACE participants (§ 460.120(a)). A PACE organization's grievance

process must include a written procedure for maintaining the confidentiality of a participant's grievance (§ 460.120(c)(4)).

PACE participants routinely file grievances with a PACE organization under the assumption that the details of their grievance will be kept confidential. This is especially important to PACE participants when a grievance involves a particular staff member of the PACE organization (for example, a home care aide, a driver, or a specific member of the interdisciplinary team). PACE organizations have typically maintained confidentiality of this information by only allowing access to the information, that is, the details of the complaint, to a limited number of PACE organization staff and/or by storing this information outside of the medical record in a secure location (for example, a separate electronic application or paper-based system).

Since we finalized the January 2021 final rule, PACE organizations have had an opportunity to implement this provision, and we have continued to receive questions related to maintaining original communications in the medical record. These questions and comments indicate that as PACE organizations have begun to operationalize this requirement, they have been challenged with maintaining the confidentiality of grievances and managing the volume of these communications in the medical record. Other inquires include whether it would be permissible for PACE organizations to scan communications and store them electronically in the medical record.

In addition to the concerns around maintaining the confidentiality of grievances, PACE organizations have also pointed out that there are instances when written communications sent to the PACE organization by the individuals and entities listed at § 460.210(b)(6)(i) and (ii) may contain sensitive information about a PACE participant, their caregivers, and/or family members, and that these communications are often accompanied by a request to keep the information private. For example, information shared with a PACE organization may pertain to a caregiver's health, and may have implications for the participant's care, and the caregiver may only want the

details of this information shared among employees and contractors who need to know the information rather than all individuals with access to the participant's medical record. There are also instances when the communications include contents or language that may be inappropriate for inclusion in the medical record, such as vulgar comments directed towards individual PACE staff. PACE organization staff have indicated that maintaining written communications related to participant grievances in the medical record allows access to the information by all PACE organization staff, thereby jeopardizing the confidentiality of such communications, and have therefore requested clarification from CMS on how to adhere to comply with the requirement in § 460.210(b)(6) when the original communication is part of a participant grievance and contains sensitive or confidential information.

Sections 1894(f)(3) and 1934(f)(3) of the Act provide authority for the establishment of certain additional beneficiary and program protections applicable to MA and Medicaid managed care programs under prepaid capitation agreements under section 1903(m) of the Act. Sections 1894(b)(2) and 1934(b)(2) of the Act require that the PACE program agreement have written safeguards of the rights of enrolled participants, including a bill of rights and procedures for grievances and appeals, in accordance with regulations and with other Federal and State laws designed for the protection of beneficiaries. This authority allows CMS to implement regulations to ensure that PACE participants' rights are protected, including the right to file a grievance anonymously.

To uphold participant rights and help PACE organizations to safeguard anonymity to the extent possible during the grievance process and in other circumstances that involve sensitive information, CMS now proposes, using the authority at sections 1894(f)(3) and 1934(f)(3) of the Act, to amend the PACE regulations at §§ 460.200(d)(2) and 460.210(b)(6) to allow for more administrative flexibility in how PACE organizations maintain written communications relating to the care, health, or safety of a participant.

Specifically, we propose to amend § 460.200(d)(2) to require that a PACE organization must maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety, including, but not limited to, the following: (i) communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's care, health or safety; and (ii) communications from an advocacy or governmental agency, such as Adult Protective Services. This proposal would move and revise language currently located in § 460.210(b)(6) that requires PACE organizations to maintain original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format. By moving this language to § 460.200(d)(2), with the proposed modifications, we would retain the requirement for PACE organizations to maintain these important communications in their original form, while removing the requirement that these communications be stored in the participant's medical record. At § 460.210(b)(6), we propose to replace the current language with a new requirement that states that original documentation or an unaltered electronic copy, of any written communication as described in § 460.200(d)(2), must be maintained in the participant's medical record unless the following requirements are met: (i) the medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication, (ii) original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and (iii) original documentation of the communication is available to CMS and the SAA upon request. This proposal would continue to require PACE organizations to ensure that these important communications relating to the care, health, or safety of a participant are included in the medical record, but it would allow PACE organizations operational flexibility on how these communications are included. PACE organizations would

be permitted, under this proposal, to summarize the information in the medical record, as long as the summary is accurate and thorough, and the original documentation of the communication is maintained outside the medical record and is accessible by the PACE organization's employees and contractors as needed, and available to CMS and the SAA upon request. We believe this proposal would balance CMS' interest in ensuring these communications are safeguarded with PACE organizations' interest in ensuring the medical record is usable and that confidential information may be protected to the extent possible. A PACE organization would be able to include a summary of the information but could choose to exclude names or other potentially sensitive information, provided the requirements under proposed § 460.210(b)(6)(i) through (iii) have been met.

O. PACE Participant Health Outcomes Data (§ 460.202)

Sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act require PACE organizations to collect, maintain, and report data necessary to monitor the operation, cost, and effectiveness of the PACE program to CMS and the State administering agency (SAA).

Following publication of the 1999 PACE interim final rule, CMS established a set of participant health outcomes data that PACE organizations were required to report to CMS. In subsequent years, we have modified the participant health outcomes data on a routine basis to ensure that we are collecting data that is relevant and useful to our efforts to monitor and oversee the PACE program. According to 5 CFR 1320.15, at least once every 3 years, in order to comply with the Paperwork Reduction Act of 1995 (P.L 104-13) (PRA), CMS is required to publish the proposed data collection and solicit public comment. The data collection requirements related to participant health outcomes data can be found in the information collection request currently approved under OMB control number 0938-1264 (CMS-10525). Section 460.202 currently requires participant health outcomes data reported to CMS and the SAA to be specified in the PACE program agreement; however, CMS does not routinely update program agreements based on changes to the required participant health outcomes data. As a result, the quality data

collection specified in the program agreement is often out of date and no longer applicable within a few years.

Since the participant health outcomes data that PACE organizations must report to CMS and the SAA are specified and routinely updated through the PRA process which requires CMS to publish and solicit comments on these data, we propose to amend paragraph (b) of § 460.202 by striking the final sentence, which states, "The items collected are specified in the PACE program agreement." This change would eliminate confusion regarding where the data collection requirements may be found. The PACE program agreement would still include a statement of the data collected, as required by § 460.32(a)(11), but it would not include the level of specificity regarding the data collection that is included in the CMS PRA information collection request approved under OMB control number 0938-1264. We believe that by modifying § 460.202 as proposed we would not be increasing the burden on PACE organizations as they are currently required to furnish information to CMS and the SAA through the aforementioned information collection request.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a "collection of information," as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement 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 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

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 (http://www.bls.gov/oes/current/oes_nat.htm), which, at the time of publication of this rule, provides May 2021 wages. In this regard, Table 7 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 7: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Final Hourly Wage ($/hr)
All Occupations (Enrollees)	00-0000	28.01	0	28.01
Business operations specialists (all others)	13-1199	38.1	38.1	76.20
Compliance officers	13-1041	36.45	36.45	72.90
Computer programmer	15-1251	46.46	46.46	92.92
Computer systems analyst	15-1211	49.14	49.14	98.28
Dietician	29-1031	31.55	31.55	63.10
Family Medicine Physicians	29-1215	113.43	113.43	226.86
General Internal Medicine	29-1216	116.44	116.44	232.88
General operations manager	11-1021	55.41	55.41	110.82
Healthcare Social workers	21-1022	29.96	29.96	59.92
Healthcare technical workers, all other	29-9099	31.19	31.19	62.38
Lawyer	23-1011	71.17	71.17	142.34
Management analysis	13-1111	48.33	48.33	96.66
Medical and health services manager (PACE Center Manager)	11-9111	57.61	57.61	115.22
Occupational therapist	29-1122	43.02	43.02	86.04
Office and administrative assistant	43-9199	20.47	20.47	40.94
Passenger vehicle driver	53-3099	17.51	17.51	35.02
Personal care aides	31-1120	14.07	14.07	28.14
Pharmacist	29-1051	60.43	60.43	120.86
Physical therapist	29-1123	44.67	44.67	89.34
Physician all others	29-1229	111.3	111.3	222.60
Recreational therapist	29-1125	25.91	25.91	51.82
Registered Nurse	29-1141	39.78	39.78	79.56
Software developer	15-1252	58.17	58.17	116.34

As indicated, except for enrollees (All Occupations), we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. However, the mean wage for enrollees (under All Occupations) applies to a group of respondents that varies widely from working and nonworking individuals and by respondent age, location, years of employment, educational attainment, and other factors. We are not adjusting this figure for fringe benefits and overhead since this group includes many individuals who are not working.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II. through VI.) of this proposed rule.

1. ICRs Regarding Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments (§ 422.514)

We propose adding a new paragraph at § 422.514(g) to clarify that the D-SNP look-alike contracting limitations at § 422.514(d) through (f) apply to segments of the MA plan. This new paragraph will address instances we have seen since adopting § 422.514(d) through (f) where a specific segment of an MA plan looks like a D-SNP look-alike and would be subject to the contracting prohibitions in § 422.514(d) if the segment were treated as an MA plan. We believe that by applying the D-SNP look-alike contracting limitations only at the MA plan level without applying it to segments of plans, our existing regulation has an unintended and unforeseen loophole through which D-SNP look-alikes could persist, contrary to the stated objectives in our prior rulemaking.

Based on January 2022 Monthly Membership Report data, we estimate that the proposed change would result in three MA plan segments being identified as D-SNP look-alikes, and these D-SNP look-alikes would likely transition the approximately 3,000 current enrollees into another

MA-PD plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization) using the transition process described in § 422.514(e). Based on our analysis of proposed D-SNP look-alike transitions for contract year 2023, two D-SNP look-alikes in contract year 2022 are proposing to transition a combined total of approximately 7,000 D-SNP look-alike enrollees into two new non-SNP MA plan segments, which could create two new D-SNP look-alikes for contract year 2023.

In the June 2020 final rule (85 FR 33877 through 33880), we estimated each D-SNP look-alike would take a one-time effort of 2 hours for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. We also stated that, after the prohibition on D-SNP look-alikes was implemented, at most five plans per year would be identified as D-SNP look-alikes under § 422.514(d) due to meeting the enrollment threshold for dually eligible individuals or operating in a State that will begin contracting with D-SNPs or other integrated plans. These estimates were submitted to OMB for approval under control numbers 0938-0753 (CMS-R-267). In association with our June 2020 final rule, the requirement and burden estimates (5 respondents, 5 total responses, and 10 total hours) were approved by OMB under control number 0938-0753 (CMS-R-267).

Our proposed clarification at § 422.514(g) does not change the transition process nor our burden estimates. Additionally, the proposed addition of non-SNP MA plan segments to the contracting limitations at § 422.514 does not change our estimates that at most five plans (including PBP segments) per year would be identified as D-SNP look-alikes; therefore, the estimated number of respondents and burden estimates in control numbers 0938-0753 (CMS-R-267) would not change.

2. ICRs Regarding Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the LI NET Program (§ 423.2500 through § 423.2536)

The following proposed changes will be submitted to OMB for review under control number 0938-TBD (CMS-10831). At this time, the control number has yet to be

determined, but will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

As described in section II.D.2 of this proposed rule, we expect that some beneficiaries will enroll in LI NET using methods that may entail providing information. Some beneficiaries, called "immediate need beneficiaries" may enroll in LI NET at the point-of-sale (POS) at a pharmacy because they are likely eligible for the Part D low-income subsidy (LIS), have immediate need for their prescription, and do not have Part D coverage. Some beneficiaries submit receipts for reimbursement for claims paid out of pocket; if they are eligible for LI NET they will be retroactively enrolled into the LI NET program by the LI NET sponsor. Another way for beneficiaries to potentially enrollment into LI NET is by complete an LI NET application form.

To estimate the total burden, we consider the burden for enrollees, pharmacists, and Part D sponsors separately. Each consideration entails counting the number of documents arising from point of sale enrollments, direct reimbursement forms, and LI NET application forms.

For Beneficiaries: To estimate the information collection burden for beneficiaries, we have estimated the number of beneficiaries submitting information to LI NET and time related to handling the information. We have not included burden estimates for individuals who would not be providing documentation, such as those CMS automatically enrolls into LI NET, individuals whose eligibility for LI NET is confirmed independently by the LI NET sponsor, or for those who opt not to provide evidence.

When enrolling in LI NET at POS, possible forms of evidence for LIS eligibility include but are not limited to, a Medicaid card, an LIS award letter, or a declaration to the pharmacist of LIS applicant status. We estimate that it would take an individual approximately 15 minutes (0.25 hr) to gather supporting documentation. There are 36,722

individuals enrolled in the LI NET demonstration at POS in 2021 who will apply at the point of sale. Based on our experience with the LI NET demonstration, we estimate approximately 250 beneficiaries would submit receipts for reimbursement for claims paid out of pocket. These beneficiaries may complete a direct reimbursement request form available online, and return by mail, e-mail, or fax, together with their receipt, to the LI NET sponsor. In the LI NET demonstration, approximately ten beneficiaries per year complete the LI NET application form, which is available online, and return it to the LI NET sponsor by mail, e-mail, or fax. Thus, in total we expect 36,982 beneficiaries (36,722 at point of sale plus 250 through direct reimbursement plus 10 applying via the LI NET application form) to spend 15 minutes (0.25 hr) resulting in an aggregate burden of 9,246 hours (36,982 enrollees * 0.25 hr) at an aggregate cost of $258,980 (9,246 hr. * $28.01/hr).

For the Private Sector (Pharmacists): We estimate that it will take 2 minutes (0.0333 hr) for a pharmacy to fax the documentation to the LI NET sponsor. However, pharmacists will not process the forms of enrollees who use direct reimbursement or the LI NET application form. Thus, pharmacists will only process the 36,722 enrollees at point of sale. Thus, the aggregate burden for pharmacists is 1,223 hours (36,722 enrollees * 0.0333 hr) at an aggregate cost of $147,812 (1,223 hr * $120.86).

For Part D Sponsors: The Part D sponsors will process the documents received from all 36,982 enrollees. Part D sponsors are estimated to spend about 2 minutes (0.0333 hr.) to fax information and to CMS and process information. Thus, the aggregate burden for Part D sponsors is 1,232 hours (36,982 enrollees * 0.0333 hr) at an aggregate cost of $93,878 (1,232 hr * $76.20/hr).

3. ICRs Regarding Adding New Behavioral Health Specialty Types Subject to Network Adequacy Evaluation (§ 422.116)

In order 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 new specialty types that will be subject to network adequacy evaluation under § 422.116. We are proposing to add Clinical Psychology, Clinical Social Work and Prescribers of Medication for Opioid Use Disorder under § 422.116(b)(1).

To determine the potential burden regarding this proposal, we considered cost estimates for CMS making programming updates to the HPMS system, which is utilized to conduct automated reviews; additional burden, including updating policies and procedures, for CMS contractor; and additional burden, including updating policies and procedures, for MA organizations.

We have determined that there is a $0 cost for programming HPMS with regard to this proposal. Adding new specialty types to the automated review conducted by HPMS would be covered under funding currently in place for updating the system.

The CMS contractor does not indicate any additional costs to carry out the work required by this proposal, therefore there is no impact.

We have determined that there is a $0 cost for MA organizations in regards to reporting new specialty types to CMS for their network adequacy reviews as this proposal requires. However, 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 three years for the triennial review. Further, organizations should already have these specialty provider types within network, as these are services covered by Medicare Part A and B and which are furnished by these specialty types, so

there is no burden related to contracting with new provider types. This proposal would only require that the proposed specialty types 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 types are included. We estimate that a business operations specialist working at an hourly wage of $76.20/hr will take five minutes (0.0833 hr) for a one-time update of policies and procedures related to this task, at a cost of $6.35 (0.0833 hr * $76.20/hr). The aggregate burden is 62 hours (742 MA contracts * 0.0833) at a cost $4,724 (62 hours * 76.20/hr).

These changes will be submitted to OMB for approval under control number OMB 0938-1346. Subject to renewal, the control number is currently set to expire on November 30, 2024. It was last approved on January 13, 2022 and remains active.

4. ICRs Regarding Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 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 described in section III.D. of this proposed rule, we are proposing to revise: (1) § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur; and (2) § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

This proposal to amend §§ 422.111(e) and 422.2267(e)(12) would impact MA organizations in terms of the burden required to identify those enrollees who must be notified of provider contract terminations per CMS requirements, to develop and send the required written

notices, to develop the scripts for the required telephonic notices, and to make the required enrollee telephone calls and any necessary follow-up calls. However, CMS does not currently collect data regarding the widely variable number of provider contract terminations an MA organization undergoes in a given contract year, nor the number of enrollees affected by each termination. Therefore, we do not have information to estimate the extent of MA provider contract terminations, how many enrollees are affected and need to be notified per § 422.111(e), or how the MA program would be impacted as we see the effects of the proposed regulation. The actual direct burden of this provision arises from MA organization staff hours spent, resources purchased, and enrollee notifications provided. MA organizations may also differ in how their spending for the proposed requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation.

Despite our inability to quantify certain burden for this proposal, we are able to estimate the one-time burden on MA organizations to update their existing written provider termination notice in compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii). We expect MA organizations to engage in some routine software development to update their notice template and related systems to incorporate the new proposed requirements, which we are proposing will be delineated in a provider termination model document developed by CMS staff (thus not incurring COI burden). This proposed model will be posted for public review and comment in conjunction with the proposed rule's CMS-R-267 PRA package. We estimate that one or two software developers working at a wage of $92.92/hr will spend a total of 8 hours updating an MA organization's existing provider termination notice template and related systems based on CMS's model. With approximately 697 MA organizations impacted by this proposed change, this results in a total of 5,576 hours (697 MA organizations * 8 hours), at an aggregate cost across all MA organizations of $518,122 (5,576 hours * $92.92/hr). We are unable to estimate the burden for the proposed telephonic notice requirement at proposed §§ 422.111(e)(1)(i) and 422.2267(e)(12)(iii) because the number of

primary care and behavioral health provider contract terminations an MA organization undergoes in a given contract year is unknown, as are the number of affected enrollees per termination.

5. ICRs Regarding Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization (§422.101)

The requirements and burden related to Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization will be submitted to OMB for approval under control number (0938-0753) (CMS-R-267). As explained in section III.E. of this rule, we propose that MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations when making medical necessity determinations. This rule proposes that MA plans must follow Traditional Medicare coverage criteria as specified in NCDs, LCD, or Medicare laws (that is, in Medicare statutes and regulations).

This rule further proposes that in the absence of coverage criteria in an applicable Medicare statute or regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature and that this evidence must be made publicly available.

This rule also proposes a new requirement that in creating these internal policies, MA organizations must provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. We expect that each plan annually will have new policies that they create.

We believe that the public posting of the summary of evidence used to develop a plan's internal coverage criteria would require minimal time. We estimate that over the course of a year 2 business days or 16 hours would be an adequate estimate of time needed for a business operations specialist to make all postings. Thus the per contract burden is 16 hours at a cost of

$1,219 (16 * $76.20) and the aggregate burden over 697 contracts is 11,152 hours (697 contracts * 16 hours/contract) at a cost of $849,782 (11,152 hr * $76.20/hr)

We invite stakeholder comment on all aspects of this proposal. More specifically, we ask (1) is our assumption that plans are already complying with the requirement of creating new guidance correct? (2) is our assumption of 16 hours annually sufficient? (3) Are there any other aspects of this proposal or its estimates upon which stakeholders have comments?

6. ICRs Regarding Utilization Management Committee (§ 422.137)

This rule proposes protections to help ensure that beneficiaries maintain access to medically necessary Part A and B services and drugs, while permitting MA plans to use utilization management tools, such as prior authorization. This proposed rule requires that MA plans establish and use a committee (similar to a P&T committee) that reviews PA policies annually to ensure the policies are consistent with current traditional Medicare coverage and guidelines in Medicare statutes and regulations, NCDs, and LCDs. This proposed rule requires the committee to review all medical services that require PA and other utilization management policies, at least on an annual basis and to document their findings. Additionally, the committee would be responsible for revising and updating the MA plan's utilization management policies as needed.

Specifically, we propose at 422.137 (c)(1) through (4) that the UM committee must clearly articulate and document processes to determine that the committee membership requirements under the proposed 422.137 (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. We estimate it would take 1 hour at $76.20 /hr for an UM Committee business specialist to perform certain tasks and review and retain documentation and information on an annual basis. Additionally, we propose at § 422.137(d)(4) and (5) that the committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available

to CMS upon request. We estimate that it will take 2 hours at $ 76.20 /hr for a UM Committee business specialist to capture and retain this required documentation on an annual basis. We invite stakeholder comment on these assumptions.

The aggregate burden for each of the 697 MA plans would be 2,091 hours (697 plans * 3 hours) at a cost of $159,334.2 (2,091 hours * 76.20/hr).

7. ICRs Regarding Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service (§§ 422.566 and 422.629)

The following proposed changes will be submitted to OMB for review under control number 0938-0753 (CMS-R-267).

In section III.N. of this proposed rule, we have proposed to strengthen the current requirement at §§ 422.566(d) and 422.629(k)(3) for who must review an organization determination or an integrated organization determination when the MA organization or AIP expects to issue a partially or fully adverse medical necessity decision.

Under the existing requirements, if a plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. We are proposing that additionally, the reviewing physician or health care professional must have expertise in the field appropriate to the requested service. As discussed in the preamble, this proposal will also apply to coverage denials from section 1876 cost plans and healthcare prepayment plans because §§ 417.600 and 417.840 require those plans to comply with the requirements in the MA regulations regarding organization determinations.

We next discuss the implications of this proposal for staffing and for appeals. We do not believe this proposal will impose additional staffing burden on plans. In light of existing review requirements applicable to organization determinations and integrated organization determinations, coupled with the requirements at § 422.152 for MA plans (including AIPs) to engage in ongoing quality improvement (including in processing requests for initial or continued authorization of services) and the contract requirement provisions at § 422.504, we believe plans already have the requisite expertise in staffing to satisfy the proposed requirement. Therefore, the proposed requirement that the physician or other appropriate health care professional have expertise in the field appropriate to the requested service may at most result in plans reallocating staff resources in certain cases to ensure that someone with appropriate expertise is reviewing the request; however, we don't believe that this proposal will require additional staffing for MA organizations and AIPs.

If this proposal is finalized, MA organizations and AIPs would maintain the flexibility to utilize a physician or other health care professional, so long as they have expertise in the field of medicine that is appropriate for the services at issue. Under this proposed approach, an appropriate physician or other health care professional with expertise appropriate to the requested service would be reviewing the coverage request at a lower level of review.

However, this proposed provision would enhance medical review activities and plan operations related to organization determinations resulting in reduced burden. We note that the existing medical necessity review function is not identified as a separate line item in the aforementioned PRA package (CMS-R-267). However, this function is inherent in, and bundled into, the overall processing of organization determinations and appeals that is accounted for in this package. Because a separate and discrete burden estimate has not previously been submitted to OMB for the medical necessity review function, we are requesting OMB's review and approval under the aforementioned control number. The following table summarizes relevant plan reported data we have on organization determinations and our estimates related to this

proposal to require medical review by physicians or other health care professionals with expertise in the field of medicine appropriate to the requested service. As explained more fully below, if this proposal is finalized we expect savings due to fewer denied organization determinations getting into the appeals process as a result of enhanced medical necessity review by appropriate experts.

TABLE 8: EXPECTED IMPACT OF PROPOSAL ON APPEALS

Item	Current Regulations	Proposed Under CMS-4201-P	Comments
Number of pre-service decisions	31,346,194	31,346,194	No change
Percent of unfavorable pre-service organization determinations	0.057	0.0285	We assume a savings of 50% in unfavorable decisions
Number of unfavorable pre-service organization determinations	1,786,733	893,367	Product of previous two rows (-893,366 or roughly 50% savings)
Percent of unfavorable pre-service organization determinations that are appealed	0.09	0.09	No change
Number of unfavorable pre-service organization determinations that are appealed	160,806	80,403	Product of previous two rows (-80,403 or 50% savings)
Percent of appeals resulting in an overturn	0.81	0.81	No change
Number of appeals resulting in an overturn	130,253	65,126	Product of previous two rows (-65,127 or roughly 50% savings)
Time for a single appeal notifications (hr)	0.25	0.25	No change
Total time (hr)	32,563	16,282	Product of previous two rows (-16,281 or roughly 50% savings)
Wage of business operations specialist	$76.20/hr	$76.20/hr	No change
Total Cost	$2,481,301	$1,240,688	Product of previous two rows

According to 2020 MA plan reported data, 1,786,733 (5.7 percent of all 31,346,194 Medicare pre-service organization determination decisions) are unfavorable coverage decisions (the decision is fully or partially unfavorable to the enrollee). Of this universe of unfavorable pre-service organization determinations, 160,806 cases (9 percent * 1,786,733) are appealed and subject to reconsideration by the plan. Of the cases reviewed on appeal, 130,253 cases (81 percent * 160,806 cases) of the reconsiderations resulted in a plan overturning its unfavorable organization determination.

Thus, the total burden is 32,563 hr (130,253 cases * 0.25 hr/case) at a cost of $2,481,317 (32,563 hr * $76.20/hr for a business operations specialist).

Assumptions about the proposal: There is a high percentage of cases overturned on appeal by the plan. We believe that strengthening the regulations at §§ 422.566(d) and 422.629(k)(3) to require the physician or other health care professional who reviews the initial

coverage decision to have expertise in the field of medicine that is appropriate for the requested service or item ensure the appropriate level of protection for enrollees. For example, if plans are able to approve more coverage requests that involve medical necessity decisions at the organization determination level of review, this is likely to reduce costs associated with the administrative appeal process because fewer denials will occur at the initial level of review and, in turn, fewer cases are likely to get into the appeals process.

While we don't know with certainty what the reduction in existing denied organization determinations will be if this proposal is finalized, we believe it is reasonable to estimate that one-half (50 percent) of the existing volume of denials will result in a favorable decision given the enhanced standard of review. In other words, having a physician or other health care professional with expertise in the field of medicine appropriate to the requested service will result in a favorable organization determination decision, thereby reducing the number of cases potentially subject to appeal. In the absence of further information, we believe this a reasonable assumption. We solicit stakeholder input on the reasonableness of this assumption and whether their experience suggests some other savings.

Proposed Burden: Therefore, if this proposal is implemented, we estimate that 2.85 percent (one-half of the current rate of 5.7 percent), or 893,367 (0.0285 * 31,346,194 pre-service organization determinations) of the organization determinations will be unfavorable. At the previously stated appeal rate of 9 percent of unfavorable pre-service organization determinations being appealed to the plan, the number of cases will be 80,403 (0.09 * 893,367) reconsiderations (plan level appeals). Assuming the overturn rate of 81 percent remains, we expect overturns of 65,126 cases (0.81 * 80,403 cases).

We estimate that a physician spends 30 minutes reviewing a case for medical necessity. Under our proposal the same 30 minutes will be used for review; however, the review will occur at the organization determination level of review rather than at the appeal level of review. Thus, we expect no savings from physician review.

However, savings will occur as a result of a reduction is issuing appeal notices if the plan is able to approve more requests at a lower level of review (resulting in fewer appeals). We estimate that a business operations specialist spends 15 minutes generating and sending the notice of the appeal decision, or 16,282 hours (80,403 cases x 0.25hr/case) at a cost of $1,240,688 (16,282 hr * $76.20/hr).

Savings: To estimate savings associated with this proposed rulemaking, we note that the proposed rule estimates 50 percent of the burden of the current practice and hence the savings is also 50 percent. That is, the numbers in the column with proposed burden are numerically equal to the savings: 16,282 hours and $1,240,688 ($76.20/hr x 16,282).

We recognize that there are circumstances in which the plan is unable to make a fully favorable organization determination based on the information they have available to them before the end of the applicable adjudication timeframe. However, we believe that there remains a proportion of cases that contain the necessary information needed to approve coverage that may have a higher likelihood of approval if the individual reviewing the case has specific expertise related to the item or service being requested.

8. ICRs Regarding Strengthening Updating Translation Requirements Standards for Required Materials and Content: Require FIDE SNPs and HIDE SNPs and Applicable Integrated Plans to Translate Materials into the Medicare Translation Standard Plus Additional Medicaid Languages (§§ 422.2267 and 423.2267)

We are proposing to require that FIDE SNPs, HIDE SNPs, and AIPs translate materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

This rule proposes to slightly modify existing policy, so the impact to FIDE SNPs, HIDE SNPs, and AIPs depends upon whether, and to what extent, these plans are already translating materials in ways that would meet our proposed requirements. We note that translation

requirements vary by State. Therefore, we expect no impact in States where the applicable Medicaid and Medicaid translation requirements result in the same outcome. We expect marginal impacts where State requirements result in translation into languages not required by the current MA rules at §§ 422.2267(a)(2) and 423.2267(a)(2). However, even in these States, FIDE SNPs, HIDE SNPs, and AIPs (in combination with their affiliated Medicaid managed care plans) have translators on staff or access them via contractors because of existing Medicare and Medicaid translation requirements.

Consistent with our April 15, 2011 final rule (76 FR 21536), (CMS–4144–F, RIN 0938–AQ00), we continue to claim that the Medicare translation requirement is exempt from the requirements of the PRA since the time, effort, and financial resources necessary to comply with the proposed translation requirements is a usual and customary business practice (see 5 CFR 1320.3(b)(2). For a full accounting of the translation burden, please see section IX.D.3.b. of this proposed rule.

9. ICRs Regarding Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

The following proposed changes will be submitted to OMB for review under control number 0938-1051 (CMS-10260).

We are proposing several changes to the marketing policies in subpart V of parts 422 and 423. Each of these proposed changes would require updates to policies and procedures on the part of a business operations specialist, entailing the addition of a phrase or sentence and, as such, not requiring much time. We will estimate the time required for each proposed regulatory change in this section of this rule. For those instances where we believe the burden to plans is greater than a change to policies and procedures, we will elaborate on what we expect that burden to be.

For our proposed reinstatement of the prohibition on MAOs and Part D sponsors marketing outside of their service areas (unless unavoidable), we estimate ½ hour to implement the change to policies and procedures (.5 hour x $76.20/hour = $38.10).

For our proposed reinstatement of the prohibition on sales presentations following educational events, we estimate ¼ hour to implement the change to policies and procedures (.25 hour x $76.20/hour = $19.05).

For our reinstatement of the prohibition on distribution and collection of Scope of Appointment and Business Reply Cards by agents at educational events, we estimate ¼ hour to implement the change to policies and procedures (0.25 hour x $76.20/hour = $19.05).

For our reinstatement of the prohibition on conducting a sales/marketing or enrollment meeting with a beneficiary before 48 hours after the beneficiary's initial consent to the meeting (via scope of appointment), we estimate ¼ hour to implement the change to policies and procedures (0.25 hours x $76.20/hour = $19.05).

For the clarification of the requirement of a plan to notify CMS of any agent that fails to adhere to CMS requirements, we estimate 1/2 hour to implement the change to policies and procedures 0(.5 hours x $76.20/hour = $38.10). We estimate that this policy change does have burden, however we have no way of estimating the number of agents and frequency of which they will violate CMS requirements. Therefore, we cannot estimate it. We do, however, solicit industry and more general input on the burden associated with this proposed requirement.

For the requirement that agents/brokers inform beneficiaries that the beneficiaries can obtain complete Medicare information from 1-800-MEDICARE, SHIPs, or Medicare.gov, we estimate ½ hour to implement the change to policies and procedures (0.5 hours x $76.20/hour = $38.10).

For the requirement that agents/brokers ask a standardized list of questions prior to enrolling the beneficiary in a plan, we estimate ½ hour to implement the change to policies and procedures (0.5 hours x $76.20/hour = $38.10). CMS has already developed the questions as part

of the Pre-Enrollment Check List. CMS does not require agents/brokers to develop the questions themselves. As the questions were already developed, and the development was by CMS staff, development of the questions does not incur COI burden.

For the requirement that agents/brokers inform beneficiaries of all the plans the agent/broker actually sells, we estimate ¼ hour to implement the change to policies and procedures (0.25 hours x $76.20/hour = $19.05).

For the changes that clarify the prohibition of the use of the term "Medicare" or CMS's logos in a way that is misleading or confusing or which misrepresents the plan, we estimate ¼ hour to implement the change to policies and procedures (0.25 hours x $76.20/hour = $19.05).

Thus, the total one-time burden per contract for these marketing provisions is 3.25 hours (0.5+0.25+0.25+0.25+0.5+0.5+0.5 +0.25+0.25 for the time required to update policies and procedures on the prohibitions of marketing outside the service area, of sales following educational events, of distribution of business cards, as well as the required 48-hour wait time for agents, reporting to CMS delinquent agents, disclosing 800-Medicare, using a standardized list of questions, for agents to notify beneficiaries of all plans they represent, and to avoid misleading use of the Medicare log respectively) at $76.20/hour for a total of $247.65. The aggregate burden across 697 contracts is 2265 hr (3.25*697) at a cost of $172,593 ($76.20/hr * 2265 hr).

10. ICRs Regarding Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

The following proposed changes will be posted for public review under control number 0938-0964 (CMS-10141) using the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. The 60-day notice will publish soon after the publication of the final rule (CMS-4201-F).

In the proposed provision, "Changes to an Approved Formulary" (see section III.Q. of this proposed rule) we propose to codify guidance in place since early in the Part D program. The

burden associated with the negative change request process and notice of negative formulary changes to CMS, affected enrollees, current and prospective enrollees, and other specified entities (as listed in § 423.120(b)(5)(i)) was not accurately captured under the aforementioned OMB control number, which simply included a lump sum of 40 hours per Part D sponsor for a business operations specialist to complete notice requirements to CMS and other entities and did not include notice to affected enrollees. Similarly, the aforementioned control number does not include burden associated with updating the Part D formulary on the Part D sponsor website as required per § 423.128(d)(2)(ii)-(iii). We are now quantifying burden associated with negative formulary changes in a more granular fashion, which includes notice to affected enrollees and online notice by updating the formulary posted on the Part D sponsor website, which we believe to reflect the operational processes which Part D sponsors have been following. As such, we do not believe this reflects added burden for Part D sponsors but rather quantifies the burden that Part D sponsors have been assuming over the course of the Part D program. As noted in section III.Q.1. of this proposed rule, we believe Part D sponsors have been following published guidance since CMS has operational oversight of negative change requests and corresponding formulary updates and we are not aware of significant complaints that beneficiaries are being subjected to negative formulary changes without proper notice.

Immediate formulary changes require advance general notice that such changes may occur at any time. Advance general notice to CMS of immediate substitutions is currently incorporated into annual bid submission workflow as a simple checkbox, which we do not believe has added substantial burden to the overall bid submission process. Language constituting advance general notice of immediate formulary changes (that is, immediate substitutions, positive formulary changes, and market withdrawals) for other specified entities and current and prospective enrollees, is already incorporated into model formulary and evidence of coverage documents and we do not believe our proposed changes would add a substantial burden to preparing the documents outside of the routine annual updates. The burden attributed

to the dissemination of Part D plan information is approved under the aforementioned control number at 80 hours annually for each Part D contract's business operations specialist to prepare required plan materials consistent with § 423.128(a), which includes annual updates to the formulary and evidence of coverage documents, among other information. Since language has already been incorporated into the model documents used by Part D sponsors to update their materials and since CMS-10141 has been posted for comment multiple times since the requirements related to advance general notice were codified at § 423.120(b)(5)(iv)(C) (which we are proposing to move to § 423.120(f)(2)), we continue to assume the accuracy of this estimate.

Part D sponsors notify CMS of their intent to make a negative formulary change by submitting a negative change request (NCR) via the Health Plan Management System (HPMS) NCR module. Part D sponsors provide CMS notice of changes which do not require NCRs by submitting updated formulary files during monthly windows, which is a standard formulary management operation. Part D sponsors submit formularies which can be used across multiple contracts and plans. In 2021, CMS approved 551 formularies which were used across 946 contracts and 6,679 plans offered by 206 parent organizations. Since there are some efficiencies with respect to formulary management and NCR submissions (for example, NCRs submitted for one formulary can be applied to others in a streamlined manner), we estimate burden at the parent organization level. However, not all Part D sponsors submit NCRs. In 2021, 136 parent organizations submitted 3,642 NCRs for 321 formularies. We believe that generally a pharmacist is responsible for managing NCR submissions and that each NCR takes approximately 5 minutes (0.0833 hr) to submit through the HPMS module, based on CMS internal user testing. In total, for 136 parent organizations, the burden to submit NCRs is estimated to be 303 hours (3,642 NCRs x 0.0833 hr per NCR) at a cost of $36,621 ($120.86/hr x 303 hr).

Part D sponsors include immediate formulary changes, approved negative changes, and any enhancements (for example, addition of newly approved drugs, moving a drug to a lower

cost-sharing tier, removing or making less restrictive utilization management requirements) to their formularies consistent with formulary requirements. Generally, every formulary is updated during these monthly formulary update windows and CMS reviews all changes to ensure they are consistent with regulatory requirements. Since every parent organization generally updates their formulary regardless of whether any negative changes are made, we estimate burden for all 206 parent organizations representing 551 formularies in 2021. There are 11 formulary update windows per year (monthly from January to November). We believe a pharmacist is generally responsible for managing formulary submissions. In this case, 6,061 formulary submissions (551 formularies x 11 submission windows). We estimate that each formulary file update requires 2 hours to prepare, for a total of 12,122 hours (6,061 submissions x 2 hr per submission) at a cost of $1,465,065 (12,122 hr x $120.86/hr).

In addition to notifying CMS in the manner described, Part D sponsors are required to notify other specified entities of formulary changes. As defined in § 423.100, "other specified entities" are State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists. Online postings that are otherwise consistent with requirements for notice to other specified entities may constitute sufficient notice of negative formulary changes, although sponsors may use mechanisms other than the online postings to notify other specified entities of midyear formulary changes as well. Requirements for Part D sponsors' internet website include the current formulary for the Part D plan, updated at least monthly consistent with § 423.128(d)(2)(ii), and advance notice of negative formulary changes for current and prospective enrollees, consistent with § 423.128(d)(2)(iii) as we propose to revise it. To estimate burden associated with providing notice of formulary changes to other specified entities, we calculate the time and cost associated with updating the formulary and providing notice of drugs affected by negative formulary changes (such as a summary table which lists such changes) on the Part D sponsor's website. For 551 formularies in 2021, monthly

updates would be posted at least 12 times annually for a total of 6,612 postings (551 formularies x 12 updates/year) by all 206 parent organizations. We estimate that it would take 1 hour to update the website consistent with the requirements at § 423.128(d)(2)(ii) and (iii) and that a computer programmer would be responsible for such postings for a total annual burden of 6,612 hours (6,612 updates x 1 hr/update) at a cost of $614,387 ($92.92/hr x 6,612 hr).

Enrollees affected by negative formulary changes are currently required to receive direct written notice as described at § 423.120(b)(5)(i)(A) and (b)(5)(ii). We propose to move this requirement to § 423.120(f) and (f)(4), respectively. CMS provides a model "Notice of Formulary Change" which sponsors may use to meet regulatory requirements. Affected enrollees include those who are subject to immediate substitutions and maintenance formulary changes. The notice requirement is the same, with the exception that enrollees subject to immediate substitutions receive notice retrospectively while enrollees subject to maintenance formulary changes receive notice in advance of the change. Under the proposed rule codifying current operational guidance, there would be no affected enrollees subject to non-maintenance changes since these types of changes would be permitted only when enrollees taking the drug subject to the non-maintenance change are exempt from the change (that is, "grandfathered") for the remainder of the contract year. CMS does not collect data on the number of enrollees affected by negative formulary changes. In order to estimate the number of affected enrollees, we used 2021 data on the total number of Part D enrollees (across the entire program) taking each drug subject to the negative formulary change during the contract year. We then calculated the estimated number of affected enrollees by prorating the number of enrollees taking the drug across the entire program based on the relative proportion of the Part D plan's enrollment to the total Medicare Part D enrollment.

The following example illustrates this process. As of December 2021, there were 49,289,670 Part D enrollees. As stated previously, multiple contracts and plans may share the same formulary. A negative formulary change submitted for Drug A on a particular formulary

impacted a total of 6 individual plans utilizing this formulary. The total number of Part D enrollees taking Drug A in 2021 was 25,717. The total number of enrollees in the 6 plans implementing the negative formulary change was 40,045, representing 0.0812 percent of the total Part D enrollment (40,045/49,289,670). We then assume that of the 25,717 Part D enrollees taking Drug A during 2021, that 0.0812 percent or 21 enrollees (25,717 x 0.000812) were affected by the negative formulary change. This logic was applied across all immediate substitutions and maintenance formulary changes submitted during 2021. We do not estimate enrollees affected by market withdrawals since these occur infrequently and unpredictably (historically occurring every few years) and the number of enrollees affected could vary substantially depending on the drug implicated.

In total, there were 164 parent organizations that implemented immediate substitutions or maintenance formulary changes for 379 formularies used for 576 contracts and 3,735 plans affecting a total of 65,535 enrollees. We do not attribute substantial burden associated with incorporating the model notice into Part D sponsors' internal systems for mailing, since this would have been a one-time initial upload with minor updates annually. We therefore calculate non-labor costs associated with sending notice of formulary change to affected enrollees. Enrollees may opt in to receiving communication materials electronically rather than via hard-copy mailings; however, consistent with informal communication from stakeholders for other required documents, we assume all affected enrollees prefer hard-copy mailings. Costs for hard-copy mailings include paper, toner, and postage.

- Cost of paper: We assume $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).

- Cost of toner: We assume a cost of $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).

• Cost of postage: The cost of first-class metered mail is $0.57 per letter up to 1 ounce. We are using metered mail because these notifications contain confidential beneficiary information and therefore a bulk mailing cannot be used.

++ A sheet of paper weights 0.16 ounces (5 pounds/500 sheets x 16 ounces/pound). We estimate each mailing to consist of 2 pages or 0.32 ounces, so no additional postage for mailings in excess of 1 ounce is anticipated.

Thus, the aggregate cost per mailing is $0.598 ([$0.007 for paper x 2 pages] + [$0.007 for toner x 2 pages] + $0.57 for postage). We estimate the total annual mailing cost at $39,190 ($0.598 per notice x 65,535 affected enrollees).

The summary of burden, labor and non-labor costs, associated with this provision is summarized in Table 9.

TABLE 9 CHANGES TO AN APPROVED FORMULARY

Regulatory Citation	Response Summary	Total Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Wage ($/hr)	Total Annual Cost ($)
Current: §423.120(b)(6)(ii)(A)(*1*) Proposed: §423.120(e)(1)	Submit Negative Change Request	136	3,642	0.0833	303	120.86	36,621
Current: §423.120(b) Proposed §423.120(f)	Update Formulary in HPMS	206	6,061	2	12,122	120.86	1,465,065
No Proposed Change: §423.128(d)(2)(ii)-(iii)	Updating Formulary and Providing Online Notice of Changes on Website	206	6,612	1	6,612	92.92	614,387
Current: §423.120(b)(5)(i)(A) and (b)(5)(ii) Proposed: §423.120(f) and (f)(4)	Direct Written Notice to Affected Enrollees	164	65,535	n/a	n/a	n/a	39,190*
TOTAL		206	81,850	Varies	19,037	Varies	2,155,263

*Non-labor cost.

11. ICRs Regarding Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d))

The following proposed changes will be submitted to OMB for review under control number 0938-1154 (CMS-10396).

Based on analyses conducted on MTM plan-reported and validated beneficiary-level data from 2020, CMS proposes the following combination of changes to the MTM program targeting criteria:

- Requiring plan sponsors to target all core chronic diseases, and continuing to allow them to add other chronic diseases;
- Codifying the current 9 core chronic diseases in regulation and adding HIV/AIDS, for a total of 10 core chronic diseases;
- Lowering the maximum number of covered Part D drugs, a sponsor may require from 8 to 5 drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and
- Revising the annual cost threshold ($4,935 in 2023) methodology to be based on the average annual cost of 5 generic drugs ($1,004 in 2020);

Taken together, we estimate that these proposed changes would increase the number (and percentage) of Part D beneficiaries eligible for MTM services by 6,485,066 from 4,508,762 (9 percent of all Part D beneficiaries) to 10,993,828 (22.93 percent of all Part D beneficiaries). While we considered multiple alternative proposals, we ultimately proposed this combination of changes as a way to close significant gaps in MTM eligibility while balancing program size and burden on Part D sponsors.

Under § 423.153(d), all MTM enrollees must be offered a CMR at least annually and Targeted Medication Reviews (TMRs) no less than quarterly. A CMR is an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider that includes a review of the individual's medications and may result in the creation of a

recommended medication action plan. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. Under § 423.153(d)(1), plans are required to provide all enrollees targeted for MTM services with information about safe disposal of prescription medications that are controlled substances. Plans may mail this information as part of the CMR summary, a TMR, or other MTM correspondence or service. In this section we are estimating the additional burden that would be placed on plan sponsors to conduct CMRs (labor cost) and mail the written CMR summaries (non-labor cost) to the additional beneficiaries that would be targeted for MTM programs based on our proposed revisions. We also estimate the cost of sending safe disposal information to the beneficiaries who would be newly targeted under these revised criteria, but do not receive a CMR.

To obtain aggregate burden we separately estimate: (1) the burden for pharmacists to complete the CMR; (2) the mailing costs of the CMRs; and (3) the cost of mailing of safe disposal instructions to those targeted beneficiaries who did not accept the offer of a CMR.

- The burden for pharmacists to complete the CMR: Based on internal data, we found 63.6 percent of MTM program enrollees accepted the offer of a CMR in 2020. To estimate the cost of conducting the additional CMRs, we multiply the expected number of additional MTM program enrollees (6,485,066) by 0.636 to obtain the number of additional CMRs we estimate will actually be conducted (4,124,502). We estimate a pharmacist would take 40 minutes (0.6667 hr) at $120.86/hr to complete a CMR. Thus, the total burden is 2,749,805 hours (0.6667 hr/CMR * 4,124,502 enrollees who accept the CMR offer) at a cost of $332,341,432 (2,749,805 hr * $120.86/hr).

- Mailing Costs of CMRs. To estimate the cost of sending the CMR summaries, we assume that the average length of a CMR is 7 pages (including 1 page for information regarding safe disposal). Therefore, the first class postage costs $0.81 per metered mailing. Paper costs are $0.007 per sheet ($3.50 per ream/500 sheets per ream) and toner costs $70.00 per cartridge and lasts for 10,000 sheets (at $0.007 per sheet = $70.00/10,000 sheets). Thus, the total cost per

CMR mailing is $0.908 ($0.81 postage + [7 sheets/CMR * $0.014]. Therefore, the annual cost of mailing CMRs to the additional 4,124,502 beneficiaries expected to accept the CMR offer is $3,745,048 (4,124,502 enrollees x $0.908/mailing).

• Mailing costs for safe disposal information: Out of the 6,485,066 additional beneficiaries expected to be targeted for MTM based on the revised criteria, we expect that 36.4 percent or 2,360,564 (6,485,066 * 0.364) will decline a CMR. These enrollees will still need to receive information regarding the safe disposal of prescription drugs that are controlled substances. For purposes of calculating the burden, we are assuming that any safe disposal information that is not included in a CMR is either (1) being mailed in a TMR, which may be as short as one page and may contain private health information; or (2) is mailed as a stand-alone document which does not contain any private health information. For purposes of impact, (1) if one additional page is included in the TMR, then there is no additional postage; and (2) if the safe disposal information is mailed separately, there would be no private health information, and the burden would be the cost of one page plus bulk postage. Due to a lack of data with regard to what percentage of safe disposal information will be mailed as part of a TMR or other MTM correspondence or service, we are assuming that all safe disposal information not sent with a CMR will be one page that is mailed separately using bulk postage in order to project the maximum cost of such mailing. The cost to mail one page of safe disposal information is $0.015 per enrollee if the letter does not contain private health information and thus bulk mailing is used (1 page $0.007/sheet) + (1 page × $0.007 toner) + ($0.20/200 items for bulk postage). Therefore, we estimate that the cost of mailing safe disposal information to those beneficiaries targeted for MTM who do not receive it in a CMR summary is $35,408 ($0.015 x 2,360,564).

Therefore, the total burden associated with the proposed revisions to the MTM targeting criteria is 2,749,805 hours and $336,121,888 ($332,341,432 for a pharmacist to produce the CMRs for beneficiaries newly targeted for MTM under the proposed revised criteria + $3,745,048 to mail the CMR written summary in the CMS standardized format with safe

disposal information + $35,408 for mailing information regarding safe disposal to beneficiaries newly targeted for MTM who do not receive a CMR).

12. ICRs Regarding Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c))

The proposed amendments to §§ 401.305(a)(2), 422.326(c), and 423.360(c) would change the standard for an "identified overpayment" for Medicare Parts A, B, C, and D and adopt by reference, the knowledge standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1). The proposed amendments for Medicare Parts A and B are associated with OMB control number 0938-1323 (CMS-10405); however, we are not making any revisions to the currently approved requirements and burden under this control number. The proposed amendments for Medicare Parts C and D are associated with OMB control number 0938-1152 (CMS-10340) and OMB control number 0938-0878 (CMS-10062); however, we are not making any revisions to the currently approved requirements and burden under either of these control numbers. Although we cannot predict if there will be any change in the number of overpayments identified or reported under the proposed amendments to the rule, we solicit comment on this assumption.

13. ICRs Regarding Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

The following proposed changes will be submitted to OMB for review under control number 0938-0753 (CMS-R-267).

MA organizations that offer special needs plans are currently effectuating involuntary disenrollments for loss of special needs status as part of existing disenrollment processes, including the member notifications outlined in our proposal; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for these member notifications has not previously been submitted to OMB, due to inadvertent oversight, we are seeking OMB approval under the aforementioned OMB control number.

We are proposing to codify current policy on MA plan notices prior to a member disenrollment for loss of special needs status. MA organizations would be required to provide the member a minimum of 30 days advance notice of disenrollment regardless of the date of the loss of special needs status. Additionally, the organization would be required to provide the member a final notice of involuntary disenrollment, sent within 3 business days following the disenrollment effective date, and before the disenrollment transaction is submitted to CMS.

Where an individual is involuntarily disenrolled from an MA plan for any reason other than death, loss of entitlement to Part A or Part B, the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual, pursuant to § 422.74(c). The notice requirement in § 422.74(c) is currently approved by OMB under the aforementioned control number.

To estimate the number of notices required due to involuntary disenrollments for loss of special needs status, we determined the average number of annual disenrollments due to loss of special needs status. Between 2017 and 2021, there were an average of 55,127 involuntary disenrollments per year due to loss of special needs status.

We estimate that it would take each MA organization 1 minute (0.017 hr) to assemble and disseminate the advance notice, 5 minutes (0.083 hr) to submit the required transaction to CMS for each disenrollment, and 0.017 hr to assemble and disseminate the final notice for each disenrollment. Therefore, the total annual time for each MA organization is 0.1170 hours (0.017 hr +0.083 hr + 0.017 hr).

We estimate the aggregate annual burden for all MA organizations to process these disenrollments to be 6,450 hours (55,127 disenrollments *0.117 hr) at a cost of $491,490 (6,450 hr * $76.20/hr)

14. ICRs Regarding Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74(b)(2))

The requirement proposed at § 422.74(b)(2)(vii) to establish a process for involuntary disenrollment for an individual who loses eligibility mid-year to be enrolled in an MA MSA plan, and more specifically, the requirement for the MA organization to give the individual a written notice of the disenrollment at § 422.74(c) with an explanation of why the MA organization is planning to disenroll the individual, will be submitted to OMB for review under control number 0938-0753 (CMS-R-267).

The annual burden associated with this requirement consists of the time and cost to notify the individual and CMS. Based on the active burden in CMS-R-267, we estimate that each disenrollment will require 1 minute (0.017 hr) for the MA MSA plan to notify CMS and 5 minutes (0.083 hr) for the MA MSA plan to notify the individual. Thus, the total burden per disenrollment is estimated at 6 minutes (0.1 hr) (1 minute to assemble and disseminate the notice to CMS and 5 minutes to assemble and disseminate the notice to the individual) at a cost of $7.62 (0.1 hr x $76.20/hr for a business operations specialist to perform the work).

To obtain aggregate burden we used data from 2019 and 2021 in which there were an average of 4 MSA contracts. We used an average since the data had no visible trend but hovered around a central value. There was an average of 8,624 enrollees during 2019 – 2021 and the average disenrollment was 124. Thus, we estimate an aggregate burden of 12 hours (124 disenrollments * 0.1 hr. per disenrollment) at a cost of $914 (12 hr * $76.20/hr).

15. ICRs Regarding Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§ 422.60 and 423.32)

The following proposed changes will be submitted to OMB for review under control number 0938-1378 (CMS-10718).

CMS's subregulatory guidance currently provides that MA and PDP plans send notification of enrollment reinstatement based on the cancellation of enrollment in a new plan.

Our proposal would not add to existing reinstatement processes; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for these enrollment reinstatement notifications has not previously been submitted to OMB, we aim to correct that oversight by requesting OMB's review and approval under the aforementioned control number.

We are proposing to codify CMS's current policy that plans notify an individual when the individual's enrollment is reinstated due to the individual's cancellation of enrollment in a different plan. The MA or PDP plan from which the individual was disenrolled would be required to send the notification of the enrollment reinstatement within 10 days of receipt of Daily Transaction Reply Report (DTRR) confirmation of the individual's reinstatement. The reinstatement notice would include confirmation of the individual's enrollment in the previous plan with no break in coverage, plan-specific information as needed, and plan contact information.

To estimate the number of reinstatement notices required due to an individual's cancellation of enrollment in a new plan, we determined the number of annual reinstatements based on the cancellations of enrollment in a new plan. In 2021, there were 5,686,989 disenrollments from MA and MA-PD plans due to enrollments in another plan and 4,292,426 disenrollments from PDP plans due to enrollments in another plan. Further, between 2017 and 2021, there was an average of 193,183 cancelled enrollments per year in a new MA plan (including MA-PD plans). Between 2017 and 2021, there was an average of 32,723 cancelled enrollments per year in a new PDP plan. Each cancelled enrollment in a new plan results in a reinstatement notice sent to the beneficiary. Thus, we estimate 225,906 (193,183 + 32,723) reinstatements annually.

We estimate that it would take 1 minute (0.017 hr) at $76.20/hr for a MA or PDP plan's business operations specialist to assemble and disseminate the notice for each reinstatement. In aggregate, we estimate an annual burden of 3,840 hours (225,906 reinstatements * 0.017 hr) at a cost of $292,608 (3,840 hr * $76.20/hr).

16. ICRs Regarding Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors that are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500, 422.528, 422.529, 423.501, 423.521, and 423.522)

The following proposed changes will be submitted to OMB for review under control number 0938-1054 (CMS-10261).

In this rule, proposed §§ 422.528, 422.529, 423.521, and 423.522 would increase burden by requiring that MA organizations and Part D sponsors who disagree with the CMS calculated final settlement amount appeal the final settlement amount, if any, for each contract that consolidates, non-renews, or terminates. There is also additional burden requiring that MA organizations and Part D sponsors respond directly to CMS. The response consists of those MA organizations and Part D sponsors requesting an appeal of the final settlement amount and filing a written request for reconsideration with CMS that includes the specific calculations with which the MA organization or Part D sponsor disagrees and any relevant evidence to support a belief that the CMS final settlement amount may have been calculated incorrectly.

In amended paragraphs §§ 422.500 and 423.501 of this proposed rule, we proposed to define final settlement amount and outline the proposed final settlement process which consists of: (1) CMS calculating the final settlement amount of any payment to be disbursed to, or collected from, an MA organization or Part D sponsor whose contract with CMS has been consolidated into another contract, non-renewed, or terminated; (2) CMS communicating to the MA organization or Part D sponsor the final settlement amount and any relevant information MA organizations and Part D sponsors need to validate the final settlement amount; and (3) final actions needed to be taken by CMS, MA organizations, and Part D sponsors to make payments to or receive final payments from CMS. The final settlement amount is calculated by summing final retroactive payment adjustments that accumulated after a contract ceased operation and all final applicable reconciliations including MLR remittances (described in §§ 422.2470 and 423.2470),

Coverage Gap Discount Program (described in § 423.2320), Part D annual reconciliation (described in § 423.343), and final risk adjustment reconciliation (described in § 422.310).

Under the current policy, CMS would send a notice, referred to as the notice of final settlement, to MA organizations and Part D sponsors with contracts that are consolidating, non-renewing, or terminating containing information on final settlement. The notice of final settlement contains (1) the final settlement amount; (2) relevant CMS banking and financial mailing information; (3) relevant CMS contact information and; (4) information for MA organizations and Part D sponsors regarding the steps for requesting a review of the final settlement amount calculation.

Historically, on average, for the period 2015 through 2020, CMS sent 47 letters annually and received 3 responses, which typically requested that CMS validate the final settlement amount.

We are proposing at new paragraphs §§ 422.528(b) (for MA) and 423.521(b) (for Part D) to require MA organizations and Part D sponsors that disagree with the final settlement amount request an appeal of the final settlement amount within 15 days of the date of issuance of the notice of final settlement.

Whereas under current CMS processes, we allow MA organizations and Part D sponsors to submit evidence supporting a review request on a case-by-case basis, proposed §§ 422.529 and 422.522 specify that MA organizations and Part D sponsors specify the calculations with which they disagree and provide evidence supporting the assertion that CMS's calculation of the final settlement amount described in the notice of final settlement is incorrect.

In calculating the burden of this proposal, we assume the following:

- 44 contracts, on average, will accept the CMS final settlement amount upon issuance of the notice of final settlement.
- 3 contracts will disagree with the CMS decision and request a review of the final settlement amount calculation.

• Burden is distributed between business operations specialists working at $76.20/hr and Medical and Health managers working at $115.21/hr, who perform a quality review of data and draft a response to CMS on behalf those MA organizations or Part D sponsors who disagree with the CMS calculated final settlement amount.

• The primary tasks of business operations specialists are to gather and validate data, determine the accuracy of the final settlement amount calculation, and draft a response.

• The primary task of the managers is to quality assure the work of the business operations specialist.

The time for MA organizations and Part D sponsors is based on the effort needed to access and analyze data in order to validate the CMS final settlement amount and provide aa request for a reconsideration. Any other burden was not considered in this analysis. For example, under proposed §§ 422.529 and 423.522, we explain that CMS will not accept, as part of the final settlement process or review, any new information that would be used for adjusting the applicable reconciliations and that the final settlement amount determined after a CMS review is final. Should a Part D sponsor request a review of the final settlement amount because of a belief that the Part D annual reconciliation was calculated inaccurately, that review would be denied because CMS will not be redetermining reconciliation amounts, and any burden associated with that request was not included in this analysis.

In estimating time, we separately consider the 44 contracts that we expect to agree with the CMS decision and the 3 contracts that we expect to request a review. Besides calculating total costs by considering each case, we also calculate a single summary line for the summary table, by dividing total burden by the 47 contracts Table 10 summarizes all burden estimates which could be useful in reviewing the bullets that follows this table. Explanatory comments for the line items in Table 10 are presented below it.

TABLE 10: SUMMARY OF AGGREGATE BURDEN FOR FINAL SETTLEMENT

Group	Routine Responses	Disagreeing Responses	Total Responses	

Number of contracts in Group	44	3	47	
Task	Time Needed (hr)	Time Needed (hr)	Wages ($/hr)	Total Cost over 47 contracts (44 routine + 3 disagreeing)
Validation	4	4	76.20 (BOS)	$14,335 = $305 (4 * $76.20 hr) * 47
Drafting a response		3	76.20 (BOS)	$686 (3 contracts * 3 hr/contract *$76.20/hr)
Quality Review		2	115.22 (Manager)	$691 (3 contracts * 2 hr/contract * $76.20/hr
Total	4	9		$15,712

• Staff time for validating data (hours): For the 47 contracts (44 routine + 3 disagreeing) receiving a notice of final settlement from CMS, which contains the information CMS used to calculate the final settlement amount, we expect each of the 47 contracts to spend 4 hours validating CMS data.

• Staff time for drafting a response (hours): For the 44 contracts agreeing with CMS, no drafting of a response is required. However, for the 3 contracts disagreeing with CMS, we estimate 3 hours of work to develop a summary of the disagreement and compile any relevant evidence for CMS. Thus the aggregate burden for the 3 disagreeing contracts is $686 (3 contracts * 3 hr/contract *$76.20/hr) for drafting a response.

We next perform a similar burden analysis to arrive at the aggregate cost.

• For each of the 47 contracts, a business operations specialist working for 4 hours validating the final settlement amount at $76.20/hr would incur a burden of $305 (4 hr * $76.20/hr). Therefore the aggregate burden over all 47 contracts is $14,335 (47 contracts * $305)

• For the 3 contracts disagreeing with the CMS decision, a business operations specialist working for 3 hours drafting a response at a cost of $76.20/hr incurs an aggregate burden of $686 (3 contracts * 3 hours/contract * $76.20/hr)

• For the 3 contracts disagreeing with CMS, a manager working for 2 hours at a cost of $115.22/hr would incur a burden of $$691 (3 contracts * 2 hours*$115.22).

• The aggregate burden over all contracts is 203 hours (44 routine contracts * 4 hours for validation + 3 disagreeing contracts * 5 hours (3 hr to write a summary report + 2 hr for quality review) at an aggregate cost of $15,712 (($14,355 for 47 validations + $686 for 3 contracts to write a summary + $691 for 3 contracts to perform a quality review)

The per contract burden differs for the 44 routine contracts and the 3 disagreeing

contracts. For the 44 routine contracts the per contract burden is 4 hours to perform a validation at a per contract cost of $305. For the 3 disagreeing contracts the per contract burden is 9 hours (4 hours for validation + 3 hours for writing a summary + 2 hours for performing a quality review) at a per contract burden of $1,682 ($305 for validation + $686 for writing a report + $691 for performing a quality review).

17. ICRs Regarding Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

As described in section V.G. of this proposed rule, we are proposing to add, remove, and update certain measures, to replace the current reward factor with a new HEI reward to further incentivize Part C and D plans to focus on improving care for enrollees with specific SRFs, to reduce the weight of patient experience/complaints and access measures, to remove guardrails when determining measure-specific-thresholds for non-CAHPS measures, to modify the hold harmless policy for the current improvement measures, to add a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, and to remove the 60 percent rule that is applied when adjusting Star Ratings for extreme and uncontrollable circumstances (for example, natural disasters like hurricanes or public health emergencies). The proposed HEI is a different way for CMS to analyze existing data and would not increase plan burden. Most of the new measures would be calculated from administrative data and, as such, there would be no increase in plan burden. The other measure-level changes entail moving existing measures from the display page to Star Ratings, which also would have no impact on plan burden. We are also proposing a series of technical clarifications related to adjusting Star Ratings for extreme and uncontrollable circumstances, QBP appeals processes, consolidations, and weighting of measures with a substantive specification change. The proposed provisions will not change any respondent requirements or burden pertaining to any of CMS's Star Ratings related PRA packages, including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–0701 for HOS (CMS–10203), OMB control number

0938–1028 for HEDIS (CMS–10219), OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261), OMB control number 0938–0992 for Part D Reporting Requirements (CMS–10185), and OMB control number 0938–1129 for Appeals of Quality Bonus Payment Determinations (CMS–10346). Since the provisions will not impose any new or revised information collection requirements or burden, we are not proposing to make changes under any of the aforementioned control numbers.

18. ICRs Regarding Personnel Requirements Under PACE (§§ 460.64 and 460.71)

The following proposed changes will be submitted to OMB for review under control number 0938-0790 (CMS-R-244).

Section 460.64 currently includes the requirements relating to the qualifications of PACE personnel who have direct contact with PACE participants. This includes the requirement that PACE organizations medically clear personnel of communicable diseases. As discussed in section VI.E. of this proposed rule, PACE organizations are currently required to ensure staff (employees and contractors) are free of communicable diseases. We proposed to allow PACE organizations the option to create and implement a risk assessment tool to assist with this medical clearance process. Therefore, we estimate there will be a one-time burden for PACE organizations associated with these new requirements to update policies and procedures related to medical clearance, and when applicable, to develop a risk assessment tool. We believe the compliance officer and primary care physician (PCP) would be responsible for ensuring the necessary materials are updated, for determining medical clearance, and developing the risk assessment tool. For revising policies and procedures related to medical clearance, we estimate it would take 1 hour at $72.90/hr for a compliance officer at each PACE organization to update these materials. For the development of the risk assessment tool, we estimate it would take each PACE organization 5 hours consisting of: 4 hours of work by the compliance officer at $72.90/hr and 1 hour of work by the PCP at $232.88/hr. The weighted hourly wage for the compliance

officer and PCP to update policies and procedures to create a risk assessment is $104.90/hr (((4 hr * $72.90/hr) + (1 hr* $232.88/ hr))/ 5 hr of aggregate burden).

In aggregate, we estimate a one-time burden of 149 hours (149 PACE organizations[225] * 1 hr) at a cost of $10,862 (149 hrs * $72.90/hr) for the development of policies and procedures.

To develop a risk assessment tool, we also estimate a one-time burden of 745 hours (149 PACE organizations * 5 hrs) at a cost of $78,151 (745 hrs * $104.90/hr) for both the compliance officer and PCP roles in developing the risk assessment tool.

19. ICRs Regarding Service Delivery Under PACE (§ 460.98)

The following proposed changes will be submitted to OMB for review under control number 0938-0790 (CMS-R-244).

Section 460.98 currently includes requirements related to delivery of services to PACE participants. This includes the minimum requirements for the provision of services PACE organizations must provide and how the services must be furnished. The current requirement that PACE organizations must provide all necessary services to meet the needs of participants as expeditiously as the participant's health conditions require would not change with this proposed rule, but as discussed in section VI.G. of this proposed rule, we are proposing to add required timeframes for arranging and scheduling services for PACE participants. We believe there will be a one-time burden for PACE organizations to update their policies and procedures to reflect the proposed timeframes. We believe the compliance officer will be responsible for updating the policies and procedures. We estimate that it would take the compliance officer 1 hour at $72.90/hr to update the necessary materials. Therefore, we estimate a one-time burden of 149 hours (149 PACE organizations * 1 hr) at a cost of $10,862 (149 hrs * $72.90/hr).

20. ICRs Regarding PACE Participant Rights (§ 460.112)

The following proposed changes will be submitted to OMB for review under control number 0938-0790 (CMS-R-244).

[225]Number of PACE organizations is current as of September 20, 2022.

Section 460.112 currently includes the specific rights to which PACE participants are entitled. As discussed in section VI.J. of this proposed rule, we are proposing to add new participant rights and modify existing participant rights to enhance participant protections. Specifically, we are proposing to add and/or modify the rights to appropriate and timely treatment; to be fully informed, in writing, of different treatment options including palliative, comfort, and end-of-life care; to fully understand the PACE organization's palliative, comfort, and end-of-life care services; and to request services from the PACE organization through the process described in § 460.121. PACE organizations are currently required to provide a copy of the participant rights listed in § 460.112 to participants at the time of enrollment, and to post a copy of the rights in the PACE center. If our proposed changes to § 460.112 are finalized, PACE organizations would be required to revise the materials they provide to participants at the time of enrollment and the posting in the PACE center to account for the new and modified requirements. Therefore, we estimate a one-time burden for PACE organizations to update the participant rights included in the enrollment information and post the new participant rights in PACE centers. We believe it would take a compliance officer 2 hours at $72.90/hr to update these materials.

The PACE organizations would also be required under this proposal to develop written templates explaining palliative care, comfort care, and end-of-life care services. We believe the development of these materials is a one-time burden and would take a compliance officer 2 hours to complete at $72.90/hr.

In aggregate, we estimate a one-time burden of 596 hours (149 PACE organizations * (2 hrs + 2 hrs)) at a cost of $43,448 (596 hrs * $72.90/hr).

We also estimate this provision would result in increased ongoing costs to PACE organizations. As discussed in section VI.J. of this proposed rule, we are proposing to require PACE organizations to provide participants with written documentation explaining the different treatment options including palliative, comfort, and end-of-life care services. Specifically, we are

proposing to require PACE organizations to describe their palliative care, comfort care, and end-of-life care services and how they differ from the care the participant is currently receiving; whether these treatment options will be provided in addition to or in lieu of the care the participant is currently receiving; a detailed description of all services that will be impacted and how they will be impacted if the participant and/or designated representative elects to initiate a different treatment option; and that the participant has the right to revoke or withdraw their consent to receive these treatment options at any time and for any reason.

We estimate that a registered nurse (RN) will need to tailor written templates for each participant based on the treatment option they choose and the impact that treatment option will have on their current services. We estimate it would take the RN 1 hour to tailor the written template to each participant at $79.56/hr. We also estimate the Master's-level Social Worker (MSW) would either provide the materials in person to the participant and/or their designated representative or they would mail the materials to the participant. We estimate it would take the MSW 10 minutes (0.1667 hr) to mail or present the materials to each participant at $59.92/hr.

We are also proposing that PACE organizations must explain the treatment options to participants and/or their designated representatives before palliative care, comfort care, or end-of-life care services can be initiated. This includes fully explaining the treatment options, providing the participant and/or designated representative with the written materials discussed previously, and obtaining written consent from the participant and/or designated representative. We estimate it would take the MSW 1 hour at $59.92/hr to explain the services and answer any questions the participant and/or designated representative might have.

To estimate the increased burden, we use the following assumptions about the number of participants who may pursue palliative care, comfort care, and/or end-of-life care services, based on our experience monitoring and auditing PACE organizations. We estimate that 2 out of every 10 participants in a given year (20 percent) will require written materials for palliative care,

comfort care, or end-of-life care services. The total national enrollment in PACE as of September 2022 was 54,637[226] with 149 active PACE organizations.

For tailoring information within the written templates and providing written materials to participants as specified at proposed § 460.112(c)(5), we estimate ongoing burden using the weighted hourly wage for the RN and MSW. The weighted average can be obtained as follows. The total cost per participant is $89.55/hr [(1 hr * $79.56/hr (RN)) + (0.1667 hr * $59.92/hr (MSW))]. The total time is 1.1667 hours (1 hr for the RN plus 0.1667 hr the MSW). Thus, the average hourly wage is $76.75/hr (total cost of $89.55/1.1667 hr).

Using these assumptions, we estimate the ongoing burden for proposed requirements at § 460.112(c)(5) would affect 10,927 participants (20 percent of participants who are expected to need end-of-life explanations * 54,637 participants). Therefore, to tailor and mail materials there is an annual burden of 12,749 hours (10,927 affected participants * 1.1667 hr) at a cost of $978,486 (12,749 hr * $76.75/hr).

We estimate an ongoing burden for PACE organizations' MSW to explain treatment options to participants as specified at § 460.112(e)(2) to be 10,927 hours ((54,637 participants * 20 percent participants who require materials) * 1 hr) at a cost of $ 654,746 (10,927 hr to discuss treatment options * $59.92/hr).

In aggregate, we estimate a one-time burden of 596 hours (149 PACE organizations * (2 hrs + 2 hrs)) at a cost of $43,448 (596 hr * $72.90/hr) and an annual ongoing burden of 23,676 hours (12,749 hrs + 10,927 hrs) at a cost of $1,633,232 ($978,486 + $654,746).

21. ICRs Regarding PACE Grievance Process (§ 460.120)

The following proposed changes will be submitted to OMB for review under control number 0938-0790 (CMS-R-244).

Section 460.120 currently includes the grievance process PACE organizations are required to follow. As discussed in section VI.K. of this proposed rule, PACE organizations are

[226]This total was accurate as of September 20, 2022.

already required to develop procedures on processing grievances, and provide notification of the grievance process to participants upon enrollment and at least annually; however, our proposed changes would require the PACE organization to update those procedures. Additionally, we are proposing that written or oral notification must include such as a summary of the issues, a summary of the findings, the steps taken to investigate the grievance (if applicable), and the corrective actions taken (if applicable). Our proposal, which adds requirements on what must be included in grievance resolution notifications, would require the PACE organization to revise and update their notification templates. Therefore, we estimate a one-time burden for PACE organizations to update their materials to meet these new requirements. We do not believe the proposed changes to § 460.120 will impact the annual hours of burden for PACE organizations, because they are already required provide notification of grievance resolutions to participants, and may opt to do so orally or in writing. Therefore, we believe that the ongoing burden will not change with this proposal.

For the one-time burden for updating policies and procedures, we estimate that it would take the compliance officer 2 hours to update these materials at $72.90/hr. For the revised notification of the grievance process, that is provided both upon enrollment and at least annually, we estimate it would take the compliance officer 1 hour to revise these notifications at $72.90/hr. For the written grievance resolution notification, we estimate it will take the compliance officer 1 hour to revise the written resolution notification at $72.90/ hr.

In aggregate, we estimate it would take PACE organizations 596 hours [149 PACE organizations * (2 hrs + 1 hr + 1 hr)] at a cost of $43,448 (596 hrs * $72.90/hr).

22. ICRs Regarding the PACE Service Determination Process (§ 460.121)

The following proposed changes will be submitted to OMB for review under control number 0938-0790 (CMS-R-244).

Section 460.121 currently includes the service determination process PACE organizations are required to follow and only allows PACE organizations to notify participants and/or their

representatives of service determination extensions in writing. Per the burden estimate that is currently seeking OMB approval under the process (August 5, 2022; 87 FR 48030), we estimate the burden of the current extension notification requirements at § 460.121 to be 2,350 hours and $140,812 in aggregate. As discussed in section VI.L. of this proposed rule, we are proposing to allow PACE organizations to notify the participant or their designated representative either orally or in writing when the PACE organization extends the timeframe for making a service determination. Under this proposal, we expect that PACE organizations will prefer to provide oral notification more frequently than written notification, because oral notification is less time consuming. In anticipation of PACE organizations' preference for oral notification over written notification and the 45 minutes per response reduction in burden oral notification offers, we estimate that the proposed changes will reduce the burden of the extension notification requirements at § 460.121.

To estimate the decreased burden, we considered: (1) the annual number of extension notifications; (2) the estimated proportions of extension notifications that are provided orally or in writing; and (3) the estimated time required to complete oral and written notification.

First, we reviewed extended service determination requests (SDRs) from 2019 through 2021 and found that there were 6,564 total extended SDRs nationally (3,942 in 2019 + 773 in 2020 + 1,849 in 2021). Then we averaged the number of extended SDRs from 2019 – 2021 to calculate 2,188 extended SDRs annually (6,564 total extended SDRs / 3 years), which is about 15 extended SDRs per PACE organization annually (2,188 extended SDRs annually/ 149 PACE organizations).

Secondly, we estimate, based on our experience with audits of similar areas of PACE requirements where PACE organizations have an option of oral or written notification, that 80 percent of extension notifications will be provided orally, at 15 minutes per notification, and 20 percent will be provided in writing at 1 hour per notification. The hourly wage for notification by an MSW in both cases is $59.92/hr. In aggregate, the new burden would be 875 hours ((2,188

extension notifications * 0.2 written notifications * 1 hr) + (2,188 extension notifications * 0.8 oral notifications * 0.25 hr)) at a cost of $52,430 (875 hrs * $59.92/hr).

Thus, the aggregate annual time and cost savings for the proposed changes are minus 1,475 hours (2,350 hr under current provisions minus 875 hr as documented in the pending OMB package) and minus $88,382 ($140,812 cost under current provisions minus $52,430 under the pending OMB package). Additionally, at the individual service determination request extension level, PACE organizations that choose to provide oral notification instead of written notification will save minus 0.75 hours and $44.94 per extension notification.

23. ICRs Regarding PACE Participant Notification Requirement for PACE Organizations with Past Performance Issues or Compliance Deficiencies (§ 460.198)

The following proposed changes will be submitted to OMB for review under control number 0938-0790 (CMS-R-244).

In this proposed rule, CMS proposes to add a new provision, § 460.198, which would give CMS the authority to, at its discretion, require a PACE organization to disclose to its PACE participants or potential PACE participants, the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS. The purpose of this proposal is to enable CMS to better protect PACE participants by ensuring that PACE participants and their caregivers have adequate information to make informed decisions regarding the PACE organization.

The overall PACE organization burden of this requirement is expected to be minimal. In the past, CMS has only required organizations to send these notices to enrollees when CMS sanctioned the organization, which is an extremely rare occurrence. Regarding PACE organizations, between CY 2019 and 2021, CMS sanctioned a total of 3 PACE organizations for an average of 1 per year. As a result, CMS projects that between one and two PACE organizations per year would be required to notify participants and potential participants of their performance and contract compliance deficiencies. In addition, CMS would provide the PACE organization with a template of what to include in the notice, and organizations have the

capability to send notices to participants. Therefore, we estimate a burden for PACE Organizations to complete and send the template to participants and potential participants.

For the annual burden for completing the template and sending it to participants and potential participants, we estimate that it would take the compliance officer at the PACE organization 1 hour to complete and send out the template (which would be automated) at $72.90 per hour. In aggregate, we estimate it would take PACE organizations 2 hours (2 PACE organizations * (1 hr) at a cost of $146 (2 hrs * $72.90/hr).

24. ICRs Regarding Safeguarding Data and Records and Medical Record Requirements (§§ 460.200 and 460.210)

PACE organizations are currently required to retain original communications related to a participant's care, health, or safety in the medical record. In this proposal, we are removing the requirement that these communications be stored in the participant's medical record, provided certain conditions are met. Therefore, our burden estimates include costs incurred related to staff (1) training; (2) software development; (3) file cabinets for document storage; and (4) updating/maintaining the organizations' policies and procedures.

- Training: We estimate that a PACE organization will spend 40 hours at a cost of $2,916 (40 hr × $72.90/hr) for a compliance specialist to establish training materials. In aggregate, we estimate a one-time burden of 5,960 hours (40 hours x 149 POs) at a cost of $434,484 (5,800 hr. x $72.90/hr).

- Software development: We estimate that PACE organizations will spend 40 hours at a cost of $4,654 (40 hours x $116.34/hr) for a software developer to make the appropriate software updates. In aggregate, we estimate a one-time burden of 5,960 hours (40 hours x 149 POs) at a cost of $693,386 (5,960 hr. x $116.34/hr).

- Storage: We estimate that a PACE organization will spend a total of $300 (2 × $150/each) for 2 four-drawer locking file cabinets. In aggregate, we estimate a one-time non-labor cost of $44,700 ($300 x 149 POs).

- Update policies and procedures: We estimate that PACE organizations will spend 10 hours at a cost of $729 (10 hours x $72.90/hr) for a compliance specialist to update and maintain related policies and procedures. In aggregate, we estimate a one-time burden of 1,490 hours (10 hours x 149 POs) at a cost of $108,621 (1,490 hr. x $72.90/hr).

The aggregate of this provision is a one-time impact of 13,410 hours (5960 hours (training materials) + 5960 hours (software development) + 1490 hours (policy updates) at a cost of $1,282,191 ($434,484 (Training materials) + $693,386 (software updates) + $44,700 (nonlabor purchase of storage) + $108,621 (policy updates).)

Since PACE organizations are already required to retain original communications related to a participant's care, health, or safety, and to make these communications accessible to CMS and the SAA upon request, this proposal does not impose any new information collection requirements for PACE organizations.

25. ICRs Regarding Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)

In this rule we are proposing to revise the Part D LIS income and resource standards at § 423.773 to expand eligibility for the full benefit to individuals who currently have the partial benefit and make a coordinating change in § 423.780. This proposal would change the level of assistance that an individual could qualify for in paying their Part D premiums, copays and deductibles. While there would be no change in the number of individuals eligible for the Part D LIS, it would create a transition of people from partial subsidy status to full benefit status.

The burden associated with determining eligibility for the Part D LIS is the time and effort for States or SSA to verify the income and resources and report eligibility to beneficiaries and CMS annually. Most individuals qualify for the Part D LIS because they qualify for Medicaid or other assistance in their State. The burden for States to determine and report eligibility is currently approved by OMB under control number 0938-0467 (CMS-R-74) at 54 respondents, 3,241 annual responses, a variable amount of time per response, and 1,082

estimated annual hours. We are not making any changes to any of the requirements or burden under the 0938-0467 control number.

C. Summary of Information Collection Requirements and Associated Burden Estimates

11: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN*

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program		Enrollees	36,982	0.25	9246	28.01	258,980	258,980
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program		Pharmacists	36,722	0.0333	1223	120.86	147,812	147,812
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program		LI NET sponsor	36,982	0.0333	1232	76.20	93,878	93,878
422.116	New Behavioral Specialty Types	0938-1346	MA Organizations	742	0.0833	62	76.20	4,724	
422.111 and 422.2267	MA Provider Termination Notices	0938-0753 (CMS-R-267)	MA Organizations	697	8	5,576	92.92	518,122	518,122
422.100 and 422.101	Posting New PA Guidance		MA Organizations	697	16	11,152	76.20	849,782	849,782
422.137	Utilization Management Review Committee	0938-0964	MA Organizations	697	1	697	76.20	159,334	159,334.
422.566 and 422.629	Medical Necessity Decisions		MA Organizations & Section 1876 Cost plans	65,126	-0.25	(16,282)	76.20	(1,240,688)	(1,240,688)

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
422.2261, 422.2264, 422.2265, 422.2267, 422.2274, 423.2261, 423.2264, 423.2267, and 423.2274	Marketing Provisions	0938-1051 (CMS-10260)	MA Organizations	697	3.25	2,265	76.20	172,593	172,593
423.4, 423.100, 423.120, and 423.128	Formulary Changes:Negative Change Request	0938-0964(CMS-10141)	Part D Parent Organizations	3,642	0.0833	303	120.86	36,621	36,621
423.4, 423.100, 423.120, and 423.128	Formulary Changes: Update in HPMS	0938-0964(CMS-10141)	Part D Parent Organizations	6,061	2	12,122	120.86	1,465,065	465,065
423.4, 423.100, 423.120, and 423.128	Formulary Changes: Update Website	0938-0964(CMS-10141)	Part D Parent Organizations	6,612	1	6,612	92.92	614,387	614,387
423.4, 423.100, 423.120, and 423.128	Formulary Changes: Enrollee Notifications	0938-0964(CMS-10141)	Part D Parent Organizations	65,535		65,535	0.59800	39,190	39,190
423.153d	MTM Eligibility: CMR Mailing cost	0938-1154	Part D Sponsors	4,124,502	0.6667	2,749,805	120.86	332,341,432	332,341,432
423.153d	MTM Eligibility: Safe disposal Mailing cost	0938-1154	Part D Sponsors	4,124,502			0.908	3,745,048	3,745,048
423.153d	MTM Eligibility: Writing CMRs	0938-1154	Part D Sponsors	2,360,564			0.015000	35,408	35,408
422.74	Involuntary Disenrollment: Loss of Special Needs Status	0938-0753	MA Organizations	55,127	0.117	6,450	76.20	491,490	491,490

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
422.74 (b)(2)	MSA Involuntary Disenrollment	0938-0753	MSA contracts	124	0.1	12	76.20	914	914
422.60 and 423.32	Reinstatement notices	0938-1378	MA Organizations and Part D Sponsors	225,906	0.017	3840	76.20	292,608	292,608
422.500, 422.513, 422.515, 423.501, 423.511, and 423.513	Final Settlement	0938-1054	MA Organizations	47	*Varies*	203	77.4	15,712	15,712
460.64	PACE Personnel Requirements	0938-0790 (CMS-R-244)	PACE Organizations	149	1	149	72.90	10,862	
460.64	PACE Personnel Requirements	0938-0790 (CMS-R-244)	PACE Organizations	149	5	745	104.9	78,151	
460.98	PACE Service Delivery Requests	0938-0790 (CMS-R-244)	PACE Organizations	149	1	149	72.90	10,862	
460.112	Notifying PACE Participants	0938-0790 (CMS-R-244)	PACE Organizations	149	4	596	72.90	43,448	
460.112	PACE Explanation of End of Life Options	0938-0790 (CMS-R-244)	PACE Organizations	10,927	1.1667	12749	76.75	978,486	978,486
460.112	PACE Explanation of End of Life Options	0938-0790 (CMS-R-244)	PACE Organizations	10,927	1	10,927	59.92	654,746	654,746
460.120	PACE Grievance Procedures	0938-0790 (CMS-R-244)	PACE Organizations	149	4	596	72.90	43,448	-
460.121	PACE Service Determination Process	0938-0790 (CMS-R-244)	PACE Organizations	2,188	-0.674	(1,475.0)	59.92	(88,382)	(88,382)
460.198	Participant Notification Requirement	0938-0790 (CMS-R-244)	PACE Organizations	2	1	2	72.90	146	146
460.200 and 460.210	Safeguarding data	0938-0790 (CMS-R-244)	PACE Organizations	149	40	5,960	72.90	434,484	
460.200 and 460.210	Safeguarding data: Software updates	0938-0790 (CMS-R-244)	PACE Organizations	149	40	5,960	116.34	693,386	
460.200 and 460.210	Safeguarding data: Storage	0938-0790 (CMS-R-244)	PACE Organizations	149			300.00	44,700	

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
460.200 and 460.210	Safeguarding data: Updating policies	0938-0790 (CMS-R-244)	PACE Organizations	149	10	1490	72.90	108,621	
Totals				*Varies*		2,899,295		343,055,370	341,064,562

*Blank cells in the "Total Cost Subsequent Years" column indicate $0 cost since the provision only has a first year cost. For two rows in the MTM provision blank cells in the "Burden per Response" and "Total Annual Burden" columns indicate "N/A" since the cost is non-labor.

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 above, please visit the CMS Web site at www.cms.hhs.gov/PaperworkReductionActof1995, 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 section of this proposed rule and identify the rule (CMS-4201-P), the ICR's CFR citation, and OMB control number.

VIII. 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) and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). This proposed rule includes a number of new policies that would improve these programs for Contract Year 2024 as well as codify existing Part C and Part D sub-regulatory guidance.

the Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018;
- The Consolidated Appropriations Act, 2021 (CAA);
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; and
- The Inflation Reduction Act of 2022 (IRA).

B. Overall Impact

We examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)).

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). 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 $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities (also referred to as "economically significant"); (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 novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This rule, under Executive Order 12866, is economically significant as it results in over $100 million in costs, benefits, or transfers annually. In accordance with the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs has designated this rule as a major rule as defined by 5 U.S.C. 804(2). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This proposed rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of $165 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory

review. There are currently 795 contracts (which includes MA, MA-PD, and PDP contracts), 55 State Medicaid Agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major PBMs). We expect that each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this proposed rule is $115.22 per hour, including fringe benefits, overhead, and other indirect costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 19 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore $2,200 (19 hours x $115.22). Therefore, we estimate that the maximum total cost of reviewing this proposed rule is $ 5.3 million ($2200 x 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. We expect that on average (with fluctuations) 10 percent of the rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be $ 0.5 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 as follows:

- Pharmacies and Drug Stores, NAICS 446110, have a $30 million threshold for "small size" with 88 percent of pharmacies, those with under 20 employees, considered small.

- Direct Health and Medical Insurance Carriers, NAICS 524114, have a $41.5 million threshold for "small size," with 75 percent of insurers having under 500 employees meeting the definition of small business. Several Medicare Advantage plans (about 30-40 percent) are not-for-profit resulting in a "small entity" status.

- Ambulatory Health Care Services, NAICS 621, including about 2 dozen subspecialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from $8 to $35 million (Dialysis Centers, NAICD 621492, have a $41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed $34 million.

- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, Specialty Hospitals have a $41.5 million threshold for small size, with half of the hospitals (those with between 20-500 employees) considered small.

- Skilled Nursing Facilities (SNFs), NAICS 623110, have a $30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this FC 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 rule).

MA plans can also offer enhanced benefits, that is, benefits not covered under Original Medicare. These enhanced benefits are paid for through enrollee premiums, extra government payments or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is. benefits not covered under Original Medicare) 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 Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original 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 premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by a variety of government funding 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 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 original 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, only 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 shows that meeting the direct cost of this proposed rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

There are certain indirect consequences of these provisions which also create impact. We have already explained that 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 a "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 partially be paid by enrollee premiums.) However, as noted previously, the number of plans bidding above the benchmark to whom this burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this rule would otherwise cause 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 even for 1 year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

We note that we do not have definitive data on this. Plans do not report to CMS the strategies behind their bids. More specifically, when supplemental benefits are reduced, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes. Notably, it may be inappropriate to consider the relevant regulatory impacts (and thus the profit considerations) as temporary because the issuance of a series of regulations sustains the effects.[227] As a result, changes in benefits packages may be plausible and we request comment on the assessment of this outcome in association with this proposed rule.

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[227] Indeed, see similar discussion in previous regulatory impact analyses: https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and and https://www.federalregister.gov/documents/2022/04/14/2022-07642/medicare-program-maximum-out-of-pocket-moop-limits-and-service-category-cost-sharing-standards

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: (1) Pharmacies and Drug Stores, NAICS 446110; (2) 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; (3) Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) SNFs, NAICS 623110. Whether these providers are contracted or, in the case of PPOs and PFFS, 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 accept payment that is at least what they would have been paid had the services been furnished in a fee-for-service setting. 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 healthcare provider or to use a particular price structure for payment under the plan by section 1854(a)(6)(B)(iii) of the Act. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

Consequently, consistent with our conclusions stated earlier, the Secretary has certified that this proposed rule will not have a significant impact on a substantial number of small entities.

D. Anticipated Effects

Many provisions of this proposed rule have negligible impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact that cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when we estimated that provisions have no impact. Additionally, this Regulatory

Impact Analysis discusses several provisions with either zero impact or qualitative impact that cannot be quantified. The remaining provisions are estimated in section VIII of this proposed rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts from section VIII. of this proposed rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been experienced as a direct result of the statute. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table 12 and the discussion afterwards.

1. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the LI NET Program (§ 423.2500 through § 423.2536)

This proposal would implement section 118 of the CAA, which amends section 1860D-14 of the Act, to establish the Limited Income Newly Eligible Transition Program as a permanent part of Medicare Part D. This will ensure that the transitional drug coverage currently provided to low-income Medicare beneficiaries under the LI NET demonstration will continue indefinitely. Therefore, we anticipate this proposal will advance health equity by improving low income individuals' access to continuous, affordable health coverage, consistent with Executive Order 13985, issued January 20, 2021, on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. We also believe this proposal would improve the customer service experience of low-income beneficiaries consistent with the goals of the Executive Order 14058, Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government.

Using drug cost data from 2021, the CMS Office of the Actuary (OACT) projects the following program costs (in millions of dollars) over the next 10 years:

TABLE 13: PROJECTED LI NET PROGRAM DRUG COSTS ($ in MILLIONS)

	Fiscal Year									
	2024	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**

Costs	5	7	8	9	9	10	11	11	12	13

We note that OACT has provided cost/savings estimates each year under the LI NET demonstration, and they have not altered their methodology based on the program becoming permanent. Therefore, these projected costs are the same as what the government would have incurred if the demonstration continued. Further, the costs of the payments provided for under this program will continue, as they were under the demonstration, to be covered through the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance (SMI) Trust Fund.

2. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service (§§ 422.566 and 422.629)

The proposal that a physician or other health professional with expertise in the field of medicine appropriate to the requested service determine medical necessity is intended to provide a more meaningful clinical review informed by specific expertise. We believe this enhanced level of review will reduce unnecessary appeals, delays in treatment and the potential for adverse outcomes. The proposal requires obtaining the opinion of an appropriate expert at the organization determination level of review, which we believe will reduce denied organization determinations and, in turn, will reduce the number of cases getting into the appeals process.

While we can (and have) quantified the expected reduced appeals in the Collection of Information section, quantifying the costs of effects of delay in treatment and consequent possible adverse medical complications is not possible because we lack adequate data. For example, we lack data on the following: (1) currently how often do doctors without expertise determine medical necessity; (2) what percentage of these determinations are appealed and what percentage of these appeals are overturned; (3) of the overturned appeals what percentage of cases have medical complications specifically arising from delays; (4) of the upheld appeals what percentage have adverse medical complications directly attributable to the lack of original

treatment; and (5) what is the average cost of these consequent adverse medical complications. In addition to requesting comment related to estimation of these listed effects, regarding the opportunity cost of medical experts' time when reallocated for the purpose of compliance with this provision, we welcome feedback related to whether this is a budget neutral reallocation, or whether a more detailed analysis would show added cost.

3. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

a. Standing Request for Translated Materials and Materials in Accessible Formats Using Auxiliary Aids and Services

We are proposing to specify in Medicare regulations that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a standing basis in an accessible format using auxiliary aids and services or any non-English languages that is the primary language of at least 5 percent of the individuals in a plan benefit package service area upon receiving a request for the materials or otherwise learning of the enrollee's preferred language. The proposal would also extend to individualized plans of care for special needs plans.

Our proposed rule clarifies existing policy, therefore the impact to MA organizations, cost plans, and Part D plan sponsors depends on whether, and to what extent, they currently have processes in place to note an enrollee's language preference and need for auxiliary aids and services. As described in this section of this proposed rule, we believe many plans would not incur significant cost from the proposed requirement because plans currently comply with the proposal.

Enrollees who need translated materials or materials in an accessible format using auxiliary aids and services who are enrolled in MA, cost, or Part D plans that do not currently create a standing request for these materials would likely spend less time contacting their plan to request these materials as a result of this proposal. Any MA, cost, or Part D plan that has not created a standing request for enrollees requiring translated materials or materials in an

accessible format using auxiliary aids and services would likely reduce their efforts to accept requests and resend the translated materials or materials in an accessible format using auxiliary aids and services.

CMS received information from Medicare-Medicaid Plans (MMPs) in Ohio and California about their requests for translated materials in 2021 and 2022. We include our assumptions from these discussions, but we are seeking comment on additional information that may better inform our estimates. Of the five MMPs in Ohio in 2021, only one of the plans accepted standing requests for translated materials or materials in an accessible format using auxiliary aids and services. A higher proportion (86 percent) of seven California MMPs that responded had established standing requests due to State oversight ensuring California MMPs followed the State-specific marketing guidance; however, we believe the Ohio MMPs landscape betters represents MA organizations as a whole. Therefore, we estimate that 20 percent or 171[228] MA organization, cost plan, and Part D plan sponsor contracts are currently accepting standing requests and would not be impacted by this proposal. Therefore, an estimated 80 percent or 683 MA organization, cost plan, and Part D plan sponsor contracts would need to implement this proposed requirement. We believe our analysis of MMP plans, which cover Part C and Part D benefits, also applies to MA organization, cost plan, and Part D plan sponsors. We request comment on whether MA organization, cost plan, and Part D plan sponsors accept standing requests for translated materials or materials in an accessible format using auxiliary aids and services at a greater or lesser extent than MMPs.

Based on the information we received from MMPs, we are uncertain if establishing a standing request for translated material or materials in an accessible format using auxiliary aids and services will increase or decrease administrative cost for the estimated 683 MA organization, cost plan, and Part D plan sponsor contracts impacted by our proposal. Based on information

[228]Based on 854 MA, cost, and Part D plan sponsor contracts in the May 2022 Monthly Contract and Enrollment Summary Report. Retrieved from https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2022-05

from MMPs who have implemented a standing request, we believe establishing a process for standing requests would require about 200 hours of business operations specialist[229] time during the first year or 136,600 hours (200 hr * 683 MA, cost, and Part D contracts) at a cost of $10,408,920 (136,600 hr x $76.20/hr wage for a business operations specialist).

We assume that this initial cost would be offset by a reduction cost for MA organizations, cost plans, and Part D plan sponsors to resend materials in the correct translated or accessible format. We also expect that implementing a standing request process would reduce future costs to MA organizations, cost plans, and Part D sponsors by decreasing rework of sending two sets of information, one in the incorrect language or format and the other in the correct format. However, establishing a standing request for translated material or materials in an accessible format using auxiliary aids and services as proposed could result in more enrollees requesting to consistently receive these materials at an additional cost to MA organizations, cost plans, and Part D plan sponsors. We request comment on our assumptions and the potential savings or costs to MA organizations, cost plans, and Part D plan sponsors.

b. Require FIDE SNPs and HIDE SNPs and Applicable Integrated Plans to Translate Materials into the Medicare Translation Standard Plus Additional Medicaid Languages

We are proposing to require that FIDE SNPs, HIDE SNPs and AIPs translate materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

Our proposed rule slightly modifies existing policy, so the impact to FIDE SNPs, HIDE SNPs, and AIPs depends upon whether, and to what extent, these plans are already translating materials in ways that would meet our proposed requirements. We note that translation requirements vary by State. Therefore, we expect no impact in States where the applicable

[229]Based on the BLS wage information for business operations specialist (code 13–1199) whose wage we estimate at $76.20 per hour, including fringe benefits and overhead costs (http://www.bls.gov/oes/current/oes_nat.htm).

Medicaid and Medicaid translation requirements result in the same outcome. We expect marginal impacts where State requirements result in translation into languages not required by the current MA rules at §§ 422.2267(a)(2) and 423.2267(a)(2). However, even in these States, FIDE SNPs, HIDE SNPs, AIPs (in combination with their affiliated Medicaid managed care plans) have translators on staff or access them via contractors because of existing translation requirements.

For contract year 2022, MA organizations sponsor 292 FIDE SNPs, HIDE SNPs, and AIPs. We expect that some portion of these FIDE SNPs, HIDE SNPs, and AIPs already translate their Medicare materials in ways that meet our proposed requirement, but we do not have good estimate of how many. While HPMS identifies the Medicare translation requirements for each MA and Part D plan sponsor at the plan level, we do not have a good source of the State-specific Medicaid translation requirements since they differ by State and there is no one source of information outlining these requirements. For purposes of this analysis, we estimate that 75 percent of the FIDE SNPs, HIDE SNPs, and AIPs currently translate their Medicare materials in ways that would meet our proposed requirement and 25 percent or 73 of these FIDE SNPs, HIDE SNPs, and AIPs do not.

Section 422.2267(e) requires MA plans to provide 29 materials to current and prospective MA plan enrollees, as applicable and § 423.2267(e) requires Part D sponsors to provide an additional 18 materials to current and prospective enrollees for a total of 47 materials. We estimate that the proposed provision would require 73 FIDE SNPs, HIDE SNPs, and AIPs to translate 47 materials into one additional language. On average, we expect these plans to translate materials into one additional language based on our experience with MMPs where, out of nine states, only two states (California and Rhode Island) required translation of materials into additional languages beyond the Medicare translation standard. California required MMPs to translate materials into nine additional languages in certain counties and Rhode Island required MMPs to translate materials into two additional languages. Collectively, these 47 materials

include an estimated 253,311 words.[230] At a cost of $56.16/hr,[231] we estimate a translator could translate 500 words/hr.[232] The aggregate cost is $2,076,988, which is the product of the following:

- 253,311 words for one set of 47 materials.
- 500 words translated per hour.
- 73 FIDE SNPs.
- $56.16/hr wage.

Translating one set of 47 materials into one other language would cost an estimated $28,452 (253,311 words /500 words/hr x $28.08/hr x 2 for (100 percent for fringe benefits)). Based on these assumptions, it would cost $2,076,996 for 73 FIDE SNPs, HIDE SNPs, and AIPs to translate one set of materials into one other language. Any additional documents needing translation would be a one-time cost with a smaller cost to update the documents in future contract years.

4. Part D Medication Therapy Management (MTM) Program Targeting Requirements (§ 423.153)

We are proposing to revise § 423.153(d)(2) to: (1) codify the current 9 core chronic diseases in regulation, and add HIV/AIDS to the list of core chronic diseases for a total of 10 core chronic diseases and require Part D sponsors to include all core chronic diseases in their MTM targeting criteria; (2) lower the maximum number of Part D drugs a Part D sponsor may require from 8 to 5 drugs and require sponsors to include all Part D maintenance drugs in their

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[230]Extrapolated based on data from CMS-4144-F (76 CFR 21549) that estimated 91,623 words for translation of approximately 17 plan materials.

[231] Mean hourly wage for interpreters and translators, May 2021 retrieved from: https://www.bls.gov/oes/current/oes273091.htm The mean rate of $28.08 was doubled to include fringe benefits and overwork time.

[232]Translation rates vary widely and also depend on the technical nature of what is translated as well as whether adequate review time is included. The consensus of multiple websoures i) https://www.proz.com/forum/money_matters/300163-words_per_hour.html ii) https://www.pactranz.com/translation-times/ iii) https://www.getblend.com/blog/output-words-per-day/ iv) https://www.trainingfortranslators.com/2011/01/20/webinar-question-how-many-words-per-day/ provides ranges from 200 words /hour to 1000 words per hour. We have selected 500 as a reasonable average and invite stakeholder feedback on the reasonableness of this assumption.

targeting criteria; and (3) change the annual cost threshold methodology to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020). We estimate that these proposals would increase the number of Part D beneficiaries eligible for MTM services.

These proposed changes would allow us to address specific problems identified in the Part D MTM program by improving access to MTM services for enrollees with multiple chronic conditions who are taking multiple Part D drugs, reducing marked variability in MTM eligibility across plans, better aligning with Congressional intent to improve medication use and reduce the risk of adverse events by focusing more on case complexity and drug regimen, and establishing a more reasonable cost threshold that would keep the MTM program size manageable. Almost all of the chronic diseases that CMS is proposing to codify as core chronic diseases are more prevalent among underserved populations, including minority and lower income populations. As a result, we anticipate that our proposed changes will increase eligibility rates among those populations, promoting consistent, equitable, and expanded access to MTM services.

We estimate that these proposals would increase the number and percentage of Part D enrollees eligible for MTM services from 4.5 million (9 percent) to 11.4 million (23 percent). Although the increase in MTM program enrollment is estimated to cost $336,121,888 for the provision of required MTM services, we cannot definitively score this proposal because there may be other administrative costs attributable to MTM, and MTM program costs are not a specific line item that can be easily extracted from the bid. Additionally, published studies have found that MTM services may generate overall medical savings, for example, through reduced adverse outcomes including reduced hospitalizations and readmissions, outpatient encounters, or nursing home admissions.[233] CMS is unable to generate reliable savings estimates from the published studies due to limitations in potential study design, including the lack of a control group and numerous intervening variables. The burden associated with these proposed changes is

[233]Ramalho de Olivera, D; Brummel, A; Miller, D. Medication Therapy Management: 10 Years of Experience in a Large Integrated Health Care System J Manag Care Pharm. 2010;16(3):185-95.

addressed in the Collection of Information section (section VII.) of this proposed rule in the ICR section for MTM targeting criteria.

5. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c))

The proposed regulatory provisions would amend the existing regulations at §§ 401.305(a)(2), 422.326(c), and 423.360(c) to change the standard for an "identified overpayment" for Medicare Parts A, B, C, and D by adopting and codifying, by reference, the knowledge standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1). The regulations implementing section 1128J(d) (C/D final overpayment rule 79 FR 29844 (May 23, 2014) §§ 422.326 and 423.360, and A/B final overpayment rule 81 FR 7654 (February 12, 2016), §§ 401.301, 401.303 and 401.305) proposed only technical changes for overpayment reporting.

We now propose to amend the final Parts A & B Overpayment Rule at § 401.305(a)(2) to remove the reference to "reasonable diligence" and replace it with language at section 1128J(d)(4)(A) of the Act that gives the terms "knowing" and "knowingly" the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). We do not have a basis for estimating the impact associated with this amendment. We solicit comment on the analysis and conclusions provided in the RIA.

The provision at § 422.326(c) was vacated by the United States District Court for the District of Columbia in 2018, and the District Court noted in its decision that "(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a-7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly … a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' " *Id.* at 190. This proposed rule proposes to codify this knowledge standard.

Since we now propose to amend the final Parts C & D Overpayment Rule at §§ 422.326(c) and 423.360(c), to remove the reference to "reasonable diligence" and replace it with language at section 1128J(d)(4)(A) that gives the terms "knowing" and "knowingly" the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A), we do not have a basis for estimating the impact associated with this amendment. We solicit comment on the analysis and conclusions provided in the RIA.

6. Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74)

This rule requires involuntary disenrollment for individuals enrolled in an MA MSA plan. The requirement proposed at §§ 422.74(b)(2)(vi) and (d)(10) would establish a process for involuntary disenrollment for an individual who loses eligibility mid-year and, more specifically, the requirement for the MA organization to give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual for disenrollment for any of the reasons other than death or loss of entitlement to Part A or Part B, or unlawful presence in the United States.

This disenrollment triggers three events:

- CMS will no longer make prospective monthly payments to the MSA plan for this individual.

- Per § 422.314(c), CMS will recover the remainder of the lump-sum deposited into the MSA enrollee's account. MSA enrollees receive a lump-sum deposited at the beginning of the calendar year or on the first month coverage begins in the plan (if the enrollee is entitled to Medicare in the middle of the year and he/she joins a Medicare MSA plan at that time). The funds deposited in the Medical Savings Account for health care expenses can be used to pay for the enrollee's health care before the high deductible is reached.

If an MSA enrollee is disenrolled, mid-year, for the first of the month after no longer meeting the MSA eligibility criteria, CMS will recover the remaining whole months from the

disenrolled beneficiary by offsetting any amount Medicare pays the plan for new enrollees in a month.

- Involuntarily disenrolled individuals would be defaulted to enrollment in Original Medicare, as proposed in § 422.74(e)(1), which will now pay claims incurred by the former MSA enrollee. The former MSA enrollee also has the option to elect to join another MA plan during a valid enrollment period.

To analyze these three effects, we note that the sum of the risk adjusted capitated payment and the contribution of the lump sum payment amount to the individual's medical savings account should equal the benchmark for payment by Medicare for MA coverage of a beneficiary. In other words, the three effects are largely cancelled out resulting in an insignificant impact to the Medicare Trust Funds. MA costs and FFS costs are somewhat different due to differences in between the two programs regarding provider contracting and coding intensity, as well as pricing for margin and profits. However, because the number of individuals who are involuntarily disenrolled from MA MSA plans is expected to be very small, the overall impact to the Medicare Trust Funds is insignificant.

7. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

We are proposing to add, remove, and update certain measures and to make methodological clarifications (to codify current practice and policies) to the Part C and D Star Ratings program. These measure additions, removals, and updates and methodological clarifications are routine, and routine changes have historically had very little or no impact on the highest ratings (that is, overall rating for MA-PD contracts, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). Hence, we anticipate there will be no, or negligible, impact on the Medicare Trust Fund from these routine changes we are proposing in this rule. Beyond the Trust Fund, there may be effects on supplemental benefits, premiums, and plan profits. These impacts will likely vary significantly from plan to plan (or contract to

contract) based on the business strategies and the competitive landscape for each plan and contract.

We are also proposing some methodological enhancements to the Star Ratings as follows: replacing the current reward factor with an HEI reward, reducing the weight of patient experience/complaints and access measures, removing guardrails, modifying the hold harmless policy used for the improvement measures, adding a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, and removing the 60 percent rule that is applied when adjusting Star Ratings for extreme and uncontrollable circumstances (for example, natural disasters like hurricanes or public health emergencies). We anticipate that removing guardrails, removing the 60 percent rule, and adding a rule for subregulatory measure removal would each have a negligible impact on the highest ratings. Three of our proposed enhancements have the potential to cause a contract's Star Rating to change: (1) applying the improvement measure highest rating hold harmless provision only to 5 star contracts instead of for those contracts with a rating of 4 or higher stars; (2) decreasing the weight of patient experience, complaints, and access measures from four to two; and (3) replacing the current reward factor with an HEI that would reward contracts for doing well serving enrollees with various social risk factors.

We simulated the cumulative impact of the proposed changes on MA-PD contracts by contract size using the 2021 Star Ratings. Consistent with what we have observed historically, there is more enrollment in high performing contracts as seen in Table 14. All enrollment categories see a small decrease in the average overall rating ranging from -0.06 to -0.15 under this simulation. The amount of the decrease in the overall rating increases as the enrollment size categories increase, with the proposed changes having a somewhat larger impact for higher rated contracts.

TABLE 14: OVERALL RATING SIMULATIONS BY CONTRACT SIZE

Enrollment Category	Number of Contracts	2021 Overall Rating Average	Simulated Overall Rating Average	Difference
< 5,000	76	3.54	3.48	-0.06
>= 5,000 - < 25,000	137	3.69	3.62	-0.07
>= 25,000 - < 100,000	125	3.94	3.84	-0.10
>= 100,000	55	4.13	3.97	-0.15

We also simulated the cumulative impact of the proposed changes to the overall rating by geographical area – specifically, by State, DC, and Puerto Rico. Since the service area of a contract can include multiple states, we assigned to each enrollee the rating of their MA contract and calculated the average rating across all enrollees residing in each State. The average change in the overall rating is a decrease of 0.17, with the changes ranging from 0.0 to -0.37 across geographic areas. Table 15 shows the simulated changes by State, DC, and Puerto Rico. The second column is the number of MA enrollees in each State in contracts that received the 2021 overall rating. In most cases, but not all, there are larger declines in areas that had on average higher 2021 overall ratings.

TABLE 15: STAR RATINGS SIMULATIONS BY STATE, DC AND PUERTO RICO

State	Number of Enrollees	2021 Overall Rating	Simulated Overall Rating	Difference
AK	1,524	4.08	3.94	-0.14
AL	443,969	4.24	3.96	-0.28
AR	170,915	3.59	3.44	-0.15
AZ	521,901	3.76	3.71	-0.05
CA	2,657,281	4.46	4.43	-0.02
CO	367,021	4.30	4.10	-0.21
CT	271,820	4.07	3.96	-0.10
DC	19,146	4.32	4.13	-0.18
DE	34,468	3.95	3.86	-0.09
FL	2,111,559	4.11	3.95	-0.16
GA	697,263	3.92	3.77	-0.15
HI	127,315	4.05	3.74	-0.31
IA	131,963	3.97	3.85	-0.13
ID	113,540	3.80	3.72	-0.08
IL	548,385	4.11	3.87	-0.24
IN	402,282	3.98	3.74	-0.23
KS	97,754	3.85	3.69	-0.15
KY	313,488	3.90	3.65	-0.25
LA	339,228	4.24	3.98	-0.26
MA	309,105	4.55	4.18	-0.37

State	Number of Enrollees	2021 Overall Rating	Simulated Overall Rating	Difference
MD	127,039	4.28	4.00	-0.28
ME	119,565	4.43	4.10	-0.33
MI	819,565	3.76	3.69	-0.08
MN	458,194	4.31	3.95	-0.36
MO	445,550	4.12	3.84	-0.28
MS	123,683	3.70	3.49	-0.21
MT	44,284	4.00	3.93	-0.07
NC	746,214	4.13	3.96	-0.17
ND	23,931	4.02	3.92	-0.10
NE	56,025	4.13	3.90	-0.23
NH	55,680	3.98	3.74	-0.23
NJ	484,539	3.87	3.83	-0.05
NM	153,762	3.73	3.63	-0.09
NV	199,573	3.92	3.87	-0.05
NY	1,510,549	3.82	3.72	-0.10
OH	943,397	3.98	3.90	-0.08
OK	149,407	3.75	3.63	-0.12
OR	391,460	4.13	3.89	-0.25
PA	1,157,687	4.10	3.98	-0.12
PR	592,702	4.03	4.03	0.00
RI	84,615	4.02	3.87	-0.15
SC	310,810	3.73	3.57	-0.16
SD	37,222	3.99	3.85	-0.13
TN	548,221	4.11	4.01	-0.10
TX	1,638,848	3.95	3.79	-0.17
UT	148,224	3.95	3.65	-0.30
VA	335,867	3.91	3.80	-0.11
VT	17,644	3.86	3.57	-0.28
WA	450,597	4.05	3.80	-0.24
WI	488,875	4.14	3.94	-0.20
WV	133,231	3.90	3.61	-0.29
WY	4,101	3.60	3.49	-0.11

We calculated the cost impacts summarized in Tables 12 and 13 due to these proposed Star Ratings updates by quantifying the difference in the MA organization's final Star Rating with the proposed changes and without the proposed changes. We assume Medicare Trust Fund impacts due to the Star Ratings changes associated with these three proposed revisions to the methodology. The first two of these changes would be effective for the 2026 Star Ratings and would impact the 2027 plan payments and 2027 Quality Bonus Payments. The introduction of the HEI reward in lieu of the current reward factor would impact the 2027 Star Ratings and would impact the 2028 plan payments and 2028 Quality Bonus Payments.

All impacts are considered transfers, but we request comment on the extent to which provision of goods or services would increase or decrease in association with the payment changes. The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those contracts that would have Star Ratings changes under this proposed rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

- A Star Rating of 4.0 or higher will result in a QBP for the MA contract, which, in turn, leads to a higher benchmark for the MA plans offered by the MA organization under that contract. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).
- The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, the Private Health Baseline assumptions are updated with the assumed Star Ratings changes described in this proposed rule. We first estimated the three proposed changes to the Star Ratings calculations as independent of each other and, since there are likely overall Star Rating interactions between the three changes, the impacts, as shown in Table 16, should be viewed separately and should not be summed. The negative values in this section of this proposed rule represent net savings to the Medicare Trust Funds. For the improvement measure hold harmless provision, net savings are estimated to be between $2.08 billion in 2027 and $3.52 billion in 2033, resulting in a ten year savings estimate of $19.53 billion, which equates to 0.3 percent of the Private Health Baseline for the years 2024 through 2033. The patient experience/complaints and access measure weight provision is expected to result in net savings of between $330 million in 2027 and $580 million in 2033, resulting in a 10 year savings estimate of $3.28 billion. This amount equates to 0.05 percent of the Private Health Baseline for 2024 – 2033. The replacement of the current reward factor with

the HEI reward is expected to result in net savings of between $670 million in 2028 and $1,050 million in 2033 resulting in a 10-year savings estimate of $5.12 billion. $5.12 billion represents 0.08 percent of the Private Health Baseline for the years 2024 – 2033. These projections are based on simulations using data from the 2020 and 2021 Star Ratings.

TABLE 16: NEW IMPACTS OF STAR RATINGS PROPOSED PROVISIONS (NET IMPACTS ($ Millions) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES)

Calendar Year	Improvement Measure Hold Harmless	Percent of Private Health Baseline	Patient Experience/Complaints/Access Measure Weight	Percent of Private Health Baseline	Health Equity Index Reward	Percent of Private Health Baseline
2024	-	0.00%	-	0.00%	-	0.00%
2025	-	0.00%	-	0.00%	-	0.00%
2026	-	0.00%	-	0.00%	-	0.00%
2027	(2,080)	-0.36%	(330)	-0.06%	-	0.00%
2028	(2,330)	-0.37%	(380)	-0.06%	(670)	-0.11%
2029	(2,550)	-0.37%	(430)	-0.06%	(750)	-0.11%
2030	(2,760)	-0.38%	(480)	-0.07%	(820)	-0.11%
2031	(2,980)	-0.38%	(530)	-0.07%	(880)	-0.11%
2032	(3,310)	-0.38%	(550)	-0.06%	(950)	-0.11%
2033	(3,520)	-0.38%	(580)	-0.06%	(1,050)	-0.11%
Total	(19,530)	-0.29%	(3,280)	-0.05%	(5,120)	-0.08%

We also estimated the cumulative impact of the proposed changes to the Star Ratings calculations since there are interactions between the changes. The impacts are showing in Table 17. The negative values represent net savings to the Medicare Trust Funds. For the Star Ratings updates, net savings are estimated to be between $2.41 billion in 2027 and $4.57 billion in 2033, resulting in a 10-year savings estimate of $ 24.97 billion, which equates to 0.37 percent of the Private Health Baseline for the years 2024 through 2033.

TABLE 17: NET IMPACTS ($ Millions) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Net Impact Star Ratings Updates	Percent of Private Health Baseline
2024	-	0.00%
2025	-	0.00%
2026	-	0.00%
2027	(2,410)	-0.42%
2028	(2,980)	-0.47%
2029	(3,280)	-0.48%
2030	(3,560)	-0.48%
2031	(3,860)	-0.49%
2032	(4,310)	-0.49%
2033	(4,570)	-0.49%
Total	(24,970)	-0.37%

8. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)

In this rule we are proposing to revise the Part D LIS income and resource standards at § 423.773 to expand eligibility for the full benefit to individuals who currently have the partial benefit and make a coordinating change in § 423.780. This proposal would change the level of assistance that an individual could qualify for in paying their Part D premiums, copays and deductibles. While there would be no change in the number of individuals eligible for the Part D LIS, it would create a transition of people from partial subsidy status to full benefit status.

The result of this change is the Federal Government providing more subsidies to low income Medicare beneficiaries for Part D coverage which would result in additional costs to the Medicare Trust Fund. The following table reflects the scored government costs for expanding the full LIS subsidy to the current partially-subsidized LIS beneficiaries starting January 1, 2024. Included in this table are the breakdown of increases for both the low income cost-sharing subsidy (LICS) and the low income premium subsidy (LIPS). OACT arrived at the cost estimate by assuming that the ratio of post-LICS-out-of-pocket as a percentage to the total drug cost for the partial subsidy beneficiaries would be similar to that of the full subsidy beneficiaries. In other words, (plan benefits + LICS)/total drug cost for the partial subsidy beneficiaries will be the same as that for the full subsidy beneficiaries.

TABLE 18: PROJECTED COSTS FOR EXPANDING LOW INCOME SUBSIDIES

	Calendar Year Incurred ($ in millions)									
	2024	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**
LIS total	$169	$180	$193	$207	$221	$237	$253	$269	$286	$304
LICS	$135	$144	$155	$166	$178	$191	$205	$218	$232	$247
LIPS	$34	$36	$38	$41	$43	$46	$48	$51	$54	$57

E. Alternatives Considered

In this section, CMS includes discussions of Alternatives Considered for several provisions. 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, , different enforcement methods and different levels of stringency, are not fully relevant since the provision is already being complied with adequately. Alternative analysis is not provided for these provisions.

1. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors that are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500(b), 423.501, 422.528, 423.521, 422.529, and 423.522)

As an alternative to our proposal to require MA organizations and Part D sponsors respond to CMS with a summary of their agreement or disagreement with the final settlement amount, we considered two others approaches.

First, we considered requiring a response by all contracts, regardless of whether or not they disagreed with CMS's calculation of the final settlement amount. This would result in an aggregate burden of $26,931.

Second, we considered requiring MA organizations and Part D sponsors that are consolidating, non-renewing, or terminating their contract to internally calculate the final settlement amount, have a financial officer attest that the final settlement amount meets actuarial standards, and report to CMS the results within a specified timeframe. For purposes of this

alternative, we are using the same assumption detailed in the ICR regarding final settlement. We would add the burden of attestation which is the burden of a chief executive and manager taking 1 hour each for the purposes of meeting to describe the final settlement amount and attest to the accuracy of the calculation. As indicated in section VII.B.16. of this proposed rule historically, on average, from the period 2015 through 2020, 44 contracts agreed with the CMS decision on final settlement amount and 3 requested a review.

The revised increased burden would be $1,018 (3 contracts *2 hours for attestation * $169.67).

For comparisons we list these two approaches and the approach, we adopted in VII.C.14. of this proposed rule.

- Finalized approach: Total burden of $15,712.
- Alternate approach where every contract writes a summary: $26,931.
- An addendum of attestation to either of the above 2 approaches: An additional $1,018.

Further information is provided in Table 19 in this section of this rule.

TABLE 19: TOTAL STAFF BURDEN (hr) FOR CALCULATING FINAL SETTLEMENT

Occupation	Burden per Entity for Required Tasks (in hours)	Wage/hr ($)	Total burden per entity ($)
Managers	1	134.52	134.52
Chief Executive	1	204.82	204.82
Total	2	169.67	339.34

We are not proposing the first alternative because we do not believe that adding a requirement to our current process for MA organizations and Part D sponsors to acknowledge receipt of the notice of final determination and indicate they agree with the final determination amount is beneficial. CMS believes this will not enhance our process by providing CMS information on whether an MA organization or Part D sponsor agrees with the final settlement and instead propose that MA organizations and Part D sponsors request a review of the CMS calculated final settlement amount if they disagree.

We are not proposing the second alternative because we believe that requiring MA organizations and Part D sponsors to calculate the final settlement amount would introduce a significant financial and administrative burden on MA organizations and Part D sponsors that are consolidating, non-renewing, or terminating without improving on the efficiency of our proposed process.

2. Part D Medication Therapy Management (MTM) Program Targeting Criteria (§ 423.153)

We considered two alternatives to our proposal. The first alternative we considered would maintain our proposed changes related to chronic diseases and Part D drug utilization, but would establish a cost threshold commensurate with the average annual cost of 2 Part D maintenance drugs. Under this alternative, CMS would calculate the dollar amount based on the average daily cost of both brand and generic drugs identified as maintenance drugs in Medi-Span. Based on 2020 PDE data, the cost threshold under this alternative would be $1,657, with an estimated program size of about 9,363,087 beneficiaries (19.53 percent of the total Part D population) and an estimated increased burden of $251,600,394.

The second alternative we considered would include our proposed changes related to chronic diseases, retain the current maximum number of Part D drugs a sponsor may require for MTM program enrollment at 8 drugs, require sponsors to include all Part D maintenance drugs in their targeting criteria, and establish a cost threshold commensurate with the average annual cost of 5 generic maintenance drugs. Under this alternative, CMS would calculate the dollar amount of the cost threshold as proposed but would only include generic maintenance drugs. Based on 2020 PDE data, the cost threshold under this alternative would be $840, with an estimated program size of 7,924,203 beneficiaries (16.53 percent of the total Part D population) and an estimated increased burden of $177,022,820.

We are not proposing the first alternative primarily because a cost threshold at $1,657 would continue to exclude too many Part D enrollees who meet the other targeting criteria. Based on 2020 data, between 25 and 50 percent of the Part D enrollees who have 3 or more core

chronic diseases and are taking 5 or more Part D maintenance drugs would be ineligible because their annual Part D covered drug cost may not meet or exceed this cost threshold amount (25th percentile is $823; median is $2,778); therefore, many eligibility gaps based on Part D drug spend would persist. We also have concerns that including brand drugs in the cost threshold calculation could potentially contribute to greater volatility in the dollar amount each year.

We are not proposing the second alternative because, as discussed in section III.R. of this proposed rule, we want to reduce MTM eligibility gaps to ensure that more individuals who would most benefit from MTM services have access. Individuals taking 5 or more prescription drugs are associated with a higher risk of potentially inappropriate medication use.[234] Thus, we believe it is appropriate to reduce the maximum number of Part D drugs a sponsor may require for MTM program enrollment to 5 drugs, as reflected in our proposed changes.

Overall, we believe our proposed changes represent the best way to address unmet beneficiary needs while balancing program size and burden on Part D sponsors.

3. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.100, 422.101, 422.112, 422.137, 422.138).

Both the reasons for proposing the UM Committee requirement provisions and the alternatives they are intended to counteract are discussed in the respective preambles. Because we cannot quantify any of these we have not included a repetition of this analysis in the RIA. A brief summary is as follows:

- The proposed regulation clarifies coverage criteria of basic benefits standards by requiring MA plans to make medical necessity determinations based on Traditional Medicare coverage and benefit criteria as reflected in Medicare statutes and regulations, NCDs and LCDs and prohibiting the use of internal coverage criteria or additional medical necessity standards

[234]M.-C. Weng, et al., The impact of number of drugs prescribed on the risk of potentially inappropriate medication among outpatient older adults with chronic diseases, QJM: An International Journal of Medicine, Volume 106, Issue 11, November 2013, Pages 1009–1015, https://doi.org/10.1093/qjmed/hct141.

except in limited situations. This is major policy shift in which MA plans may only deny coverage for Medicare items and services based on Traditional Medicare coverage rules. We understand that this provision will create new burden which is difficult to quantify.

- The proposed regulation also requires plans to follow a specific process in developing internal coverage policies and to provide a public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations. We provided an impact analysis in section VII.C.4 of this proposed rule of one quantifiable aspect of this proposal. We will also solicit stakeholder input on aspects of the proposal and its impact.

- The regulation requires a PA approval to be valid for the duration of the approved course of treatment. In combination with the proposals to limit when MA plans may deny coverage (or use internal coverage criteria that are not used in Traditional Medicare), this will limit an MA organization's ability to approve only part of what a provider has ordered or prescribed. In addition, the proposal would minimize repetitive PA requirements for enrollees on an appropriate, chronic, stable therapy. It would be qualitatively beneficial for the enrollee.

- The proposed regulation establishes a minimum 90-day transition period when an enrollee switches to a new plan, or switches from FFS to an MA plan (including new MA plan members who are also new to Medicare as well) for any ongoing courses of treatment so that treatment is not interrupted while UM requirements are addressed. This was adopted from similar transition periods in Part D; we believe it is appropriate to align the transition period and scope with the current transition requirements in Part D. This proposal is qualitatively beneficial for the enrollee.

- The proposed regulation requires MA organizations to establish a committee (similar to a P&T committee), led by the Medical Director, that reviews utilization management policies annually and keeps current of Medicare statutes and regulations, LCDs and NCDs. It also includes a discussion of "gold-carding" in the preamble that encourages MA plans to implement

gold-carding programs to improve efficiency and reduce burden on providers with a proven track record of compliance. This is qualitatively beneficial for the enrollee. It was modeled on similar committees used for Part B step therapy programs and by Part D plans. Its major effect is to ask plans to review their policies.

We re-emphasize that we are not able to fully quantify all of these and the discussion of reasons is discussed in the preamble.

4. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

As an alternative to our proposal to have a tiered health equity index reward, we have considered a non-tiered approach. We have proposed a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified SRFs. We propose that contracts that have percentages of enrollees with any of the specified SRFs in a given year that are greater than or equal to one-half of the contract-level median percentage of enrollees with the specified SRFs up to, but not including, the contract-level median would qualify for one-half of the HEI reward. Contracts that have percentages of enrollees with any of the specified SRFs greater than or equal to the contract-level median would qualify for the full HEI reward.

We have also considered and are soliciting comment on an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRF greater than or equal to one-half of the contract-level median would qualify for the full HEI reward. Both the tiered and non-tiered HEI reward structures align with our goals of promoting enrollment of enrollees with SRFs and not rewarding contracts that may do well among enrollees with SRFs but serve very few enrollees in this population, although the tiered HEI reward structure goes further in aligning with these goals. The non-tiered HEI reward structure aligns better with the goal of ease of use and understanding for contracts and other stakeholders. Although the non-tiered approach would slightly increase the mean HEI reward, it does not impact the number of contracts qualifying for the reward.

F. Accounting Statement and Table

The following Table 20 summarizes costs and transfers by provision. As required by OMB Circular A–4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Table 20, we have prepared an accounting statement showing the costs and transfers associated with the provisions of this final rule for calendar years 2024 through 2033. Table 20 is based on Table 21 which lists transfers and costs by provision and year. Table 20 is expressed in millions of dollars with costs listed as positive numbers and transfers of savings (reduction in dollar spending) to the Medicare Trust Fund listed as a savings. As can be seen, the net annualized cost of this rule is about $580 million per year. This cost is offset by a reduction in dollar spending (savings) to the Medicare Trust Fund of about $2 billion per year. Minor seeming discrepancies in totals in Tables 21 reflects use of underlying spreadsheets, rather than intermediate rounded amounts. A breakdown of these costs of this proposed rule by provision may be found in Table 21.

TABLE 20: ACCOUNTING TABLE (MILLIONS $)*

Item	Annualized at 7%	Annualized at 3%	Period	Who is Impacted
Net Annualized Monetized Cost in 2023 dollars	575.4	580.0	2024-2033	Federal Government, MA organizations, and Part D sponsors
Transfers to the Medicare Trust Fund	(2,175.5)	(2,356.8)	2024-2033	From MA plans and Part D Sponsors to the Medicare Trust Fund

* Cost is expressed as a positive number. The savings (reductions in dollar spending) to the Medicare Trust Fund is expressed as a negative Note: These estimates reflect a non doubling of wages to account for fringe benefits for enrollees. Had we doubled wages for enrollees then the annualized impact at 7% (and 3%) would be 575.6 and 580.2 respectively rather than 575.4 and 580.0.

The following Table 21 summarizes costs, and transfers by provision and year and forms a basis for the accounting Table 20. In Table 21, costs are expressed as positive numbers while savings to the Medicare Trust Fund (reduced dollar spending) are expressed as negative numbers. All numbers are in millions. The costs in this table are true costs reflecting increased consumption of services and goods. However, the savings (reduced dollar spending) to the Medicare Trust Funds reflect a transfer from MA plans, Part D sponsors, and enrollees, who increase their spending, to the Trust Fund.

Table 21 combines related provisions. For example, all PACE provisions in the COI summary table are combined into one line item. Similarly, the paperwork burden of the LI NET

provision in the COI Summary Table is combined with the drug costs listed in Table 17 into one line item.

TABLE 21: SUMMARY OF COST AND TRANSFERS BY PROVISION AND YEAR*

	2024 Cost	2025 Cost	2026 Cost	2027 Cost	2027 Transfers	2028 Cost	2028 Transfers	2029 Costs	2029 Transfers	2030 Cost	2030 Transfers	2031 Cost	2031 Transfers	2032 Cost	2032 Transfers	2033 Cost	2033 Transfers	Raw 10 Year Totals
Total Costs	529.3	527.8	541.8	556.8		570.8		587.8		604.8		620.8		638.8		657.8		5,836.5
Savings of the Medicare Trust Fund					(2,410.0)		(2,980.0)		(3,280.0)		(3,560.0)		(3,860.0)		(4,310.0)		(4,570.0)	(24,970.0)
Translation (FIDE, HIDE SNPS)	2.1		-	-		-		-		-		-		-		-		2.1
Translation (Standing request)	10.4																	10.4
Low Income NET program	5.3	7.3	8.3	9.3		9.3		10.3		11.3		11.3		12.3		13.3		97.6
Prior Authorization	1.0	1.0	1.0	1.0		1.0		1.0		1.0		1.0		1.0		1.0		10.1
MTM Eligibility	336.1	336.1	336.1	336.1		336.1		336.1		336.1		336.1		336.1		336.1		3,361.2
Formulary changes	2.2	2.2	2.2	2.2		2.2		2.2		2.2		2.2		2.2		2.2		21.6
Reinstatement notices	0.3	0.3	0.3	0.3		0.3		0.3		0.3		0.3		0.3		0.3		2.9
Involuntary Disenrollment: Loss of Special Needs Status	0.5	0.5	0.5	0.5		0.5		0.5		0.5		0.5		0.5		0.5		4.9
Star Ratings					(2,410.0)		(2,980.0)		(3,280.0)		(3,560.0)		(3,860.0)		(4,310.0)		(4,570.0)	(24,970.0)
PACE Provisions	3.0	1.5	1.5	1.5		1.5		1.5		1.5		1.5		1.5		1.5		16.9
Marketing Provisions	0.17	0.17	0.17	0.17		0.17		0.17		0.17		0.17		0.17		0.17		1.7
Medical Necessity Determinations	(1.24)	(1.24)	(1.24)	(1.24)		(1.24)		(1.24)		(1.24)		(1.24)		(1.24)		(1.24)		(12.4)
Notification of Provider Terminations	0.5	0.52	0.52	0.52		0.52		0.52		0.52		0.52		0.52		0.52		5.2
Expansion of low-income subsidies	169.00	180.00	193.00	207.00		221.00		237.00		253.00		269.00		286.00		304.00		2,319.0

*Numbers are in millions. Costs are positive numbers while savings (reduced dollar spending) of the Medicare Trust Fund are expressed as negative numbers. Note: These estimates reflect a nondoubling of wages to account for fringe benefits for enrollees. Had we doubled wages for enrollees then the annual impact of the low coverage provision would increase by 0.26 million annually.

Notes to the summary table:

*Raw 10-year totals are found in the right most column. Monetized annual amounts are found in the accounting table.

**Almost all individual entries are costs. However, the medical necessity determinations are a savings. Since this is the only item that was a savings it was not believe necessary to create a new column of savings. Consequently, these savings are listed with the costs as negative numbers. The actual computations were presented in the section VIII. of this rule.

***There are 3 provisions that impact the Medicare Trust Fund:

(i) The Star Rating provision is estimated to save $25.0 billion over 10 years. These savings are transfers.

(ii) The low-income NET program will cost (increase spending of) the Medicare Trust Fund $95 million over 10 years (the $97.6 figure actually mentioned reflects an extra 2.6 million in paperwork burden).

(iii) The expansion of low-income subsidies with cost (increase spending of the Medicare Trust Fund) $2.3 billion over 10 years.

Both items (ii) and (iii) reflects actual costs not transfers; they reflect the costs of increased benefits by plans which are passed over to the Trust Fund. The net impact to the Trust Fund over 10 years is $22.6 billion in savings (decreased spending).

G. Conclusion

As indicated in Table 19 the star rating provisions whose impact begins in 2027 reduces dollar spending of the Medicare Trust Fund by $22.6 billion over 10 years. This is offset by the paperwork costs of this rule which amount to $3.5 billion over 10 years. The major driver of the paperwork costs is the MTM provisions. Over an infinite horizon the aggregate costs of this rule expressed in 2016 dollars is $384 million per year. In accordance with requirements, this major rule has been reviewed by OMB.

IX. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 2, 2022.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, and Privacy.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health Insurance, Health maintenance organizations (HMO), Loan programs-health Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), 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:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w-5) and sec. 105, Pub. L. 114-10, 129 Stat. 87.

2. Section 401.305 is amended by revising paragraph (a)(2) to read as follows:

§ 401.305 Requirements for reporting and returning of overpayments.

(a) * * *

(1) * * *

(2) A person has identified an overpayment when the person knowingly receives or retains an overpayment. The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

Subpart K - Enrollment, Entitlement, and Disenrollment under Medicare Contract

3. 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.

4. Section 417.454 is amended by revising paragraph (e)(4) to read as follows:

§ 417.454 Charges to Medicare Enrollees.

* * * * *

(e) * * *

(4) A COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

5. Section 417.460 is amended by revising paragraphs (c)(3) and (e)(2) and (4) and adding paragraph (e)(7) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or a third party to which CMS has assigned this responsibility, such as an HMO or CMP) may reinstate enrollment in the plan, without interruption of coverage, if the individual submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date, has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment, shows good cause for failure to pay, and pays all overdue premiums or other charges within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(e) * * *

(2) *Effort to resolve the problem*. The HMO or CMP must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures, and including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. The HMO or CMP must inform the individual of the right to use the

organization's grievance procedures, through the notices described in paragraph (e)(7) of this section.

* * * * *

(4) *Documentation.* The HMO or CMP must document the problems, efforts, and medical conditions as described in paragraphs (e)(1) through (3) of this section. Dated copies of the notices required in paragraph (d)(2)(iv) of this section must also be submitted to CMS.

* * * * *

(7) *Other required notices.* The HMO or CMP must provide the individual two notices prior to submitting the request for disenrollment to CMS. The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action. If the disruptive behavior ceases after the enrollee receives the advance notice and then later resumes, the HMO or CMP must begin the process again. The HMO or CMP must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-days period the individual has the to provide an opportunity for the individual to cease their behavior. The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the enrollee that the HMO or CMP will request CMS permission to involuntarily disenroll the enrollee. This notice must be provided prior to submission of the request to CMS.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

6. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

7. Section 422.2 is amended by –

a. Adding definitions in alphabetical order for “Chronic Condition Special Needs Plan”, “Facility-based Institutional Special Needs Plan”, “Hybrid Institutional Special Needs Plan”, “Institutional-equivalent Special Needs Plan”, and “Institutional Special Needs Plan”; and

b. Revising the definition of “Severe or disabling chronic condition”.

The additions and revision read as follows:

§ 422.2 Definitions.

* * * * *

Chronic Condition Special Needs Plan (C-SNPs) means a SNP that restricts enrollment to MA eligible individuals who have one or more severe or disabling chronic conditions, as defined under this section, including restricting enrollment based on the multiple commonly co-morbid and clinically-linked condition groupings specified in § 422.4(a)(1)(iv) of this chapter.

* * * * *

Facility-based Institutional special needs plan (FI-SNP) means a type of 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 this section, for each county within the plan’s county-based service area; and must own or have a contractual arrangement with each institutionalized facility serving enrollees in the plan.

* * * * *

Hybrid Institutional special needs plan (HI-SNP) means a type of I-SNP that restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent in this section. HI-SNPs must meet the standards specified in the definitions of FI-SNP and IE-SNP.

* * * * *

Institutional-equivalent special needs plan (IE-SNP) means a type of I-SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent in this section.

* * * * *

Institutional special needs plan (I-SNP) means a SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent in this section. I-SNPs include the following subtypes: IE-SNP, HI-SNP, and FI-SNP

* * * * *

Network-based plan is defined as a coordinated care plan as specified in § 422.4(a)(1)(ii), a network-based MSA plan, or a section 1876 reasonable cost plan. A network-based plan excludes an MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

* * * * *

Severe or disabling chronic condition means, for the purpose of defining a special needs individual, the following co-morbid and medically complex chronic conditions that are life-threatening or significantly limit overall health or function, has a high risk of hospitalization or other significant adverse health outcomes, and requires intensive care coordination, and that which is designated by the Secretary under subsections 1859(b)(6)(B)(iii)(II) and 1859(f)(9)(A) of the Act:

(1) Chronic alcohol use disorder and other substance use disorders (SUDs).

(2) Autoimmune disorders:

(i) Polyarteritis nodosa.

(ii) Polymyalgia rheumatica.

(iii) Polymyositis.

(iv) Dermatomyositis.

(v) Rheumatoid arthritis.

(vi) Systemic lupus erythematosus.

(vii) Psoriatic arthritis.

(viii) Scleroderma.

(3) Cancer.

(4) Cardiovascular disorders:

(i) Cardiac arrhythmias.

(ii) Coronary artery disease.

(iii) Peripheral vascular disease.

(iv) Valvular heart disease.

(5) Chronic heart failure.

(6). Dementia.

(7) Diabetes mellitus.

(8) Overweight, obesity, and metabolic syndrome.

(9) Chronic gastrointestinal disease:

(i) Chronic liver disease.

(ii) Non-alcoholic fatty liver disease (NAFLD)

(iii) Hepatitis B.

(iv) Hepatitis C

(v) Pancreatitis.

(vi) Irritable bowel syndrome.

(vii) Inflammatory bowel disease.

(10) Chronic kidney disease (CKD):

(i) CKD requiring dialysis/End-stage renal disease (ESRD).

(ii) CKD not requiring dialysis.

(11) Severe hematologic disorders:

(i) Aplastic anemia.

(ii) Hemophilia.

(iii) Immune thrombocytopenic purpura.

(iv) Myelodysplastic syndrome.

(v) Sickle-cell disease (excluding sickle-cell trait).

(vi) Chronic venous thromboembolic disorder.

(12) HIV/AIDS;

(13) Chronic lung disorders:

(i) Asthma, Chronic bronchitis.

(ii) Cystic Fibrosis.

(iii) Emphysema.

(iv) Pulmonary fibrosis.

(v) Pulmonary hypertension.

(vi) Chronic Obstructive Pulmonary Disease (COPD).

(14) Chronic and disabling mental health conditions:

(i) Bipolar disorders.

(ii) Major depressive disorders.

(iii) Paranoid disorder.

(iv) Schizophrenia.

(v) Schizoaffective disorder.

(vi) Post-traumatic stress disorder (PTSD).

(vii) Eating Disorders.

(viii) Anxiety disorders.

(15) Neurologic disorders:

(i) Amyotrophic lateral sclerosis (ALS).

(ii) Epilepsy.

(iii) Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia).

(iv) Huntington’s disease.

(v) Multiple sclerosis.

(vi) Parkinson’s disease.

(vii) Polyneuropathy.

(viii) Fibromyalgia.

(ix) Chronic fatigue syndrome.

(x) Spinal cord injuries.

(xi) Spinal stenosis.

(xii) Stroke-related neurologic deficit.

(16) Stroke.

(17) Post-organ transplantation care.

(18) Immunodeficiency and Immunosuppressive disorders.

(19) Conditions associated with cognitive impairment:

(i) Alzheimer's disease.

(ii) Intellectual disabilities and developmental disabilities.

(iii) Traumatic brain injuries.

(iv) Disabling mental illness associated with cognitive impairment.

(v) Mild cognitive impairment.

(20) Conditions with functional challenges and require similar services including the following: spinal cord injuries, paralysis, limb loss, stroke, and arthritis;

(21) Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell.

(22) Conditions that require continued therapy services in order for individuals to maintain or retain functioning.

* * * * *

8. Section 422.4 is amended by adding paragraphs (a)(1)(iv)(A) and (B) to read as follows:

§ 422.4 Types of MA plans.

(a) * * *

(1) * * *

(iv) * * *

(A) A C-SNP may focus on one severe or disabling chronic condition, as defined in § 422.2, or on a grouping of severe or disabling chronic conditions.

(B) Upon CMS approval, an MA organization may offer a C-SNP that focuses on multiple commonly co-morbid and clinically-linked conditions from the following list of groupings:

(*1*) Diabetes mellitus and chronic heart failure.

(*2*) Chronic heart failure and cardiovascular disorders.

(*3*) Diabetes mellitus and cardiovascular disorders.

(*4*) Diabetes mellitus, chronic heart failure, and cardiovascular disorders.

(*5*) Stroke and cardiovascular disorders.

(*6*) Anxiety associated with COPD.

(*7*) Chronic kidney disease (CKD) and post-(renal) organ transplantation.

(*8*) Substance use disorders (SUD) and chronic mental health disorders.

* * * * *

9. Section 422.52 is amended by adding paragraph (g) to read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

* * * * *

(g) *Special eligibility rule for certain C-SNPs*. For C-SNPs that use a group of multiple severe or disabling chronic conditions as described in § 422.4(a)(1)(iv) of this chapter, special needs individuals need only have one of the qualifying severe or disabling chronic conditions in order to be eligible to enroll.

10. Section 422.60 is amended by adding paragraph (h) to read as follows:

§ 422.60 Election process.

* * * * *

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment*. When an individual is disenrolled from an MA plan due to the election of a new plan, the MA organization must reinstate the individual's enrollment in that plan if the individual cancels the election in the new plan within timeframes established by CMS. The MA organization offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

11. Section 422.62 is amended by—

a. Adding a sentence to the end of paragraph (b)(2);

b. Revising paragraph (b)(18) introductory text;

c. Redesignating paragraphs (b)(18)(i) through (iii) as paragraphs (b)(18)(ii) through (iv);

d. Adding new paragraph (b)(18)(i);

e. Redesignating paragraph (b)(26) as paragraph (b)(27); and

f. Adding new paragraph (b)(26).

The additions and revision read as follows:

§ 422.62 Election of coverage under an MA plan

* * * * *

(b) * * *

(2) * * * Also eligible for this SEP are individuals who, as a result of a change in permanent residence, have new MA plan options available to them.

* * * * *

(18) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for a SEP to make a MA enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full

calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable State or local law, or, if incident end date is not otherwise identified, the incident end date specified in paragraph (b)(18)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date will be one year after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. Therefore, the maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration.

* * * * *

(26) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR 406.27 and 407.23. The SEP begins when the individual submits their application for premium-Part A and Part B, or Part B only, and continues for the first 2 months of enrollment in Part A (premium or premium-free) and Part B. The MA plan enrollment is effective the first of the month following the month the MA plan receives the enrollment request.

* * * * *

12. Section 422.66 is amended by adding paragraphs (b)(3)(v) and (b)(6) to read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(b) * * *

(3) * * *

(v) In the case of an incomplete disenrollment request –

(A) Document its efforts to obtain information to complete the disenrollment request;

(B) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request.

(C) The organization must deny the request if any additional information needed to make the disenrollment request "complete" is not received within the following timeframes:

(*1*) For disenrollment requests received during the AEP, by December 7, or within 21 calendar days of the request for additional information, whichever is later; and

(*2*) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

* * * * *

(6) *When a disenrollment request is considered incomplete.* A disenrollment request is considered to be incomplete if the required but missing information is not received by the MA organization within the timeframe specified in paragraph (b)(3)(v)(C)of this section.

* * * * *

13. Section 422.74 is amended by –

a. Adding paragraph (b)(2)(vi);

b. Revising paragraphs (c), (d)(1)(i)(B)(*1*), and (d)(1)(v);

c. Revising paragraphs (d)(2)(iii) and (iv);

d. Adding paragraph (d)(2)(vii);

e. Revising paragraph (d)(4)(i);

f. Adding paragraphs (d)(4)(ii)(A), reserved (d)(4)(ii)(B), and (d)(4)(iii)(F);

g. Revising paragraph (d)(4)(iv)

h. Redesignating paragraph (d)(8) as paragraph (d)(9) and adding new paragraph (d)(8);

i. Adding paragraph (d)(10); and

j. Revising paragraph (e)(1).

The revisions and additions read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(b) * * *

(2) * * *

(vi) The individual no longer meets the MA MSA's eligibility criteria specified under § 422.56 due to a mid-year change in eligibility.

* * * * *

(c) *Notice requirement*. If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i) and (vi), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(vi) must -

(1) Be provided to the individual before submission of the disenrollment to CMS; and

(2) Include an explanation of the individual's right to submit a grievance under the MA organization's grievance procedures.

(d) * * *

(1) * * *

(i) * * *

(B) * * *

(*1*) Be at least 2 whole calendar months; and

* * * * *

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as an MA organization) may reinstate enrollment in the MA plan, without interruption of coverage, if the individual -

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date; and

(B) Has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment; and

(C) Shows good cause for failure to pay within the initial grace period; and

(D) Pays all overdue premiums within 3 calendar months after the disenrollment date; and

(E) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(2) * * *

(iii) *Effort to resolve the problem*. The MA organization must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. In addition, the MA organization must inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (d)(2)(vii) of this section. The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation*. The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS. Dated copies of the notices required in paragraph (d)(2)(vii) of this section must also be submitted to CMS.

* * * * *

(vii) *Required notices*. The MA organization must provide the individual two notices prior to submitting the request for disenrollment to CMS. The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action. If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the organization must begin the process again. The organization must wait at least 30 days after sending the advance notice before sending the second notice, during which 30- day period the individual has the opportunity to cease their behavior. The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the MA organization will request CMS permission to involuntarily disenroll the member. This notice must be provided prior to submission of the request to CMS. These notices are in addition to the disenrollment submission notice required under paragraph (c) of this section.

* * * * *

(4) * * *

(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual, and must document the basis for such action, if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved -

* * * * *

(ii) * * *

(A) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the US Postal Service as undeliverable and a forwarding address is not provided.

(B) [Reserved]

(iii) * * *

(F) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the US Postal Service as undeliverable and a forwarding address is not provided.

* * * * *

(iv) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area or within the first 10 calendar days of the sixth month of an individual's temporary absence from the plan service area or, for individuals using a visitor/traveler benefit, within the first 10 calendar days of the last month of the allowable absence. If the plan learns of an individual's temporary absence from the plan service area after the expiration of the allowable period, the plan must send this notice within 10 calendar days of the plan learning of the absence.

* * * * *

(8) *Loss of Special Needs Status.* If an enrollee loses special needs status and must be disenrolled under paragraph (b)(2)(iv) of this section, the SNP must provide the enrollee with a minimum of 30 days advance notice of disenrollment, regardless of the date of loss of special needs status.

(i) The advance notice must be provided to the enrollee within 10 calendar days of the plan learning of the loss of special needs status and must afford the enrollee an opportunity to prove that they are still eligible to remain in the plan.

(ii) The advance notice must include the disenrollment effective date, a description of eligibility for the SEP described in § 422.62(b)(11), and, if applicable, information regarding the period of deemed continued eligibility, the duration of the period of deemed continued eligibility, and the consequences of not regaining special needs status within the period of deemed continued eligibility.

(iii) A final involuntary disenrollment notice must be sent within 3 business days following the disenrollment effective date, which is either the last day of the period of deemed continued eligibility, if applicable, or a minimum of 30 days after providing the advance notice of disenrollment. The final involuntary disenrollment notice must be sent before submission of the disenrollment to CMS.

(iv) The final involuntary disenrollment notice must include an explanation of the enrollee's right to file a grievance under the MA organization's grievance procedures that are required by § 422.564.

* * * * *

(10) *Mid-year change in MSA eligibility.* If an individual is no longer eligible for an MA MSA plan due to a mid-year change in eligibility, disenrollment is effective the first day of the calendar month following the MA organization's notice to the individual that they are ineligible in accordance with paragraph (b)(2)(vi) of this section.

(e) * * *

(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B or mid-year loss of MSA eligibility.* An individual who is disenrolled under paragraph (b)(1)(i), (ii), or (iii), or (b)(2)(ii) or (vi) of this section is deemed to have elected original Medicare.

* * * * *

14. Section 422.101 is amended by –

a. Revising paragraph (b)(2);

c. Adding paragraph (b)(6);

d. Revising paragraph (c);

e. Adding paragraph (f)(2)(vi);

f. Revising paragraph (f)(3)(iii); and

g. Adding paragraph (f)(3)(iv)

The revisions and additions read as follows:

§ 422.101 Requirements relating to basic benefits

* * * * *

(b) * * *

(2) General coverage and benefit conditions included in Traditional Medicare laws , unless superseded by laws applicable to MA plans. For example, this includes coverage criteria for inpatient admissions at 42 CFR 412.3, requirements for coverage of Skilled Nursing Facility (SNF) Care and Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) coverage criteria at 42 CFR 412.622(3).

* * * * *

(6) When coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, MA organizations may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question. For internal coverage policies, the MA organization must provide:

(i) A publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;

(ii) A list of the sources of such evidence; and

(iii) Include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination.

(c) Medical necessity determinations and special coverage provisions— (1) *Medical necessity determinations.* (i) MA organizations must make medical necessity determinations based on:

(A) Coverage and benefit criteria as specified at paragraphs (b) and (c) of this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) or (c) of this section;

(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act;

(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and

(D) Where appropriate, involvement of the organization’s medical director as required at § 422.562(a)(4).

(ii) [Reserved]

(2) *Exception for qualifying hospital stay*. MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

* * * * *

(f) * * *

(2) * * *

(vi) For I-SNPs, ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in § 422.2) contain requirements allowing I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized.

(3) * * *

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent and each MOC must meet an aggregate minimum benchmark of 70 percent, and a

plan's model of care will only be approved if each element of the model of care meets the minimum benchmark and the model of care meets aggregate minimum benchmark.

(A) An MOC for a C-SNP that receives a passing score is approved for 1 year.

(B) An MOC for an I-SNP or D-SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years. An MOC for an I-SNP or D-SNP that receives a score of 75 percent to 84 percent is approved for 2 years. An MOC for an I-SNP or D-SNP that receives a score of 70 percent to 74 percent is approved for 1 year.

(C) For an MOC that fails to meet a minimum element benchmark score of 50 percent or an MOC that fails to meet the aggregate minimum benchmark of 70 percent, the MA organization is permitted a one-time opportunity to resubmit the corrected MOC for reevaluation; and an MOC that is corrected and resubmitted using this cure period is approved for only 1 year.

(iv) An MA organization that offers a SNP that seeks to revise the MOC before the end of the MOC approval period may submit changes to the MOC as off-cycle MOC submissions for review by NCQA as follows:

(A) D-SNPs and I-SNPs may submit updates and corrections to their NCQA-approved MOC any number of times between June 1st and November 30th of each calendar year or when CMS requires an off-cycle submission to ensure compliance with applicable law.

(B) D-SNPs and I-SNPs are required to submit updates or corrections as part of an off-cycle submissions based on:

(*1*) Substantial changes in policies or procedures pertinent to: the health risk assessment (HRA) process; revising processes to develop and update the Individualized Care Plan (ICP); the integrated care team process; risk stratification methodology; or care transition protocols;

(*2*) Target population changes that warrant modifications to care management approaches;

(*3*) Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations;

(*4*) Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel); or

(*5*) Changes to quality metrics used to measure performance.

(C) NCQA will only review off-cycle submissions after the start of the effective date of the current MOC unless CMS deems it necessary to ensure compliance with the applicable regulations.

(D) SNPs may not implement any changes to a MOC until NCQA has approved the changes and the MOC is not rescored during the off-cycle review of changes to the MOC.

(E) Successful revision of the MOC under paragraph (f)(3)(iii)(B) of this section does not change the MOC's original period of approval by NCQA.

(F) C-SNPs are only eligible to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.

(G) When a deficiency identified in the off-cycle revisions to a MOC, the SNP may cure the deficiency a single time between June 1st and November 30th of each calendar year.

15. Section 422.109 is amended by revising the section heading and adding paragraphs (e) and (f) to read as follows:

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials

* * * * *

(e) *Clinical trials*. (1) With the exception specified in paragraph (e)(3) of this section, original Medicare is responsible for coverage of MA enrollees participating in CMS-approved

clinical trials to include routine costs, as specified in NCD 310.1, and any coverage for the diagnosis or treatment of complications related to the clinical trial.

(2) MA enrollees are not charged traditional Medicare Part A and B deductibles for clinical trial coverage.

(3) MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services.

(4) An enrollee's in-network cost-sharing portion must be included in the MA plan's maximum out-of-pocket calculation.

(5) MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial.

(f) *A and B IDE trials*. (1) MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies that are covered under § 405.211(a) of this chapter.

(2) MA plans are responsible for coverage of CMS-approved Category B devices that are covered under § 405.211(b) of this chapter.

16. Section 422.111 is amended by –

a. Revising paragraphs (b)(3)(i) and (e);

b. Revising pargraph (h)(1)(iii)(A); and

c. Revising paragraph (h)(1)(iv)(B).

The revisions and additions read as follows:

§ 422.111 Disclosure Requirements.

* * * * *

(b) * * *

(3) * * *

(i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office; notations for MOUD-Waivered Providers as defined in § 422.116(b)(1)(xxx) who are listed on the Substance Abuse and Mental Health Services Administration's Buprenorphine Practitioner Locator; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

* * * * *

(e) *Changes to provider network*. The MA organization must provide enrollees notice of a termination of a contracted provider, irrespective of whether the termination was for cause or without cause, in accordance with § 422.2267(e)(12). The MA organization must make a good faith effort to provide enrollees notice of a for-cause termination of a contracted provider within the timeframes required by this paragraph (e). For all terminations, the MA organization must meet the following requirements:

(1) For contract terminations that involve a primary care or behavioral health provider:

(i) Provide both written and telephonic notice,

(ii) At least 45 calendar days before the termination effective date, and

(iii) To all enrollees who have ever been patients of that primary care or behavioral health provider.

(2) For contract terminations that involve specialty types other than primary care or behavioral health:

(i) Provide written notice,

(ii) At least 30 calendar days before the termination effective date, and

(iii) To all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The phrase "enrollees who are patients seen on a regular basis by the provider whose contract is terminating" means enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated.

* * * * *

(h) * * *

(1) * * *

(iii) * * *

(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals. Such interpreters must:

(*1*) Adhere to generally accepted interpreter ethics principles, including confidentiality;

(*2*) Demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(*3*) Interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

* * * * *

(iv) * * *

(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

* * * * *

17. Section 422.112 is amended by—

a. Adding a sentence at the end of paragraph (a)(1)(i);

b. Adding paragraph (a)(1)(iii);

c. Removing the last sentence of paragraph (a)(3);

d. Revising paragraphs (a)(6)(i) and (a)(8);

f. Revising paragraph (b)(3); and

g. Adding paragraphs (b)(8) and (9).

The additions and revisions read as follows:

§ 422.112 Access to services.

(a) * * *

(1) * * *

(i) * * * The network must include providers that specialize in behavioral health services.

* * * * *

(iii) Arrange for 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.

* * * * *

(6) * * *

(i) Timeliness of access to care and member services that meet or exceed standards in this paragraph. The MA organization must continuously monitor access to care and member services and must take corrective action as necessary to ensure that appointment wait times in the provider network comply with these standards. The minimum standards for appointment wait times for primary care and behavioral health services are as follows for appointments:

(A) Urgently needed services or emergency—immediately;

(B) Services that are not emergency or urgently needed, but the enrollee requires medical attention—within 1 week; and

(C) Routine and preventive care—within 30 days.

* * * * *

(8) *Ensuring equitable access to Medicare Advantage (MA) Services.* Ensure that services are provided in a culturally competent manner and to promote equitable access to all enrollees, including the following:

(i) People with limited English proficiency or reading skills.

(ii) People of ethnic, cultural, racial, or religious minorities.

(iii) People with disabilities.

(iv) People who identify as lesbian, gay, bisexual, or other diverse sexual orientations.

(v) People who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex.

(vi) People living in rural areas and other areas with high levels of deprivation.

(vii) People otherwise adversely affected by persistent poverty or inequality.

* * * * *

(b) * * *

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the MA plan, including nursing home and community-based services, and behavioral health services; and

* * * * *

(8)(i) With respect to basic benefits, policies for using prior authorization that at a minimum include that for enrollees undergoing an active course of treatment—

(A) Approval of a prior authorization request for a course of treatment is valid for the entire duration of the approved course of treatment; and

(B) A minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. This includes enrollees new to a plan and enrollees new to Medicare. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

(ii) For purposes of this paragraph (b)(8), the following definitions apply:

(A) *Course of treatment* means as a prescribed order or ordered course of treatment for a specific individual with a specific condition is outlined and decided upon ahead of time with the patient and provider. A course of treatment may but is not required to be part of a treatment plan.

(B) *Active course of treatment* means a course of treatment in which a patient is actively seeing the provider and following the course of treatment.

(9) Procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135.

(i) The MA organization must make information about its digital health literacy screening and digital health education programs available to CMS upon request. Requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of this section.

(ii) [Reserved].

* * * * *

18. Section 422.113 is amended by revising paragraph (b)(1)(i) introductory text to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(1) * * *

(i) *Emergency medical condition* means a medical condition, mental or physical, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in –

* * * * *

19. Section 422.114 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

* * * * *

(a) * * *

(3) * * *

(ii) Network-based plan means a plan as defined in § 422.2.

* * * * *

20. Section 422.116 is amended by —

a. Removing "§ 422.114(a)(3)(ii)" and adding "§ 422.2" in its place in paragraph (a)(1)(i);

b. Adding paragraphs (b)(1)(xxviii) through (xxx);

c. Adding in alphabetical order entries for "Clinical Psychology", "Licensed Clinical Social Work", and "Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)" to Table 1 to Paragraph (d)(2);

d. Adding paragraphs (d)(5)(xiii) through (xv); and

e. Adding in alphabetical order entries for "Clinical Psychology", "Clinical Social Work", and "Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)" to Table 2 to Paragraph (e)(3)(i)(C).

The revisions and additions read as follows:

§ 422.116 Network adequacy.

* * * * *

(b) * * *

(1) * * *

(xxviii) Clinical Psychology.

(xxix) Clinical Social Work.

(xxx) Prescribers of Medication for Opioid Use Disorder (MOUD) (including MOUD-Waivered Providers and/or Opioid Treatment Programs (OTPs)). For purposes of this regulation, MOUD-Waivered Providers means providers who are waived by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Agency to administer, dispense, or prescribe narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment for opioid use disorder in accordance with section 303(g)(2) of the Controlled Substances Act, and OTPs means OTPs as defined in section 1861(jjj)(2) of the Act.

* * * * *

(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
*	*	*	*	*	*	*				
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
*	*	*	*	*	*	*				
Licensed Clinical Social Work	20	10	30	20	50	35	75	60	125	110
*	*	*	*	*	*	*				
Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)	20	10	30	20	50	35	75	60	110	100
*	*	*	*	*	*	*				

* * * * *

(5) * * *

(xiii) Clinical Psychology.

(xxiv) Clinical Social Work.

(xv) Providers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)

* * * * *

(e) * * *

(3) * * *

(i) * * *

(C) * * *

Table 2 to Paragraph (e)(3)(i)(C)

Minimum Ratio	Large Metro	Metro	Micro	Rural	CEAC
* *	*	*	*	*	*
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
* *	*	*	*	*	*
Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)	0.03	0.03	0.03	0.03	0.03

* * * * *

21. Section 422.137 is added to read as follows:

§ 422.137 Medicare Advantage Utilization Management Committee

(a) *General.* An MA organization that uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan's medical director (described in § 422.562(a)(4)).

(b) *Limit on use of UM policies and procedures.* 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.

(c) *Utilization Management Committee Composition.* The UM committee must—

(1) Include a majority of members who are practicing physicians.

(2) Include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan.

(3) Include at least one practicing physician who is an expert regarding care of elderly or disabled individuals.

(4) Include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies.

(d) *Utilization Management Committee Responsibilities.* The UM committee must—

(1) At least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. Such review must consider:

(i) The services to which the utilization management applies;

(ii) Coverage decisions and guidelines for Traditional Medicare, including NCDs, LCDs, and laws; and

(iii) Relevant current clinical guidelines.

(2) Approve only utilization management policies and procedures that:

(i) Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);

(ii) For prior authorization policies, comply with requirements and standards at § 422.138;

(iii) Comply with the standards in § 422.202(b)(1); and

(iv) Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

(3) Revise the utilization management policies and procedures as necessary to comply with the standards in this regulation, including removing requirements for UM for services and items that no longer warrant UM.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

22. Section 422.138 is added to read as follows:

§ 422.138 Prior authorization.

(a) *Requirement.* When a coordinated care plan, as specified in § 422.4(a)(iii) (including MSA network plans), uses prior authorization processes in connection with basic benefits or supplemental benefits, the MA organization must comply with the requirements in this section. (MA PFFS are not permitted to use prior authorization policies or "prior notification" policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS plan in advance that services will be furnished).

(b) *Application.* Prior authorization policies and procedures for coordinated care plans may only be used for one or more the following purposes:

(1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or

(2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1), or

(3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) *Effect of prior authorization or pre-service approval*. If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity unless the MA organization has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616.

23. Section 422.152 is amended by adding paragraph (a)(5) to read as follows:

§ 422.152 Quality Improvement Program.

(a) * * *

(5) Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.

* * * * *

24. Section 422.162 is amended by –

a. Adding in alphabetical order to paragraph (a) a definition for "health equity index"; and

b. Revising paragraphs (b)(1) and (b)(3)(iv)(A)(*1*).

The addition and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

* * * * *

(b)(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA-PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with § 422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 422.166(c), with both the reward factor and CAI applied as applicable, as described in § 422.166(f). Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 422.166(d) with both the reward factor and CAI applied as applicable, as described in § 422.166(f). CMS includes the

Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

* * * * *

(3) * * *

(iv) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures, call center measures, and improvement measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

* * * * *

25. Section 422.164 is amended by revising paragraph (d)(1)(v) and adding paragraph (e)(1)(iii) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(e) * * *

(1) * * *

(iii) The measure steward other than CMS retires a measure.

* * * * *

26. Section 422.166 is amended by—

a. Revising paragraphs (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii) and (iv), (e)(2), (f)(1) introductory text, and (f)(2)(i) introductory text;

b. Adding paragraph (f)(3); and

c. Revising paragraphs (g)(1), (i)(3)(iv), (i)(9)(i), and (i)(10)(i).

The revisions and addition read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 through October 2024, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(c) * * *

(1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(d) * * *

(1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

* * * * *

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, the measure will be assigned the weight associated with its category.

* * * * *

(f) * * *

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

* * * * *

(2) * * *

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

* * * * *

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA-PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA-PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA-PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low income subsidy or being dual eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings would be adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2

years of data used. Data are used for contracts that have data for only the most recent year of the 2 years, but data are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA-PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the health equity index. CMS will announce the measures being evaluated for inclusion in the calculation of the health equity index under this paragraph (f)(3) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's health equity index, the measure must meet the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees in the contract with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each measure for the subset enrollees that have one or more of the specified SRFs will be

assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the health equity index and 0.4 if the contract receives a score of 1 on the health equity index. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the health equity index reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the health equity index and 0.2 if the contract receives a score of 1 on the HEI. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have an HEI score calculated (that is, contracts that are not scored on at least half of the measures included in the index) would not receive a HEI reward.

(ix) The HEI reward is added to the overall rating, Part C rating for MA-PDs and MA-only contracts (and cost contracts), Part D rating for MA-PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

* * * * *

(g) * * *

(1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA-PD contracts and Part C summary rating for MA-only contracts), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement

measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) If the highest rating for each contract-type is 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and the CAI adjustment under paragraph (f) of this section, a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and CAI adjustment, the rating will be calculated with the improvement measure(s).

* * * * *

(i) * * *

(3) * * *

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS-HOS measure. The adjustment is for 3 years after the extreme and uncontrollable circumstance.

* * * * *

(9) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

* * * * *

(10) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

* * * * *

27. Section 422.202 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 422.202 Participation procedures.

(b) * * *

(1) * * *

(i) Are based on current evidence in widely used treatment guidelines or clinical literature;

* * * * *

28. Section 422.254 is amended by adding paragraph (a)(5) to read as follows.

§ 422.254 Submission of bids.

(a) * * *

(5) After an MA organization is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 422.2263(a)), the MA organization shall not change and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined in § 422.162) for the following contract year without modification, except where a modification in benefits is required by law. This prohibition on changes applies to cost sharing and premiums as well as benefits.

* * * * *

29. Section 422.260 is amended by –

a. Revising paragraphs (c)(1)(i) and (c)(2)(v);

b. Adding paragraph (c)(3)(iii); and

c. Revising paragraph (d).

The revisions and addition read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

* * * * *

(c) * * *

(1) * * *

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. Requests are limited to those circumstances where the error could impact an individual measure's value or the overall Star Rating. Based on any corrections, any applicable measure-level Star Ratings could go up, stay the same, or go down. The overall Star Rating also may go up, stay the same, or go down based on any corrections.

* * * * *

(2) * * *

(v) The MA organization must prove by a preponderance of evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect. The burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status.

* * * * *

(3) * * *

(iii) The MA organization may not request a review based on data inaccuracy for the following data sources: HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources.

* * * * *

(d) *Reopening of QBP determinations*. CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process that demonstrates that the initial QBP determination was incorrect. If a contract's QBP determination is reopened as a result of a systemic calculation issue that impacts more than the MA organization that submitted an appeal, the QBP rating for MA organizations that did not appeal will only be updated if it results in a higher QBP rating.

30. Section 422.326 is amended by revising paragraph (c) to read as follows:

§ 422.326 Reporting and returning of overpayments.

* * * *

(c) *Identified overpayment.* The MA organization has identified an overpayment when the MA organization knowingly receives or retains an overpayment. The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

31 Section 422.500 is amended by adding in alphabetical order to paragraph (b) definitions for "Final Settlement Adjustment Period", "Final Settlement Amount", and "Final Settlement Process" to read as follows:

§ 422.500 Scope and Definitions.

* * * * *

(b) * * *

Final settlement adjustment period means the period of time between when the contract terminates and the date the MA organization is issued a notice of the final settlement amount.

Final settlement amount is the final payment amount that CMS owes and ultimately pays to an MA organization, or that an MA organization owes and ultimately pays to CMS, with

respect to an MA contract that has consolidated, non-renewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(i) Risk adjustment reconciliation (described in § 422.310);

(ii) Part D annual reconciliation (described in § 423.343);

(iii) Coverage Gap Discount Program annual reconciliation (described in § 423.2320) and;

(iv) MLR remittances (described in §§ 422.2470 and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS calculates the final settlement amount, issues the final settlement amount along with supporting documentation in the notice of final settlement to the MA organization, receives responses from the MA organization requesting an appeal of the final settlement amount, and takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the MA organization. The final settlement amount will be calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

* * * * *

32. Section 422.502 is amended by adding paragraph (a)(3) to read as follows:

§ 422.502 Evaluation and determination procedures.

(a) * * *

(3)(i) CMS does not evaluate or issue a notice of determination described in paragraph (c) of this section when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 422.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

* * * * *

33. Section 422.503 is amended by revising paragraphs (e)(1) and (2) to read as follows:

§ 422.503 General provisions.

* * * * *

(e) * * *

(1) The contract will be amended to exclude any MA plan, MA plan segment, or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan, segment, or entity will be deemed to be in place when such a request is made.

34. Section 422.504 is amended by adding paragraph (a)(19) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(19) Not to establish a segment of an MA plan that meets the criteria in § 422.514(d), as determined in the procedures described in § 422.514(e)(3), with the addition of the newly enrolled individuals.

* * * * *

35. Section 422.510 is amended by adding paragraph (a)(4)(xvi) to read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(a) * * *

(4) * * *

(xvi) Meets the criteria in § 422.514(d)(1) or (2).

* * * * *

36. Section 422.514 is amended by revising paragraph (d)(1) and adding paragraph (g) to read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(d) * * *

(1) Enter into or renew a contract under this subpart, for plan year 2024 and subsequent years, for a MA plan that –

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Projects enrollment in its bid submitted under § 422.254 that 80 percent or more enrollees of the plan's total enrollment are enrollees entitled to medical assistance under a State plan under title XIX.

* * * * *

(g) *Applicability to segments*. The rules under paragraphs (d) through (f) of this section also apply to segments of the MA plan as provided for local MA plans under § 422.262(c)(2).

32. Section 422.528 is added to read as follows:

§ 422.528. Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the MA organization a notice of final settlement. The notice of final settlement contains at least the following information:

(1) A final settlement amount, which may be either an amount due to the MA organization, or an amount due from the MA organization, or $0 if nothing is due to or from the MA organization, for the contract that has been consolidated, nonrenewed, or terminated;

(2) Relevant banking and financial mailing instructions for MA organizations that owe CMS a final settlement amount;

(3) Relevant CMS contact information, and;

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 422.529.

(b) *Request for an appeal.* An MA organization that disagrees with the final settlement amount will have 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 422.529.

(1) If a MA organization agrees with the final settlement amount, no response is required.

(2) If an MA organization disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS will not consider subsequent requests for appeal.

(c) *Actions if a MA organization does not request an appeal*. (1) For MA organizations that are owed money by CMS, CMS will remit payment to the MA organization within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For MA organizations that owe CMS money, the MA organization will be required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the MA organization fails to remit payment within that 120-calendar-day period, CMS will refer the debt owed to CMS to the Department of Treasury for collection.

(d) *Actions following submission of a request for appeal.* If an MA organization responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS will conduct a review under the process described at§ 422.529.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under paragraph (a) of this section, is issued to the MA organization, CMS will no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there will be no adjustments applied to amounts used in the calculation of the final settlement amount.

33. Section 422.529 is added to read as follows:

§ 422.529. Requesting an appeal of the final settlement amount.

(a) *Appeals process*. If an MA organization does not agree with the final settlement amount described in § 422.528(a) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the final settlement amount described in § 422.528(a) according to the following process:

(i) *Manner and timing of request*. A written request for reconsideration must be filed within 15 calendar days from the date that CMS issued the notice of final settlement to the MA organization.

(ii) *Content of request*. The written request for reconsideration must:

(A) Specify the calculations with which the MA organization disagrees and the reasons for its disagreement,

(B) include evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect, and

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration*. In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the MA organization.

(iv) *Reconsideration decision*. The CMS reconsideration official informs the MA organization of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision*. The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing*. An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (iv) of this section.

(i) *Manner and timing of request*. A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS' reconsideration decision.

(ii) *Content of request*. The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures*. The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) CMS provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer*. The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision*. The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator*. The Administrator's review will be conducted in the following manner:

(i) *Manner and timing of request*. An MA organization that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (2)(iv) of this section. An MA organization may submit written arguments to the Administrator for review.

(ii) *Discretionary review*. After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Administrator's review*. If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision*. The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof*. (1) The MA organization's appeal is limited to CMS' calculation of the final settlement amount. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The MA organization bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

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

(d) *Continued compliance with other law required.* Nothing in this section limits an MA organization's responsibility to comply with any other applicable statute or regulation, including under section 1128J(d) of the Social Security Act.

34. Section 422.550 is amended by revising paragraph (d) to read as follows:

§ 422.550 General provisions.

* * * * *

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that –

(1) The current MA organization, with respect to the affected contract, has substantially failed to comply with the regulatory requirements pursuant to § 422.510(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 422.750(a)(1) and (3); intermediate sanctions imposed as part of this section will remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 423 of this chapter if applicable; and, if the application is

conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under paragraph (c) of this section for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in (d)(1) of this section, submit the documentation required under paragraph (c) of this section for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (d)(1)(i) or (ii) of this section within 30 days of imposition of intermediate sanctions as outlined in paragraph (d)(1) of this section, the existing contract will be subject to termination in accordance with § 422.510(a)(4)(ix).

* * * * *

35. Section 422.566 is amended by revising paragraph (d) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

36. Section 422.590 is amended by revising paragraph (b)(1) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(b) * * *

(1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)(2)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

* * * * *

37. Section 422.629 is amended by revising paragraph (k)(3) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(k) * * *

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. Any physician or other health care professional who reviews an integrated organization determination must have a current and unrestricted license to practice within the scope of his or her profession.

* * * * *

38. Section 422.760 is amended by revising paragraph (b)(3) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(3)(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(ii) *Calculation of penalty amounts.* (A) CMS will set minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(B) CMS will announce the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(C) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

* * * * *

39. Section 422.2261 is amended by revising paragraph (a)(2) and removing paragraph (a)(3).

The revision reads as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) * * *

(2) Materials must be submitted to the HPMS Marketing Module by the MA organization or, where materials have been developed by a Third Party Marketing Organization for multiple MA organizations or plans, by a Third Party Marketing Organization with prior approval of each MA organization on whose behalf the materials were created.

* * * * *

40. Section 422.2262 is amended by revising paragraph (a)(1)(ii) and adding paragraph (a)(1)(xix) to read as follows:

§ 422.2262 General communications materials and activity requirements.

* * * * *

(a) * * *

(1) * * *

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that has been published in either the current contract year or prior contract year.

* * * * *

(xix) Use the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card, in a misleading way.

* * * * *

41. Section 422.2263 is amended by adding paragraphs (b)(8) through (10) to read as follows:

§ 422.2263 General marketing requirements.

* * * * *

(b) * * *

(8) Advertise benefits that are not available to beneficiaries in the service area where the marketing appears, unless unavoidable in a local market.

(9) Market any products or plans, benefits, or costs, unless the MA organization or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) MA organization or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or fine print.

(ii) For television, online, or social media, the MA organization or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number or benefits.

(iii) For radio or other voice-based advertisements, MA organization or marketing names must be read at the same pace as the advertised phone numbers.

(10) MA organizations may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

* * * * *

42. Section 422.2264 is amended by –

a. Adding paragraphs (a)(2)(i)(A) and reserved (a)(2)(i)(B);

b. Revising paragraph (b)(2);

c. Removing paragraphs (c)(1)(ii)(C) and (E).

d. Redesignating paragraph (c)(1)(ii)(D) as paragraph (c)(1)(ii)(C); and

e. Revising paragraphs (c)(2)(i), (c)(3)(i), and (c)(3)(iii)(A) and (B).

The additions and revisions read as follows:

§ 422.2264 Beneficiary contact.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(A) Contact is considered to be unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable date and time, was previously scheduled.

(B) [Reserved].

(b) * * *

(2) If the MA organization reaches out to beneficiaries regarding plan business, as outlined in this section, the MA organization must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

* * * * *

(c) * * *

(2) * * *

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

* * * * *

(3) * * *

(i) At least 48 hours prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

* * * * *

(iii) * * *

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 6 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment, identifying the additional lines of business to be discussed; such Scope of Appointment is valid for six (6) months following the beneficiary's signature date.

* * * * *

43. Section 422.2265 is amended by revising paragraph (b)(4) to read as follows:

§ 422.2265 Websites.

* * * * *

(b) * * *

(4) A provider directory searchable by every element required in the model provider directory, such as name, location, specialty.

* * * * *

44. Section 422.2267 is amended by –

a. Redesignating paragraph (a)(3) as paragraph (a)(5);

b. Adding new paragraph (a)(3) and paragraph (a)(4);

c. Revising paragraph (e)(4) introductory text;

d. Adding paragraph (e)(4)(viii);

e. Revising paragraphs (e)(5)(ii)(A) introductory text, (e)(10) introductory text, and (e)(12); and

f. Revising paragraphs (e)(30)(vi) and (e)(41).

The additions and revisions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(a) * * *

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section or accessible format using auxiliary aids and services

upon receiving a request for the materials in another language or accessible format using auxiliary aids and services or when otherwise learning of the enrollee's preferred language or need for an accessible format using auxiliary aids and services. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan, as defined at § 422.2, or applicable integrated plan, as defined at § 422.561, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

(5) * * *

(e) * * *

(4) *Pre-Enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments, the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

* * * * *

(viii) Effect on current coverage.

(5) * * *

(ii) * * *

(A) Information on the following medical benefits, starting in the top half of the first page and in the order as identified in paragraphs (A)(1) through (A)(10), including--

* * * * *

(10) *Non-renewal Notice.* This is a standardized communications material through which plans must provide the information required under § 422.506.

* * * * *

(12) *Provider Termination Notice*. This is a model communications material through which plans must provide the information required under § 422.111(e).

(i) The written Provider Termination Notice must be provided in hard copy via U.S. mail (first class postage is recommended, but not required).

(ii) The written Provider Termination Notice must do all of the following:

(A) Inform the enrollee that the provider will no longer be in the network and the date the provider will leave the network.

(B) Include names and phone numbers of in-network providers that the enrollee may access for continued care (this information may be supplemented with information for accessing a current provider directory, including both online and direct mail options).

(C) Explain how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider.

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is impacted by the provider termination may contact 1-800-MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period, as specified in § 422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP.

(E) Include the MA organization's call center telephone number, TTY number, and hours and days of operation.

(iii) The telephonic Provider Termination Notice specified in § 422.111(e)(1)(i) must relay the same information as the written Provider Termination Notice as described in paragraph (e)(12)(ii) of this section.

* * * * *

(30) * * *

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all MA organizations in the service area the disclaimer consists of the statement: "We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are plans offered by [insert list of MA organizations here]. Please contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program to get information on all of your options." If the TPMO sells for all MA organizations in the service area the disclaimer consists of the statement: "We offer the following plans in your area [insert list of MA organizations]. You can always contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program for help with plan choices." The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

45. Section 422.2272 is amended by adding paragraph (e) to read as follows:

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

46. Section 422.2274 is amended by adding paragraph (c)(12), revising paragraph (g)(2)(ii), and adding paragraph (g)(4) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.

* * * * *

(g) * * *

(2) * * *

(ii) Record all marketing, sales, and enrollment calls, including calls via web-based technology, in their entirety.

* * * * *

(4) Personal beneficiary data collected by a TPMO may not be distributed to other TPMOs.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

47. 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.

48. Section 423.4 is amended by adding in alphabetical definitions for "Authorized generic drug", "Biological product", "Brand name biological product", "Immediate need individual", "Interchangeable biological product", "Limited Income Newly Eligible Transition (LI NET) sponsor", "MTM program", "Reference biological product", and "Unbranded biological product" to read as follows:

§ 423.4 Definitions.

* * * * *

Authorized generic drug means a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)).

Biological product means a product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Brand name biological product means a product licensed under section 351(a) or 351(k) of the Public Health Service Act and marketed under a brand name.

* * * * *

Immediate need individual means a beneficiary whose enrollment into LI NET is on the basis of presumed low income subsidy eligibility and immediate need of a Part D drug.

* * * * *

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 to be interchangeable with a reference product in accordance with sections 351(i)(3) and 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(i)(3) and 262(k)(4)).

Limited Income Newly Eligible Transition (LI NET) sponsor means a Part D sponsor selected by CMS to administer the LI NET program.

* * * * *

MTM program means a medication therapy management program described at § 423.153(d).

* * * * *

Reference biological product means a product as defined in section 351(i)(4) of the Public Health Service Act (42 U.S.C. 262(i)(4)).

* * * * *

Unbranded biological product means a product licensed under a biologics license application (BLA) under section 351(a) or 351(k) of the Public Health Service Act (42 U.S.C. 262(a) or 262(k)) and marketed without a brand name. It is licensed under the same BLA as the corresponding brand name biological product.

49. Section 423.32 is amended by adding paragraphs (h) and (i) to read as follows:

§ 423.32 Enrollment process.

* * * * *

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment*. When an individual is disenrolled from a Part D plan due to the election of a new plan, the Part D plan sponsor must reinstate enrollment if the individual cancels the election in the new plan timeframes established by CMS. The Part D plan sponsor offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

(i) *Exception for employer group health plans*. (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (i)(1) of this section, the beneficiary must certify that, at the time of enrollment in the PDP, he or she received the disclosure statement specified in § 423.128.

(3) Upon receipt of the election from the employer, the PDP sponsor must submit the enrollment to CMS within timeframes specified by CMS.

50. Section 423.36 is amended by adding paragraphs (b)(4), (d), (e), and (f) to read as follows:

§ 423.36 Disenrollment process.

* * * * *

(b) * * *

(4) In the case of an incomplete disenrollment request –

(i) Document its efforts to obtain information to complete the disenrollment request;

(ii) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request.

(iii) The organization must deny the request if any additional information needed to make the disenrollment request "complete" is not received within the following timeframes:

(A) For disenrollment requests received during the AEP by December 7, or within 21 calendar days of the request for additional information, whichever is later; and

(B) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

* * * * *

(d) *Incomplete disenrollment***.** A disenrollment request is considered to be incomplete if the required but missing information is not received by the PDP sponsor within the timeframe specified in paragraph (b)(4)(iii) of this section.

(e) *Exception for employer group health plans*. (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the PDP sponsor must submit the disenrollment to CMS within timeframes specified by CMS.

(f) *Effect of failure to submit disenrollment notice to CMS promptly*. If the PDP sponsor fails to submit the correct and complete notice required in paragraph (c)(1) of this section, the PDP sponsor must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

51. Section 423.38 is amended by—

a. Revising paragraphs (c)(7), (16), and (23).

b. Redesignating paragraph (c)(34) as paragraph (c)(35); and

c. Adding new paragraph (c)(34).

The revisions and addition read as follows:

§ 423.38 Enrollment periods

* * * * *

(c) * * *

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered. Also eligible for this SEP are individuals who, as a result of a change in permanent residence, have new Part D plan options available to them.

* * * * *

(16) The individual who is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B that starts January 1, 2023, is eligible to request enrollment in a Part D plan. The special enrollment period begins when the individual submits their Part B application and continues for the first 2 months of Part B enrollment. The Part D plan enrollment is effective the first of the month following the month the Part D sponsor receives the enrollment request.

* * * * *

(23) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for a SEP to make a Part D enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable State or local law, or, if the incident end date is not otherwise identified, the incident end date specified in paragraph (c)(23)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date will be 1 year after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. Therefore, the maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration.

(ii) The individual is eligible for this SEP provided the individual—

(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (c)(23), in an area for which a Federal, State or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area; and

(C) Was eligible for another election period at the time of the SEP eligibility period described in this paragraph (c)(23); and

(D) Did not make an election during that other election period due to the emergency or major disaster.

* * * * *

(34) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR parts 406.27 and 407.23. The SEP begins when the individual submits their premium-Part A or Part B application and continues for the first 2 months of enrollment in premium Part A or Part B. The Part D plan enrollment is effective the first of the month following the month the Part D plan receives the enrollment request.

* * * * *

52. Section 423.44 is amended by—

a. Adding paragraph (b)(1)(iii);

b. Revising paragraphs (d)(1) introductory text, (d)(1)(iii)(A), and (d)(1)(v) and (vi);

c. Revising paragraphs (d)(2)(iii) and (iv);

d. Adding paragraph (d)(2)(viii);

e. Revising paragraphs (d)(5)(i) and (ii); and

f. Adding paragraph (d)(9).

The additions and revisions read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(b) * * *

(1) * * *

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(9) of this section.

* * * * *

(d) * * *

(1) Except as specified in paragraph (d)(1)(v) of this section, a PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

* * * * *

(iii) * * *

(A) Be at least 2 whole calendar months; and

* * * * *

(v) A PDP sponsor may not disenroll an individual who had monthly premiums withheld per § 423.293(a) and (e) of this part or who is in premium withhold status, as defined by CMS. In addition, sponsors may not disenroll a member or initiate the disenrollment process if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer.

(vi) When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as a Part D sponsor) may reinstate enrollment in the PDP, without interruption of coverage, if the individual submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date, has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment, shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within

the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(2) * * *

(iii) *Effort to resolve the problem*. The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimer's disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures, through the notices described in paragraph (d)(2)(viii) of this section. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation*. The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS. Dated copies of the notices required in paragraph (d)(2)(viii) of this section must also be submitted to CMS.

* * * * *

(viii) *Required notices*. The PDP sponsor must provide the individual two notices prior to submitting the request for disenrollment to CMS. The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action. If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the sponsor must begin the process again. The sponsor must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-day period the individual has the opportunity to cease their behavior. The second notice, the notice of intent

to request CMS permission to disenroll the member, notifies the member that the PDP sponsor will request CMS permission to involuntarily disenroll the member. This notice must be provided prior to submission of the request to CMS. These notices are in addition to the disenrollment submission notice required under § 423.44(c).

* * * * *

(5) * * *

(i) The PDP must disenroll an individual, and must document the basis for such action, if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area.

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been determined by the PDP sponsor to be absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan, and document the basis for such action, effective on the first day of the 13th month after the individual left the service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within the first ten calendar days of the twelfth month of an individual's temporary absence from the plan service area or, if the sponsor learns of the individual's temporary absence from the plan service area after the expiration of the 12 month period, within 10 calendar days of the sponsor learning of the absence. The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 423.2267(e), if provided by mail, is returned to the Part D plan sponsor by the US Postal Service as undeliverable and a forwarding address is not provided.

* * * * *

(9) *Individual commits fraud or permits abuse of enrollment card*—(i) *Basis for disenrollment*. A PDP may disenroll the individual from a Part D plan if the individual -

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the PDP; or

(B) Intentionally permits others to use his or her enrollment card to obtain drugs under the PDP

(ii) *Notice of disenrollment.* The Part D plan must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

* * * * *

53. Section 423.100 is amended by:

a. Revising the definition for "Affected enrollee"; and

b. Adding, in alphabetical order, definitions for "Corresponding drug"; "Formulary crosswalk"; "Immediate negative formulary change"; "Maintenance change"; "Negative formulary change"; "Non-maintenance change"; "Other specified entities"; and "Safety-based claim edit".

The revision and addtions read as follows:

§ 423.100 Definitions.

* * * * *

Affected enrollee, as used in this subpart, means a Part D enrollee who is currently taking a covered Part D drug that is subject to a negative formulary change that affects the Part D enrollee's access to the drug during the current plan year.

* * * * *

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference biological product, or an unbranded biological product of a biological product.

* * * * *

Formulary crosswalk means the process during bid submission by which a formulary (as defined at § 423.4) is assigned to one or more Part D plans with single- or multi-tier benefit structures.

* * * * *

Immediate negative formulary change means an immediate substitution or market withdrawal that meets the requirements of § 423.120(e)(2)(i) or (ii) respectively.

* * * * *

Maintenance change means 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 limit (QL) requirements (other than immediate substitutions that meet the requirements of § 423.120(e)(2)(i));

(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 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.

Negative formulary change means the following changes with respect to a covered Part D drug: removing a drug from a formulary; moving a drug to a higher cost-sharing tier; or 3) adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements. Negative formulary changes do not include safety-based claim edits which are not submitted to CMS as part of the formulary.

* * * * *

Non-maintenance change means a negative formulary change that is not a maintenance change or an immediate negative formulary change.

* * * * *

Other specified entities means State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists.

* * * * *

Safety-based claim edit means a claim edit consistent with drug utilization review (DUR) requirements described at § 423.153(c)(2).

* * * * *

§ 423.104 [Amended]

54. Section 423.104 is amended in paragraph (d)(2)(iv)(A)(*6*) by:

a. Removing the phrase "subparagraph (d)(2)(iv)(A)(*2*)" and adding its place the phrase "paragraph (d)(2)(iv)(A)(*2*) of this section; and

b. Removing the phrase "subject to the requirements at § 423.120(b)" and adding in its place the phrase "subject to the requirements at §§ 423.120(b), (e), and (f)".

55. Section 423.120 is amended by –

a. Revising paragraph (b)(3) introductory text;

b. Adding (b)(3)(i)(A)(*5*);

c. Revising paragraphs (b)(3)(i)(B) and (b)(3)(iii) and (iv);

d. Adding paragraphs (b)(3)(vii) and (viii);

e. Revising paragraphs (b)(5) and (6); and

f. Adding paragraphs (b)(8) and (9);.

g. Revising the paragraph (c) subject heading; and

h. Adding paragraphs (c)(7) and (e) through (g).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(3) *Transition process*. A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary, including Part D drugs that are on a sponsor's formulary, but require prior authorization, step therapy, or under a plan's drug utilization management rules, are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100. The transition process must:

(i) * * *

(A) * * *

(*5*) Current enrollees experiencing a level of care change, if the sponsor is notified of such change by the enrollee or their representative, their prescriber, the hospital or facility, or a pharmacy before or at the time of the request for the fill referenced in § 423.120(b)(3)(iii).

* * * * *

(B) Not apply in cases of immediate changes as permitted under paragraph (e)(2) of this section.

* * * * *

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug (including Part D drugs that are on a plan's formulary but under a plan's utilization management rules require prior authorization, step therapy, or are subject to a quantity

limit that is not a safety-based claim edit as defined in § 423.100 during the time period specified in paragraph (b)(3)(ii) of this section by providing a one-time, temporary supply of at least an approved month's supply of medication, unless the prescription is written by a prescriber for less than an approved month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of an approved month's supply of medication.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill, counting the end of the first business day after adjudication as the end of business day 1. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-or-less, consistent with the requirements under § 423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill.

* * * * *

(vii)(A) If a Part D sponsor has access prior drug claims history for an enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history lookback period to determine whether a pharmacy claim represents a new prescription which does not require a transition fill or ongoing drug therapy which requires a transition fill.

(B) If a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or ongoing therapy, the sponsor must treat the prescription as ongoing therapy which requires a transition fill.

(viii) A sponsor's transition policies and procedures must include assurances that the Part D sponsor’s Pharmacy & Therapeutics Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures to comply with this paragraph (b)(3) and any applicable requirement under subpart M. Such policies and procedures must be submitted through a process specified by CMS as part of the plan's annual bid.

* * * * *

(5) *Notice of formulary changes.* Part D sponsors must provide notice of changes to CMS-approved formularies as specified in § 423.120(f). Paragraph (e)(2)(i) of this section is the successor regulation to paragraph (b)(5)(iv) of this section for purposes of section 1860D-4(b)(3)(I)(ii) of the Act .

(6) *Changes to CMS-approved formularies.* Changes to CMS-approved formularies may be made only in accordance with paragraph (e) of this section.

* * * * *

(8) *Emergency supplies.* A Part D sponsor must cover an emergency supply of a non-formulary Part D drug for a long-term care facility resident after any applicable transition period under paragraph (b)(3) of this section, including Part D drugs that are on a sponsor's formulary but require prior authorization, step therapy, or are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100. An emergency supply must be for at least 31 days of medication, regardless of dispensing increments, unless the prescription is written by a prescriber for less than 31 days.

(9) *Single-tier benefit requirement for defined standard coverage*. A Part D plan offering Defined Standard coverage may not apply multi-tier benefit structures to the formulary (as defined in § 423.4) to which it has been assigned via the formulary crosswalk (as defined in § 423.100). The formulary for such Part D plan must be assigned to a single-tier benefit structure, except when such formulary has also been assigned to one or more other Part D plans that use multi-tier benefit structures. When a formulary has been assigned to a Part D plan offering Defined Standard coverage and to one or more other Part D plans with multi-tier benefit structures, such multi-tier benefit structures do not apply to the plan offering Defined Standard coverage.

* * * * *

(c) *Use of standardized technology and identifiers.*

* * * * *

(7)(i) A Part D sponsor must attempt to confirm the validity of a prescriber Drug Enforcement Administration (DEA) registration number for a pharmacy claim for a Part D drug that is a Schedule II, III, IV or V drug, and if and that if the DEA registration number is not on the claim, the sponsor must cross-reference the prescriber's Type 1 National Provider Identifier (NPI) on the claim to any associated individual prescriber DEA number.

(ii) If the DEA registration number is not valid or active, or does not have an associated Schedule that is consistent with the drug for which a claim was submitted, the Part D sponsor must:

(A) Reject the claim, and

(B) Provide the pharmacy with the electronic reason code when rejecting the claim.

(iii) If the pharmacy confirms the validity of the DEA registration number via electronic override code, or the sponsor is not able to cross-reference the Type 1 NPI to a prescriber DEA registration number, the sponsor must process the claim under the applicable benefit plan rules.

(iv) With respect to written member requests for reimbursement, the Part D sponsor must determine whether the DEA registration number of the prescriber was valid and active for the date of service, and if the DEA registration number had an associated Schedule that was consistent with the drug for which the member request for reimbursement was submitted for the date of service. If the DEA number was not valid or active, or there was not an associated Schedule that was consistent with the drug, the Part D sponsor must:

(A) Deny the member request for reimbursement, and

(B) Provide the beneficiary with a written notice consistent with § 423.568(g).

* * * * *

(e) *Approval of changes to CMS-approved formularies*. A Part D sponsor may not make any negative formulary changes to its CMS-approved formulary except as specified in this section.

(1) *Negative change request*. Except as provided in paragraph (e)(2) of this section, prior to implementing a negative formulary change, Part D sponsors must submit to CMS, at a time and in a form and manner specified by CMS, a negative formulary change request.

(2) *Exception for immediate negative formulary changes*, A negative change request is not required in the following circumstances:

(i) *Immediate substitutions.* A Part D sponsor may immediately make negative formulary changes to a brand name drug, a reference biological product, or a brand name biological product provided that at the same time, it adds a corresponding drug to its formulary on the same or lower cost-sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of this section.

(ii) *Market withdrawals.* A Part D sponsor may immediately remove from its formulary any Part D drugs deemed unsafe by the Food and Drug Administration (FDA) or withdrawn from sale by their manufacturer.

(3) *Approval process for negative formulary changes*—(i) *Maintenance changes.* Negative change requests for maintenance changes are deemed approved 30 days after submission unless CMS notifies the Part D sponsor otherwise.

(ii) *Non-maintenance changes*. Part D sponsors must not implement non-maintenance changes until they receive notice of approval from CMS. Affected enrollees are exempt from non-maintenance changes for the remainder of the contract year.

(4) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided in paragraph (e)(2) of this section, a Part D sponsor may not make a negative formulary change that takes effect between the beginning of the annual coordinated election period

described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(f) *Provision of notice regarding changes to CMS-approved formularies*—(1) *Notice of negative formulary changes*: Except as specified in paragraphs (f)(2) and (3) of this section, prior to making any negative formulary change, a Part D sponsor must provide notice to CMS and other specified entities at least 30 days prior to the date such change becomes effective, and must either: provide written notice to affected enrollees at least 30 days prior to the date the change becomes effective, or when an affected enrollee requests a refill of the Part D drug, provide such enrollee with an approved month's supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change. The requirement to provide notice to CMS is satisfied upon a Part D sponsor's submission of a negative change request described in paragraph (e) of this section. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

(2) *Advance general notice of immediate negative formulary changes*. In the case of immediate negative formulary changes described in paragraph (e)(2) of this section, a Part D sponsor must provide advance general notice to all current and prospective enrollees and other specified entities in its formulary and other applicable beneficiary communication materials advising that the Part D sponsor may make immediate negative formulary changes consistent with the requirements of paragraph (e)(2) at any time. Such advance general notice must include information about how to access the plan's online formulary; how to contact the plan; and that written notice of any change made will describe the specific drugs involved. Advance general notice of immediate substitutions must also specify that the written notice will contain information on the steps that enrollees may take to request coverage determinations and exceptions. Advance general notice of immediate substitutions is provided to CMS during bid submission. Advance general notice of market withdrawals is provided to CMS in the advance

notice of immediate negative formulary changes that Part D sponsors provide to enrollees and other specified entities required earlier in this paragraph (f)(2).

(3) *Retrospective notice and update*. In the case of a negative formulary change described in paragraph (e)(2) of this section, the Part D sponsor must provide notice to other specified entities and written notice to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2). Part D sponsors also must submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

(4) *Content of written notice*: Any written notice required under this paragraph (other than advance general notice) must contain the following information-

(i) The name of the affected covered Part D drug;

(ii) Whether the plan is removing the covered Part D drug from the formulary, moving it to a higher cost-sharing tier, or adding or making more restrictive PA, ST, or QL requirements;

(iii) The reason for the negative formulary change;

(iv) Appropriate alternative drugs in the same or a lower cost-sharing tier and the expected cost-sharing for those drugs; and

(v) For formulary changes other than those described in paragraph (e)(2)(B) of this section, the means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(5) *Notice of other formulary changes*. Part D sponsors provide appropriate notice of all formulary changes other than negative formulary changes by (A) providing advance general notice to all current and prospective enrollees, CMS, and other specified entities in formulary and other applicable beneficiary communication materials advising them that the Part D sponsor may make formulary changes other than negative formulary changes at any time and providing information about how to access the plan's online formulary and how to contact the plan; and (B)

providing notice of specific formulary changes to other specified entities by complying with § 423.128(d)(2) and to CMS by submitting such changes to CMS in their next required or scheduled formulary update.

(g) *Drug shortages.* For the purpose of this section, a drug or biological product is subject to a shortage if it is on the U.S. Food and Drug Administration drug shortages list. With respect to a product on a Part D plan's formulary that is subject to a shortage, a Part D sponsor must -

(1) For at least the duration of the shortage, permit enrollees affected by the shortage to obtain coverage of -

(i) A therapeutically equivalent non-formulary drug or interchangeable biological product, if any, without requiring enrollees affected by the shortage to meet formulary exception requirements at § 423.578(b); or

(ii) A therapeutically equivalent formulary drug or interchangeable biological product, if any, that requires prior authorization or step therapy without requiring enrollees affected by the shortage to meet prior authorization or step therapy requirements.

(2) Part D sponsors may charge the applicable cost sharing based on the therapeutically equivalent drug's or interchangeable biological product's formulary status and plan benefit design for claims submitted consistent with paragraph (g)(1)(i) or (ii) of this section.

56. Section 423.128 is amended by revising paragraphs (d)(1)(iii)(A), (d)(1)(v)(B), (d)(2)(iii), and (e)(6) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(d) * * *

(1) * * *

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals. Such interpreters must:

(*1*) Adhere to generally accepted interpreter ethics principles, including confidentiality;

(*2*) Demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(*3*) Interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

* * * * *

(v) * * *

(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

* * * * *

(2) * * *

(iii) Provides current and prospective Part D enrollees with notice that is timely under § 423.120(f) regarding any negative formulary changes on its Part D plan's formulary.

* * * * *

(e) * * *

(6) Include any negative formulary changes applicable to an enrollee for which Part D plans are required to provide notice as described in § 423.120(f).

* * * * *

§ 423.150 [Amended]

57. Section 423.150 is amended in paragraph (a) by removing the phrase “medication therapy management programs (MTMP)” and adding in its place “MTM programs”.

58. Section 423.153 is amended by:

a. Revising the section heading;

b. Removing the paragraph (d) subject heading;

c. Removing the phrase “MTMP” and adding in its place the phrase “MTM program” in paragraph (d)(1) introductory text;

d. Revising paragraphs (d)(1)(vii)(B)(*1*)(*i*) and (d)(1)(vii)(B)(*2*),

e. Removing the phrase “MTMP” and adding in its place the phrase “MTM program” in paragraph (d)(2) introductory text;

f. Revising paragraphs (d)(2)(i)(B) and (C);

g. Adding paragraphs (d)(2)(iii) and (iv);

h. Removing the phrase “MTMP” and adding in its place the phrase “MTM program” in paragraphs (d)(3) and (4);

i. Revising paragraph (d)(5)(i) and (ii); and

j. Removing the phrase “MTMP” and adding in its place the phrase “MTM program” in paragraph (d)(6);

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, MTM programs, drug management programs, and access to Medicare Parts A and B claims data extracts.

* * * * *

(d) *MTM program*.

(1) * * *

(vii) * * *

(B) * * *

(*1*) * * *

(*i*) Must include an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth; and

* * * * *

(*2*) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate due to cognitive impairment, the pharmacist or other qualified

provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

* * * * *

(2) * * *

(i) * * *

(B) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment for a plan year starting before January 1, 2024, and five Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment for a plan year starting on or after January 1, 2024; and

(C) Are likely to incur annual covered Part D drug costs greater than or equal to the MTM cost threshold determined by CMS, as specified in this paragraph (d)(2)(i)(C).

(*1*) For 2011, the MTM cost threshold is set at $3,000.

(*2*) For 2012 through 2023, the MTM cost threshold is set at $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv).

(*3*) Beginning January 1, 2024, the MTM cost threshold is set at the average annual cost of five generic drugs, as defined at § 423.4, as determined using the PDE data specified at § 423.104(d)(2)(iv)(C).

* * * * *

(iii) Beginning January 1, 2024, in identifying beneficiaries who have multiple chronic diseases under paragraph (d)(2)(i)(A) of this section, Part D plan sponsors must include all of the following diseases, and may include additional chronic diseases:

(A) Alzheimer’s disease;

(B) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis);

(C) Chronic congestive heart failure (CHF);

(D) Diabetes;

(E) Dyslipidemia;

(F) End-stage renal disease (ESRD);

(G) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS);

(H) Hypertension;

(I) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions); and

(J) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders).

(iv) Beginning January 1, 2024, in identifying the number of Part D drugs under paragraph (d)(2)(i)(B) of this section, Part D plan sponsors must include all maintenance drugs, relying on information in a widely accepted, commercially or publicly available drug database to make such determinations.

* * * * *

(5) * * *

(i) Describe in its application how it takes into account the resources used and time required to implement the MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

* * * * *

59. Section 423.154 is amended by revising paragraph (c) to read as follows:

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA-PD plans

* * * * *

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section, except paragraphs (a)(2) and (3), for pharmacies when they service intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

* * * * *

60. Section 423.160 is amended by--

a. Revising paragraphs (b)(1)(i) through (v);

b. Adding paragraphs (b)(1)(vi) and (vii);

c. Adding paragraphs (b)(2)(v) and (b)(3)(iii);

d. Revising paragraph (b)(4)(ii);

e. Adding paragraphs (b)(4)(iii), (b)(7)(i), and a reserved (b)(7)(ii);

f. Revising paragraph (b)(8)(ii); and

g. Adding paragraph (b)(8)(iii).

The revisions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(1) * * *

(i) Prior to April 1, 2009, the standards specified in paragraphs (b)(2)(i), (b)(3)(i) and (ii), (b)(4), (b)(5)(i), and (b)(6).

(ii) On or after April 1, 2009, to February 7, 2014, the standards specified in paragraphs (b)(2)(ii), (b)(3)(i) and (ii), (b)(4), (b)(5)(i) and (b)(6).

(iii) From February 8, 2014, until February 28, 2015, the standards specified in paragraphs (b)(2)(ii), (b)(3)(i) and (ii), (b)(4), (b)(5)(ii), and (b)(6).

(iv) From March 1, 2015 until December 31, 2019, the standards specified in paragraphs (b)(2)(iii), (b)(3)(i) and (ii), (b)(4)(i), (b)(5)(iii), and (b)(6).

(v) From January 1, 2020 until June 30, 2023, the standards specified in paragraphs (b)(2)(iv) and (b)(3)(i) and (ii), (b)(4)(ii), (b)(5)(iii), and (b)(6) of this section.

(vi) Beginning July 1, 2023, the standards required by paragraphs (b)(2)(v), (b)(3)(iii), (b)(4)(iii), (b)(5)(iii), and (b)(6) of this section.

(vii) Beginning January 1, 2025, the standard specified in paragraph (b)(7)(i) of this section.

* * * * *

(2) * * *

(v) Communication of a prescription or related prescription-related information between prescribers and dispensers or between dispensers must comply with 45 CFR 170.205(b) for the business functions supported by the following transactions:

(A) GetMessage.

(B) Status.

(C) Error.

(D) NewRxRequest.

(E) NewRx.

(F) RxChangeRequest.

(G) RxChangeResponse.

(H) RxRenewalRequest.

(I) Resupply.

(J) RxRenewalResponse.

(K) Verify.

(L) CancelRx.

(M) CancelRxResponse.

(N) RxFill.

(O) DrugAdministration.

(P) NewRxResponseDenied.

(Q) RxTransferInitiationRequest.

(R) RxTransfer.

(S) RxTransferConfirm.

(T) RxFillIndicatorChange.

(U) Recertification.

(V) REMSIinitiationRequest.

(W) REMSIinitiationResponse.

(X) REMSRequest.

(Y) REMSResponse.

* * * * *

(3) * * *

(iii) 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.

(4) * * *

(ii) From January 1, 2020, until June 30, 2023 the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section).

(iii) Beginning July 1, 2023, comply with 45 CFR 170.205(b).

* * * * *

(7) * * *

(i) Beginning January 1, 2025, Part D sponsors' RTBT must comply with 45 CFR 170.205(c).

(ii) [Reserved]

(8) * * *

(ii) From January 1, 2022 until June 30, 2023, Part D sponsors and prescribers must use the standard specified in paragraph (b)(8)(i) of this section for the transactions listed in paragraphs (b)(8)(i)(A) through (D) of this section.

(iii) Beginning July 1, 2023, Part D sponsors and prescribers must comply with 45 CFR 170.205(b) for the business functions supported by the following applicable transactions:

(A) PAInitiationRequest.

(B) PAInitiationResponse.

(C) PARequest.

(D) PAResponse.

(E) PAAppealRequest.

(F) PAAppealResponse.

(G) PACancelRequest.

(H) PACancelResponse.

(I) PANotification.

* * * * *

§ 423.165 [Amended]

15. Section 423.165 is amended in paragraph (b)(2) by removing the phrase "MTMPs" and adding the phrase "MTM programs" in its place.

61. Section 423.182 is amended by in paragraph (a) by adding in alphabetical order a definition for "health equity index" and revising paragraphs (b)(1) and (b)(3)(ii)(A)(*1*) to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

* * * * *

(b) * * *

(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA-PD contract and a Part D summary rating for each PDP contract using the 5-star rating system described in this subpart. For PDP contracts, the Part D summary rating is the highest rating. Measures are assigned stars at the contract level and weighted in accordance with § 423.186(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 423.186(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 423.186(c), with both the reward factor and CAI applied as applicable, as described in § 423.186(f). Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 423.186(d) with both the reward factor and CAI applied as applicable, as described in § 423.186(f). CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

* * * * *

(3) * * *

(ii) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures, call center measures, and improvement measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

* * * * *

62. Section 423.184 is amended by revising paragraph (d)(1)(v) and adding paragraph (e)(1)(iii) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(e) * * *

(1) * * *

(iii) The measure steward other than CMS retires a measure.

* * * * *

63. Section 423.186 is amended by—

a. Revising paragraphs (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii) and (iv), (e)(2), (f)(1) introductory text, and (f)(2)(i) introductory text;

b. Adding paragraphs at (f)(3); and

c. Revising paragraphs (g)(1), (i)(7)(i), and (i)(8)(i).

The revisions and addition read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 through October 2024, CMS will

add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(c) * * *

(1) CMS will calculate the Part D summary ratings using the weighted mean of the measure-level Star Ratings for Part D, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(d) * * *

(1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

* * * * *

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, the measure will be assigned the weight associated with its category.

* * * * *

(f) * * *

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

* * * * *

(2) * * *

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

* * * * *

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA-PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA-PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA-PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low income subsidy or being dual eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings would be adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Data are used for contracts that have data for only the most recent of the 2 years, but data are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA-PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the health equity index. CMS will announce the measures being evaluated for inclusion in the calculation of

the health equity index under this paragraph (f)(3) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's health equity index, the measure must meet the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each measure for the subset enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score

of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale with a contract receiving 0 if the contract receives a score of 0 or less on the health equity index and 0.4 if the contract receives a score of 1 on the health equity index. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.2 if the contract receives a score of 1 on the health equity index. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have a health equity index score

calculated (that is, contracts that are not scored on at least half of the measures included in the index) would not receive a HEI reward.

(ix) The HEI reward is added to the overall rating, Part C rating for MA-PDs and MA-only contracts (and cost contracts), Part D rating for MA-PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

(g) * * *.

(1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA-PD contracts and Part D summary rating for PDPs), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) If the highest rating for each contract-type is 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and the CAI adjustment under paragraph (f) of this section, a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and CAI adjustment, the rating will be calculated with the improvement measure(s).

* * * * *

(i) * * *

(7) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

* * * * *

(8) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

* * * * *

64. Section 423.265 is amended by

a. Redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;

b. Adding paragraph heading to the newly redesignated paragraph (b)(4); and

c. Adding new paragraph (b)(2) and paragraph (b)(5).

The additions read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Substantial differences between bids*—(i) *General rule*. Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered “substantially different,” each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(ii) *Exception*. A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions.

* * * * *

(4) *Bid acceptance*. * * *

(5) *Limitations on changes*. After a Part D sponsor is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), the Part D sponsor must not change, and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182) for the contract year without modification, except where a modification in benefits is required by law.

* * * * *

65. Section 423.272 is amended by adding paragraph (b)(5) to read as follows:

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

* * * * *

(b) * * *

(5) *Limit on number of PDP contracts held by subsidiaries of the same parent organization in a region*—(i) *General*. Except as provided in paragraphs (b)(5)(ii) and (iii) of this section, CMS does not approve a bid when it would result in a PDP sponsor (or a PDP sponsor's parent organization), directly or through its subsidiaries, offering plan benefit packages under more than one PDP contract in a PDP region.

(ii) *Transition period for PDP sponsors with new acquisitions*. CMS does not approve a bid offered by a PDP sponsor (or a PDP sponsor's parent organization, directly or through a subsidiary) that purchased, otherwise acquired, or merged with another PDP sponsor if, after a transition period of two bid cycles after such purchase, acquisition, or merger, as determined by CMS, such bid approval would result in the PDP sponsor (or the PDP sponsor's parent

organization), directly or through its subsidiaries, offering plan benefit packages under more than one PDP contract in a PDP region.

(iii) *Transition period for PDP sponsors offering plans in a region under more than one contract on January 1, 2024.* After a transition period of two bid cycles, as determined by CMS, CMS does not approve a bid offered by a PDP sponsor (or a PDP sponsor's parent organization, directly or through a subsidiary) that offered plan benefit packages in a PDP region under more than one PDP contract if it such bid approval would result in the PDP sponsor (or a PDP sponsor's parent organization), directly or through its subsidiaries, offering plan benefit packages under more than one PDP contract in a PDP region.

(iv) *Limitation on PDP contracts per region not applicable to employer group waiver plans*. Notwithstanding any other provisions of this paragraph, a PDP sponsor may offer a PDP contract in the same region as another contract held by the sponsor or the sponsor's parent organization, directly or through its subsidiaries, if one or both contracts only offer employer group waiver plans in that region.

* * * * *

§ 423.293 [Amended]

66. Section 423.293 is amended in paragraph (a)(4) by removing the phrase "Medicare Advantage organization" and adding in its place "Part D sponsor".

67. Section 423.294 is added to subpart F to read as follows:

§ 423.294 Failure to collect and incorrect collections of premiums and cost sharing.

(a) *Requirement to collect premiums and cost sharing*. A Part D sponsor violates the uniform benefit provisions at § 423.104(b) if it fails to collect or incorrectly collects applicable cost sharing, or fails to collect or incorrectly collects premiums as required by § 422.262(e) of this chapter:

(1) In accordance with the timing of premium payments; or

(2) At the time a drug is dispensed; or

(3) By billing the enrollee or another appropriate party after the fact.

(b) Refunds of incorrect collections—

(1) *Definitions*. As used in this section the following definitions are applicable:

Amounts incorrectly collected. (A) Means amounts that exceed the monthly Part D enrollee premium limits under § 423.286 or exceed permissible cost-sharing or copayment amounts as specified in § 423.104(d) through (f), whether paid by or on behalf of the enrollee;

(B) Includes amounts collected with respect to an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled; and

(C) Excludes de minimis amounts, as calculated per PDE transaction or per monthly premium billing.

De minimis amounts means an amount per PDE transaction for claims adjustments and per month for premium adjustments that does not exceed the de minimis amount determined for purposes of § 423.34(c)(2).

Other amounts due means amounts due to affected enrollees or others on their behalf (other than de minimis amounts) for covered Part D drugs that were—

(A) Accessed at an out-of-network pharmacy in accordance with the requirements at § 423.124; or

(B) Initially denied but, upon appeal, found to be covered Part D drugs the enrollee was entitled to have provided by the Part D plan.

(2) *General rule*. A Part D sponsor must make a reasonable effort to identify all amounts incorrectly collected and to pay any other amounts due during the timeframe for coordination of benefits as established at § 423.466(b). A Part D sponsor must issue a refund for an identified enrollee overpayment within the timeframe specified at § 423.466(a).

(3) *Refund methods*—(i) *Lump-sum payment.* The Part D sponsor must use lump-sum payments for the following:

(A) Amounts incorrectly collected as cost-sharing.

(B) Other amounts due.

(C) All amounts due if the Part D plan is going out of business or terminating its Part D contract for a prescription drug plan(s).

(ii) *Premium adjustment, lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the Part D sponsor may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(iii) *Refund when enrollee has died or cannot be located*. If an enrollee has died or cannot be located after reasonable effort, the Part D sponsor must make the refund in accordance with State law.

(4) *Premium reduction and compliance.* If the Part D sponsor does not issue the refund as required under this section within the timeframe specified at § 423.466(a), CMS will reduce the premium the Part D sponsor is allowed to charge a Part D enrollee by the amounts incorrectly collected or otherwise due. In addition, the Part D plan may receive compliance notices from CMS or, depending on the extent of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) in accordance with subpart O of this part.

(c) *Collections of cost-sharing and premium amounts*—(1) *General rule.* A Part D sponsor must make a reasonable effort to attempt to collect cost sharing from a beneficiary or to bill cost sharing or premiums to another appropriate party for all amounts other than de minimis amounts.

(2) *Timeframe.* Recovery notices must be processed and issued in accordance with the timeframe specified at § 423.466(a). A Part D sponsor must make a reasonable effort to attempt to collect these amounts during the timeframe for coordination of benefits as established at § 423.466(b).

(3) *Retroactive collection of premiums*. Nothing in this section alters the requirements of § 423.293(a)(4) of this part with respect to retroactive collection of premiums.

68. Section 423.308 is amended by:

a. Revising the introductory text and paragraph (1) of the definition of "Gross covered prescription drug costs"; and

b. Adding in alphabetical order a definition for "Reopening".

The revisions and addition read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of actual costs (as defined by § 423.100 of this part) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.

* * * * *

Reopening—(1) *Global reopening* means a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

(2) *Targeted reopening* means a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

* * * * *

69. Section 423.346 is amended by—

a. Revising paragraph (a) introductory text;

b. Removing “within 4 years” and adding “within 6 years” in its place in paragraph (a)(2); and

c. Adding paragraphs (e) through (g).

The revision and additions read as follows:

§ 423.346 Reopening.

(a) CMS may conduct a global or targeted reopening to reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) or the Coverage Gap Discount Reconciliation (as described at § 423.2320(b))—

* * * * *

(e) CMS will notify the sponsor(s) that will be included in the reopening of its intention to conduct a global or targeted reopening when it is necessary for the sponsor(s) to submit prescription drug event (PDE) data and/or direct and indirect remuneration (DIR) for the reopening. The notification to sponsor(s) will include the following:

(1) The date by which PDE and/or DIR data must be accepted by CMS to be included in the reopening, which will be at least 90 calendar days after the date of the notification, and

(2) A statement indicating the Part D contracts or types of contracts that will be included in the reopening.

(f) CMS will announce when it has completed a reopening and provide the sponsor(s) with the following information:

(1) A description of the data used in the reopening,

(2) A statement indicating the Part D contracts or types of contracts that were included in the reopening,

(3) The date by which reports describing the reopening results will be available to the sponsor, and

(4) The date by which a sponsor must submit an appeal, pursuant to § 423.350, if the sponsor disagrees with the reopening results.

(g) Inclusion criteria:

(1) For a global reopening, CMS includes only those Part D sponsor contracts that were in effect for the contract year being reopened and for whom CMS has not sent the final settlement "Notice of final settlement," as described at § 423.521(a), as of the date CMS announces the completion of the reopening pursuant to paragraph (f) of this section.

(2) For a target reopening, CMS includes only Part D sponsor contracts that meet the criteria for inclusion in a global reopening as specified in paragraph (1) of this section and that CMS specifies for inclusion in the reopening as provided in paragraph (e)(2) or (f)(2) of this section.

70. Section 423.360 is amended by revising paragraph (c) to read as follows:

§ 423.360 Reporting and returning of overpayments.

* * * * *

(c) *Identified overpayment*. The Part D sponsor has identified an overpayment when the Part D sponsor knowingly receives or retains an overpayment. The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

71. Section 423.501 is amended by adding in alphabetical order definitions for "Final settlement amount", "Final settlement process", and "Final settlement adjustment period" to read as follows:

§ 423.501 Definitions.

* * * * *

Final settlement amount is the final payment amount that CMS owes and ultimately pays to a Part D sponsor, or that a Part D sponsor owes and ultimately pays to CMS, with respect to a Part D contract that has consolidated, non-renewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation, as applicable (described in § 422.310);

(2) Part D annual reconciliation (described in § 423.343);

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320) and;

(4) MLR remittances (described in §§ 422.2470 and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS calculates the final settlement amount, issues the final settlement amount along with supporting documentation in the notice of final settlement to the Part D sponsor, receives responses from the Part D sponsor requesting an appeal of the final settlement amount, and takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the Part D sponsor. The final settlement amount will be calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

Final settlement adjustment period means the period of time between when the contract terminates and the date the Part D sponsor is issued a notice of the final settlement amount.

* * * * *

72. Section 423.503 is amended by adding paragraph (a)(4) to read as follows:

§ 423.503 Evaluation and determination procedures.

(a) * * *

(4)(i) CMS does not evaluate or issue a notice of determination described in paragraph (c) of this section when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS..

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 423.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

* * * * *

73. Section 423.505 is amended by revising paragraph (b)(22), adding paragraph (b)(28), and adding paragraph (i)(6) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Through the CMS complaint tracking system, address and resolve complaints received by CMS against the Part D sponsor.

* * * * *

(28) Require network pharmacies that offer automatic shipment of prescription refills to comply with the following requirements-

(i) *Voluntary participation*. Provide automatic shipments only to Part D enrollees that opt-in, on a drug-by-drug basis, after an initial fill.

(ii) *Enrollee notification*. (A) Send a minimum of two (2) shipping reminders to the Part D enrollee prior to shipment of each prescription refill.

(B) Network pharmacies must provide the shipping reminders by hard copy mailing, telephone, electronic delivery, or other comparable means of communication.

(C) All types of reminders must, at a minimum, include the name of the Part D drug, any applicable cost sharing, the scheduled shipping date, instructions on how to cancel the pending automatic shipment, and instructions on how to opt-out of any future automatic shipments.

(iii) *Refund policy*. Return any cost sharing paid by the Part D enrollee for any shipped prescription refills that such Part D enrollee reports as unneeded or otherwise unwanted, regardless of whether the drug is returned to the network pharmacy, and reverse the claim.

(iv) *Discontinuation*. (A) Stop automatic shipments if the enrollee, the enrollee's provider, or the enrollee's authorized representative requests to opt-out of automatic shipments at any time.

(B) Stop automatic shipments upon receiving notification that the Part D enrollee has entered a skilled nursing facility or elected hospice coverage.

* * * * *

(i) * * *

(6) If the Part D Plan sponsor delegates any of the following functions to a first tier, downstream, or related entity, the Part D sponsor's written arrangements must state that a termination initiated by such entity must provide, at minimum, 60-days' prior notice and have an effective termination date that coincides with the end of a calendar month:

(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale;

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers;

(iii) Operation of an enrollee appeals and grievance process; or

(iv) Contracting with or selection of prescription drug providers for inclusion in the Part D sponsor's network.

* * * * *

74. Section 423.507 is amended by revising paragraph (a)(3) to read as follows:

§ 423.507 Nonrenewal of contract.

* * * * *

(a) * * *

(3)(i) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years in the PDP region or regions served by the contract unless there are circumstances that warrant special consideration, as determined by CMS.

(ii) If a PDP sponsor does not renew any of its PBPs in a PDP region, CMS cannot approve plan bids submitted by the organization in that PDP region for 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(iii) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.

* * * * *

75. Section 423.508 is amended by revising paragraph (e) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

* * * * *

(e) *Agreement to limit new Part D applications*. (1) As a condition of the consent to a mutual termination, CMS will require, as a provision of the termination agreement language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions in the PDP region or regions served by the contract for a period up to 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(2) A PDP sponsor that agrees to terminate its offering of PBPs in a PDP region also agrees that it will not be eligible to apply to resume offering plans in that region for 2 years.

(3) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.

* * * * *

76. Section 423.521 is added to subpart K to read as follows:

§ 423.521. Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the Part D sponsor a notice of final settlement. The notice of final settlement contains at least the following information:

(1) A final settlement amount, which may be either an amount due to the Part D sponsor, or an amount due from the Part D sponsor, or $0 if nothing is due to or from the Part D sponsor, for the contract that has been consolidated, nonrenewed, or terminated;

(2) Relevant banking and financial mailing instructions for Part D sponsors that owe CMS a final settlement amount;

(3) Relevant CMS contact information, and;

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 423.522.

(b) *Request for an appeal.* A Part D sponsor that disagrees with the final settlement amount will have 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 423.522.

(1) If a Part D sponsor agrees with the final settlement amount, no response is required.

(2) If a Part D sponsor disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS will not consider subsequent requests for appeal.

(c) *Actions if a Part D sponsor does not request an appeal*. (1) For Part D sponsors that are owed money by CMS, CMS will remit payment to the Part D sponsor within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For Part D sponsors that owe CMS money, the Part D sponsor will be required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the Part D sponsor fails to remit payment within that 120-calendar-day period, CMS will refer the debt owed to CMS to the Department of Treasury for collection.

(d) *Actions following a request for appeal.* If a Part D sponsor responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS will conduct a review process under the process described at § 423.522.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under paragraph (a) of this section, is issued to the Part D sponsor, CMS will no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there will be no adjustments applied to amounts used in the calculation of the final settlement amount.

77. Section 423.522 is added to subpart K to read as follows:

§ 423.522. Requesting an appeal of the final settlement amount.

(a) *Appeals process*. If a Part D sponsor does not agree with the final settlement amount described in § 423.521(a) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the final settlement amount described in § 423.521(a) according to the following process:

(i) *Manner and timing of request*. A written request for reconsideration must be filed within 15 days from the date that CMS issued the notice of final settlement to the Part D sponsor.

(ii) *Content of request*. The written request for reconsideration must:

(A) Specify the calculations with which the Part D sponsor disagrees and the reasons for its disagreement;

(B) Include evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect; and

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration*. In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision*. The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision*. The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing*. A Part D sponsor dissatisfied with CMS' reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (iv) of this section.

(i) *Manner and timing of request*. A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS' reconsideration decision.

(ii) *Content of request*. The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures*. The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date;

(B) CMS provides a copy of the record that was before CMS when CMS made its decision to the hearing officer;

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer*. The CMS hearing officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision*. The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator*. The Administrator's review will be conducted in the following manner:

(i) *Manner and timing of request*. A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review;

(ii) *Discretionary review*. After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding;

(iii) *Administrator's review*. If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by

the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision;

(iv) *Effect of Administrator's decision*. The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS' calculation of the final settlement amount. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The Part D sponsor bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

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

(d) *Continued compliance with other law required.* Nothing in this section limits a Part D sponsor's responsibility to comply with any other statute or regulation, including under section 1128J(d) of the Social Security Act.

78. Section 423.530 is added to subpart K to read as follows:

§ 423.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of plan crosswalk.* A plan crosswalk is the movement of enrollees from one plan benefit package (PBP) in a PDP contract to another PBP under a PDP contract between a Part D Sponsor and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions*. (i) Plan crosswalks between PBPs under one PDP contract and PBPs under another PDP contract are prohibited unless both the PDP sponsors with which CMS contracts are the same legal entity or have the same parent organization.

(ii) Plan crosswalks are prohibited that split the enrollment of one PBP into multiple PBPs.

(iii) Plan crosswalks are prohibited from a PBP offering basic prescription drug coverage to a PBP offering enhanced alternative coverage.

(3) *Compliance with renewal/non-renewal rules*. The PDP sponsor must comply with renewal and non-renewal rules in §§ 423.506 and 423.507 in order to complete plan crosswalks.

(4) *Eligibility*. Enrollees must be eligible for enrollment under § 423.30 in order to be moved from one PBP to another PBP.

(5) *Applicability to employer group health or waiver plans*. Nothing in this section permits the crosswalk of enrollees in an employer group health or waiver plan PBP to another PBP outside the usual process for enrollment in employer group health or waiver plans.

(b) *Mandatory plan crosswalks*. A Part D sponsor of a PDP must perform a plan crosswalk in the following circumstances:

(1) *Renewal of a PBP offering basic prescription drug coverage*. A PDP sponsor that plans to continue operating a PBP offering basic prescription coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering basic prescription drug coverage in the current contract year into a PBP offering basic prescription drug coverage under the same PDP contract in the upcoming contract year. The PBP for the upcoming contract year must retain the same plan ID as the PBP for the current contract year;

(2) *Renewal of a PBP offering enhanced alternative drug coverage*. A PDP sponsor that plans to continue operating a PBP offering enhanced alternative coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering enhanced alternative drug coverage in the current contract year into a PBP offering enhanced alternative

drug coverage in the upcoming contract year. The PBP for the upcoming contract year PBP must retain the same plan ID as the PBP for the current contract year.

(c) *Plan crosswalk exceptions*. A Part D sponsor of a PDP may perform a plan crosswalk in the following circumstances after receiving approval from CMS under the procedures described in paragraph (d) of this section.

(1) *Consolidated renewals*. If a PDP sponsor wishes to non-renew a PBP offering enhanced alternative prescription drug coverage under a PDP contract that is not non-renewing or reducing its service area so that the contract no longer includes the service area of the non-renewing PBP, it may crosswalk enrollment from the non-renewing PBP into a PBP offered under the contract in the upcoming contract year.

(i) The plan ID for the upcoming contract year PBP must be the same plan ID as one of PBPs for the current contract year.

(ii) The PBPs being consolidated must be under the same PDP contract.

(iii) A PBP offering basic prescription drug coverage may not be discontinued if the PDP contract continues to offer coverage (other than employer group waiver plans) in the service area of the PBP.

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering either enhanced alternative or basic prescription drug coverage.

(v) If the PDP contract includes more than one renewing PBP into which enrollment of the non-renewing PBP can be crosswalked, the enrollment of the non-renewing PBP must be crosswalked into the renewing PBP that will result in lowest increase in monthly premiums for the enrollees.

(vi) A plan crosswalk will not be approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of:

(A) The current year's premium for the non-renewing PBP; or

(B) The current year's average base beneficiary premium, as described in § 423.286(c) of this part, for the PDP region in which the PBP operates.

(vii) If an organization that non-renews an enhanced alternative PBP does not request and receive a plan crosswalk exception as provided in paragraph (d) of this section, CMS will not approve a new enhanced alternative PBP in the same service area as the non-renewing PBP in the following contract year.

(2) *Contract consolidations*. If a PDP sponsor non-renews all or part of the service area of its contract with CMS pursuant to §§ 423.507 or 423.508, the enrollees of the non-renewing PBPs may be crosswalked into one or more PBPs in another PDP contract (the surviving contract).

(i) The non-renewing PDP contract and the surviving contract must be held by the same legal entity or by legal entities with the same parent organization.

(ii) The approved service area of the surviving contract must include the service area of the non-renewing PBPs whose enrollment will be crosswalked into the surviving contract.

(iii) Enrollment may be crosswalked between PBPs offering the same type of prescription drug coverage (basic or enhanced alternative).

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering basic prescription drug coverage.

(v) Enrollment from a PBP offering enhanced alternative coverage must be crosswalked into the PBP in the surviving contract that will result in the lowest premium increase.

(vi) A plan crosswalk will not be approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of:

(A) The current year's premium for the non-renewing PBP; or

(B) The current year's average base beneficiary premium, as described in § 423.286(c) of this part, for the region in which the PBP operates.

(d) *Procedures*. (1) A PDP sponsor must submit all plan crosswalks described in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline.

(2) A PDP sponsor must submit all plan crosswalk exception requests described in paragraph (c) of this section in writing through the plan crosswalk exceptions process in HPMS by the plan crosswalk exception request deadline announced annually by CMS. CMS verifies the requests and notifies requesting PDP sponsors of the approval or denial after the crosswalk exception request deadline.

79. Section 423.551 is amended by revising paragraph (e) to read as follows

§ 423.551 General provisions.

* * * * *

(e) *Effect of change of ownership without novation agreement*. Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that -

(1) The current PDP sponsor, with respect to the affected contract, has substantially failed to comply with the regulatory requirements pursuant to § 423.510(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 423.750(a)(1) and (3); intermediate sanctions imposed as part of this section will remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 422 if applicable; and, if the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under § 423.551(d) for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in this (e)(1), submit the documentation required under paragraph (d) of this section for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (d)(1)(i) or (ii) of this section within 30 days of imposition of intermediate sanctions as outlined in (d)(1) of this section, the existing contract will be subject to termination in accordance with § 423.509(a)(4)(ix).

* * * * *

80. Section 423.562 is amended by revising paragraph (a)(1)(v) to read as follows:

§ 423.562 General provisions.

(a) * * *

(1) * * *

(v) Appeal procedures that meet the requirements of this subpart for issues that involve at-risk determinations. Determinations made in accordance with the processes at § 423.153(f) are collectively referred to as an at-risk determination, defined at § 423.560, made under a drug management program.

* * * * *

81. Section 423.760 is amended by removing paragraph (b)(3)(i)(E) and revising paragraph (b)(3)(ii).

The revision reads as follows:

§ 423.760 Definitions for calculating penalty amounts.

* * * * *

(b) * * *

(3) * * *

(ii) *Calculation of penalty amounts*. (A) CMS will set minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(B) CMS will announce the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(C) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

* * * * *

82. Section 423.773 is amended by:

a. Revising paragraph (b)(1);

b. Removing the phrase "For subsequent years," and adding in its place the phrase "For years 2007 through 2023," in paragraph (b)(2)(ii);

c. Adding paragraph (b)(2)(iii); and

d. Revising paragraph (d) introductory text.

The revisions and addition read as follows:

§ 423.773 Requirements for eligibility.

* * * * *

(b) * * *

(1) Has income below 135 percent of the FPL applicable to the individual's family size or, with respect to a plan year beginning on or after January 1, 2024, has income below 150 percent of the FPL applicable to the individual's family size; and

(2) * * *

(iii) For years beginning on or after January 1, 2024, the amount of resources specified at paragraph (d)(2) of this section.

* * * * *

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who, for plan years beginning before January 1, 2024—

* * * * *

83. Section 423.780 is amended by revising paragraph (d) introductory text to read as follows:

§ 423.780 Premium subsidy.

* * * * *

(d) *Other low-income subsidy eligible individuals - sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy for plan years beginning before January 1, 2024, based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

* * * * *

84. Section 423.2261 is amended by revising paragraph (a)(2) and removing paragraph (a)(3).

The revision reads as follows:

§ 423.2261 Submission, review, and distribution of materials.

* * * * *

(a) * * *

(2) Materials must be submitted to the HPMS Marketing Module by the Part D sponsor or, where materials have been developed by a Third Party Marketing Organization for multiple Part D sponsors or plans, by a Third Party Marketing Organization with prior approval of each Part D sponsor on whose behalf the materials were created.

* * * * *

85. Section 423.2262 is amended by revising paragraph (a)(1)(ii) and adding paragraph (a)(1)(xviii) to read as follows:

§ 423.2262 General communications materials and activity requirements.

* * * * *

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that has been published in either the current contract year or prior contract year.

* * * * *

(xviii) Use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card in a misleading way.

* * * * *

86. Section 423.2263 is amended by adding paragraphs (b)(8) through (10) to read as follows:

§ 423.2263 General marketing requirements.

* * * * *

(b) * * *

(8) Advertise benefits that are not available to beneficiaries in the service area where the marketing appears, unless unavoidable in a local market.

(9) Market any products or plans, benefits, or costs, unless the Part D sponsor or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) Part D sponsor or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or in fine print.

(ii) For television, online, or social media the Part D sponsor or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number or benefits.

(iii) For radio or other voice-based advertisements, Part D sponsor or marketing names must be read at the same pace as phone numbers.

(10) Part D sponsors may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

* * * *

87. Section 423.2264 is amended by:

a. Adding paragraph (a)(2)(i)(A) and reserved paragraph (a)(2)(i)(B);

b. Revising paragraphs (b)(2);

c. Removing paragraphs (c)(1)(ii)(C) and (E);

d. Redesignating paragraph (c)(1)(ii)(D) and new paragraph (c)(1)(ii)(C); and

e. Revising paragraphs (c)(2)(i), (c)(3)(i), and (c)(3)(iii)(A) and (B).

The addition additions and revisions read as follows:

§ 423.2264 Beneficiary contact.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(A) Contact is considered to be unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable time and date, was previously scheduled.

(B) [Reserved]

* * * * *

(b) * * *

(2) If the Part D sponsor reaches out to beneficiaries regarding plan business, as outlined in this section, the Part D sponsor must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

(c) * * *

(2) * * *

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

* * * * *

(3) * * *

(i) At least 48 hours prior to the personal marketing appointment beginning, the Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

* * * * *

(iii) * * *

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 6 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment, identifying the additional lines of business to be discussed; such Scope of Appointment is valid for six (6) months following the beneficiary's signature date.

* * * * *

88. Section 423.2265 is amended by removing and reserving paragraph (b)(12) and revising paragraph (c)(1)(vi).

The revision reads as follows:

§ 423.2265 Websites.

* * * * *

(c) * * *

(1) * * *

(vi) Utilization Management Criteria for physicians and enrollees.

* * * * *

89. Section 423.2267 is amended by –

a. Redesignating paragraph (a)(3) as paragraph (a)(5);

b. Adding new paragraph (a)(3) and pargraph (a)(4);

c. Revising paragraph (e)(4) introductory text;

d. Adding paragraph (e)(4)(viii);

e. Revising paragraphs (e)(13) introductory text, (e)(32)(vi), and (e)(41); and

f. Adding paragraphs (e)(42) through (44).

The revisions and additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(a) * * *

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section and/or accessible format using auxiliary aids and services upon receiving a request for the materials in another language or accessible format using auxiliary aids and services or when otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) of this chapter for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan as defined at § 422.2 of this chapter, or applicable integrated plan as defined at § 422.561 of this chapter, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in

addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

* * * * *

(e) * * *

(4) *Pre-enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

* * * * *

(viii) Effect on current coverage.

* * * * *

(13) *Non-renewal notice.* This is a standardized communications material through which plans must provide the information required under § 423.507.

* * * * *

(32) * * *

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all Part D sponsors in the service area the disclaimer consists of the statement: “We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are plans offered by [insert list of Part D sponsors here]. Please contact Medicare.gov, ~~or~~ 1-800-MEDICARE, or your local State Health Insurance Program to get information on all of your options.” If the TPMO sells for all Part D sponsors in the service area the disclaimer consists of the statement: “We offer the following

plans in your area [insert list of Part D sponsors]. You can always contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program for help with plan choices." The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

(42) *Required Content when offering defined standard coverage.* This is model content which –

(i) Applies to all plans offering defined standard coverage (as defined at § 423.100);

(ii) Must be used in all relevant communications (as defined at § 423.2260) that pertain to the formulary (as defined at § 423.4) or preferential status of covered Part D drugs; and

(iii) When discussing the Part D sponsor's formulary, conveys that all covered drugs have a single-tier benefit structure.

(43) *Comprehensive medication review - written summary.* This is the standardized communications material Part D sponsors must provide to all MTM program enrollees who receive a comprehensive medication review, as required under § 423.153(d)(1)(vii)(B).

(44) *Safe disposal information.* This is model communications material Part D sponsors must provide to all enrollees targeted for its MTM program, as required under § 423.153(d)(1)(vii)(E).

90. Section 423.2272 is amended by adding paragraph (e) to read as follows:

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

91. Section 423.2274 is amended by adding paragraph (c)(12), revising paragraph (g)(2)(ii), and adding paragraph (g)(4) to read as follows:

§ 423.2274 Required materials and content.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), premiums, and other services (such as over-the-counter medications and other incentives).

* * * * *

(g) * * *

(2) * * *

(ii) Record all marketing, sales, and enrollment calls, including calls occurring via web-based technology, in their entirety.

* * * * *

(4) Personal beneficiary data collected by a TPMO may not be distributed to other TPMOs.

92. Subpart Y is added to read as follows:

Subpart Y – Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

Sec.

Subpart Y – Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

§ 423.2500 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D-14 of the Social Security Act.

(b) *Scope.* This subpart sets forth the requirements for the Limited Income Newly Eligible Transition (LI NET) program that begins no later than January 1, 2024. Under this program, eligible individuals are provided transitional coverage for part D drugs.

§ 423.2504 LI NET eligibility and enrollment.

(a) *Eligibility.* An individual is eligible for LI NET coverage if they satisfy the criteria at paragraph (a)(1) or (2) of this section.

(1) *LIS-eligible.* The individual is a low-income subsidy eligible individual as defined at § 423.773 and—

(i) Has not yet enrolled in a prescription drug plan or an MA-PD plan; or

(ii) Has enrolled in a prescription drug plan or MA-PD plan but their coverage has not yet taken effect.

(2) *Immediate need individuals*. An individual who states their eligibility for LIS and immediate need for their prescription, but whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale, will be granted immediate need LI NET coverage.

(i) Immediate need individuals may provide documentation to the LI NET sponsor to establish LIS eligibility. Documentation may include, but is not limited to:

(A) A copy of the beneficiary's Medicaid card that includes their name and the eligibility date;

(B) A copy of a letter from the State or SSA showing LIS status;

(C) The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call;

(D) A copy of a State document that confirms active Medicaid status;

(E) A screen-print from the State's Medicaid systems showing Medicaid status; or

(F) Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy's patient profile.

(ii) If CMS cannot confirm the individual's eligibility during the period of LI NET coverage, the individual will not be auto-enrolled into a standalone Part D plan in accordance with § 423.34(d) following their LI NET coverage.

(b) *Enrollment.* Individuals are enrolled into the LI NET program as follows:

(1) *Automatic enrollment.* Beneficiaries who are LIS-eligible and whose auto-enrollment into a Part D plan (as outlined in § 423.34(d)(1)) has not taken effect will be automatically enrolled by CMS into the LI NET program unless the beneficiary has affirmatively declined enrollment in Part D per § 423.34(e);

(2) *Point-of-sale enrollment*. An individual with an immediate need whose claim is submitted at the point-of-sale and billed to LI NET will be enrolled into the LI NET program by the LI NET sponsor; or

(3) *Direct reimbursement request.* An individual who is LIS-eligible and who submits receipts for reimbursement for claims paid out of pocket will be retroactively enrolled into the LI NET program by the LI NET sponsor. The LI NET sponsor has 14 calendar days to reply with a coverage decision; or

(4) *LI NET application form*. An individual who is not enrolled through the methods in paragraphs (b)(1) though (3) of this section may submit an application form to the LI NET sponsor with supporting documentation demonstrating their LIS status. The LI NET sponsor will periodically check for eligibility and enroll applicants once eligibility is confirmed.

(c) *Duration of LI NET enrollment*. (1) Enrollment begins on the first day of the month an individual is identified as eligible under this section and ends after 2 months, with a longer LI NET enrollment for those with retroactive coverage per paragraph (c)(2) of this section.

(2) Retroactive LI NET coverage begins on the date an individual is identified as eligible for a low-income subsidy as a full-benefit dual eligible or an SSI benefit recipient, or 36 months prior to the date such individual enrolls in (or opts out of) Part D coverage, whichever is later. LI NET coverage ends with enrollment into a Part D plan or opting out of Part D coverage.

(d) *Ending LI NET enrollment.* An individual's enrollment in the LI NET program ends when:

(1) The individual is auto-enrolled into a standalone Part D plan in accordance with the guidelines at § 423.34(d) and that coverage has taken effect.

(2) The individual elects another Part D plan and that coverage has taken effect.

(3) The individual voluntarily disenrolls from the LI NET program.

(4) The individual is involuntarily disenrolled under § 423.44(b).

(5) LIS-eligibility for an individual in LI NET due to an immediate need cannot be confirmed within the period of LI NET coverage.

§ 423.2508 LI NET benefits and beneficiary protections.

(a) *Formulary.* The LI NET program provides access to all Part D drugs under an open formulary.

(b) *Network*. The LI NET sponsor must allow their network and out-of-network pharmacies that are in good standing, as determined by CMS, to process claims under the program. Licensed pharmacies that have not been revoked from Medicare under § 424.535, that do not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act and from Medicare under section 1156 of the Act (unless waived by the OIG), and do not appear on the preclusion list as defined at § 423.100 are considered to be in good standing for the LI NET program.

(c) *Safety.* The following provisions necessary to improve patient safety and ensure appropriate dispensing of medication apply to the LI NET program and LI NET sponsor, as applicable:

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Cost sharing.* (1) LI NET beneficiaries under § 423.2504(a)(1) will pay the applicable cost sharing for their low-income category as established for each year in the Rate Announcement publication specified in § 422.312 of this chapter.

(2) LI NET beneficiaries under § 423.2504(a)(2) will pay the cost sharing associated with the category of non-institutionalized full-benefit dual eligible individuals with incomes above 100% of the Federal poverty level and full-subsidy-non-FBDE individuals. If the beneficiary is later confirmed to belong to a different LIS category, the LI NET sponsor must reimburse the beneficiary for the difference between the cost sharing they paid versus what they would have paid in their LIS category.

(e) *Appeals*. LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of this part.

§ 423.2512 LI NET sponsor requirements.

The LI NET program is administered by one or more Part D sponsor(s) that meet all of the requirements in paragraphs (a) through (c) of this section.

(a) *Pharmacies and access to Part D drugs*. (1) The LI NET sponsor must be a PDP sponsor that has an established contracted pharmacy network in all geographic areas of the United States in which low-income subsidies are available.

(2) The LI NET sponsor must meet the requirements for providing access to Part D drugs under § 423.120(a), (c), and (d).

(b) *Experience*. The LI NET sponsor must have a minimum of two consecutive years contracting with CMS as a Part D sponsor.

(c) *Other LI NET sponsor requirements*. The LI NET sponsor must:

(1) Have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees;

(2) Have the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees.

(3) Identify, develop, and carry out outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program.

(4) Establish and manage a toll-free customer service telephone line and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf, for purposes that include but are not limited to: handling inquiries about services under the LI NET program, providing the status of eligibility or claims, and having the ability to accept best available evidence.

(5) Timely respond to beneficiary requests for reimbursement of claims by issuing reimbursement for eligible claims submitted by beneficiaries no later than 30 days after receipt, or, if the drug is not covered, the LI NET sponsor has 14 days to send communication to the beneficiary with a reason for the denial.

(6) Adjudicate claims from out-of-network pharmacies according to the LI NET sponsor's standard reimbursement for their network pharmacies.

§ 423.2516 Selection of LI NET sponsor and contracting provisions.

(a) *Appointment by CMS.* CMS appoints a Part D sponsor that meets the requirements at § 423.2512 to serve as the LI NET sponsor.

(b) *Selection criteria*. In appointing a LI NET sponsor, CMS evaluates the following:

(1) Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.34;

(2) Pharmacy access as outlined in § 423.120;

(3) Past performance, including Star Ratings (as detailed in § 423.186), previous intermediate sanctions (as detailed in § 423.750), and consistent with past performance in § 423.503(b); and

(4) Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536.

(c) *Term of appointment*. The term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per § 423.2524(b)) to determine payment rates for the upcoming year.

§ 423.2518 Intermediate sanctions for the LI NET sponsor.

In the event it is determined that the LI NET sponsor violated its contract, CMS may impose intermediate sanctions as outlined in subpart O of this part.

§ 423.2520 Non-renewal or termination of appointment.

(a) *Notice of non-renewal*. If the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS notifies the LI NET sponsor by January 1 of the year before the next contract year.

(b) *Selection of successor and transition period*. After a notice of non-renewal or termination, CMS selects a successor for the LI NET contract from among potentially eligible entities (as detailed in § 423.2516). The outgoing LI NET sponsor must coordinate with the successor for a period of no less than 3 months to ensure seamless transition of the LI NET program, including timely transfer of any data or files.

(c) *Immediate termination for cause*. (1) Notwithstanding paragraph (a) of this section, CMS may immediately terminate the existing LI NET contract for any of the reasons specified at § 423.509(a)(4)(i) and (xii) or (b)(2)(i)(A) and (B).

(2) CMS sends notice of an immediate termination as specified at § 423.509(b)(2)(ii).

(d) *Appeal rights*. Subpart N of this part applies to a termination under paragraph (c) of this section.

§ 423.2524 Bidding and payments to LI NET sponsor.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) Submission of bids and related information.

(1) The submission of LI NET bids and related information must follow the requirements and limitations in § 423.265(b), (c), (d)(1), (d)(2)(i), (ii), (iv), and (v), (d)(4) and (6), and (e).

(2) The review, negotiation, and approval of the LI NET bid would follow the provisions in § 423.272(a) and (b)(1) and (4).

(3) Basic rule for bid. The bid must reflect the LI NET sponsor's estimate of its revenue needs for Payment Rates A and B per paragraph (c) of this section.

(c) *Monthly payments.* CMS provides advance monthly LI NET payments equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid, as outlined in paragraph (b) of this section. LI NET payments are made on a prospective per-member, per-month basis.

(1) Payment Rate A is an annual rate of payment for projected administrative costs. An annual percentage-based cap on Payment Rate A limiting the year over year increase to Payment Rate A is set as part of the bid review and negotiation under § 423.272(a).

(i) For the 2024 plan year, the LI NET sponsor includes in their bid the assumption that Payment Rate A cannot exceed a 2% increase from the prior year's Payment A, which is a figure CMS will provide to the LI NET sponsor.

(ii) For the 2025 plan going forward, the LI NET sponsor will specify their assumption for any increase needed to the prior year's Payment Rate A, submitting justification to CMS in their bid if the cap exceeds 2%.

(2) Payment Rate B reflects the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit.

(d) *Payment reconciliation and risk corridors*—(1) *Reconciliation*. CMS conducts LI NET payment reconciliation each year for Payment Rates A and B after the annual PDE data submission deadline has passed and makes the resulting payment adjustment consistent with § 423.343(a).

(2) *Risk corridors*. As part of LI NET payment reconciliation, CMS will apply risk corridors to Payment Rate B as follows:

(i) There will be no risk sharing in the symmetrical 1% risk corridor around the target amount as defined in § 423.308.

(ii) There will be symmetrical risk sharing of 0.1% beyond the 1% risk corridor.

(iii) To carry out this section, § 423.336(c) applies to LI NET.

(e) *Reopening*. The LI NET contract will be subject to payment reopenings per § 423.346 as applicable.

(f) *Payment appeals*. The LI NET sponsor can appeal under § 423.350.

(g) *Overpayments*. The overpayment provisions at §§ 423.352 and 423.360 apply to LI NET.

§ 423.2536 Waiver of Part D program requirements.

CMS waives the following Part D program requirements for the LI NET program:

(a) *General information.* Paragraphs (1) and (3)(B) of section 1860D-4(a) of the Act (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(b) *Formularies*. Subparagraphs (A) and (B) of section 1860D-4(b)(3) of the Act (relating to requirements on development and application of formularies; formulary development) and formulary requirements in §§ 423.120(b) and 423.128(e)(5) and (6).

(c) *Cost control and quality improvement requirements*. Provisions under subpart D of this part, including requirements about medication therapy management, are waived except for the provisions in § 423.2508(d)(1) through (5).

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Out-of-network access*. Section 423.124 Special rules for out-of-network access to Part D drugs at out-of-network pharmacies, except for § 423.124(a)(2), which applies to LI NET.

(e) *Medicare contract determinations and appeals*. Subpart N, except for the provisions that apply to LI NET in § 423.2520(d).

(f) *Risk-sharing arrangements*. Section 423.336(a), (b), and (d).

(g) *Certification of accuracy of data for price comparison*. Section 423.505(k)(6).

(h) *Part D communication requirements*. Portions of subpart V of this part related to Part D communication requirements that are inapplicable to LI NET, including:

(1) Section 423.2265(b)(4), (5), (11), and (13);

(2) Section 423.2265(c);

(3) Section 423.2266(a);

(4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), and (33); and

(5) Section 423.2274.

(i) *Medicare Coverage Gap Discount Program*. Subpart W of this part.

(j) *Requirements for a minimum medical loss ratio*. Subpart X of this part.

(k) *Recovery audit contractor Part C appeals process*. Subpart Z of this part.

Subpart Z - Recovery Audit Contractor Part D Appeals Process

93. The heading for subpart Z is revised to read as set forth above.

PART 460--PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

94. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f).

95. Section 460.6 is amended by revising the definition of "contract year" to read as follows:

§ 460.6 Definitions.

* * * * *

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 19 to 30 months, as determined by CMS, but in any event will end on December 31.

* * * * *

96. Section 460.12 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 460.12 Application requirements.

(a) *Submission of application*. (1) An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area and/or add a PACE center site must submit to CMS a complete application in the form and manner**,** including timeframes for submission, specified by CMS, that describes how the entity or PACE organization meets all requirements in this part.

(2) An individual authorized to act for an entity that seeks to become a PACE organization must submit an application to qualify as a Part D sponsor in the form and manner required by CMS pursuant to 42 CFR part 423, subpart K.

(b) * * *

(3) Any PACE application that does not include a signed and dated State assurances document that includes accurate service area information and the physical address of the PACE center, as applicable, is considered incomplete and invalid and will not be evaluated by CMS.

* * * * *

97. Section 460.18 is amended by adding paragraphs (c) and (d) to read as follows:

§ 460.18 CMS evaluation of applications.

* * * * *

(c)(1) If, during the 12 months preceding the deadline established by CMS for the submission of an application or submission of a response to a CMS request for additional

information, a PACE organization fails to comply with the requirements of the PACE program under any current or prior PACE program agreement or fails to complete a corrective action plan during the applicable 12-month period, CMS may deny an application based on the applicant's failure to comply with the requirements of the PACE program under any current or prior PACE program agreement even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with the requirements of the PACE program under a PACE program agreement for purposes of an application denial under paragraph (c)(1) of this section if any of the conditions in paragraphs (c)(1)(i)(A) through (D) of this section apply with respect to the applicant during the applicable 12-month review period. The applicant:

(A) Was subject to the imposition of an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40.

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 460.80(a) after the end of the trial period.

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Met or exceeded 13 points for compliance actions for any one PACE program agreement.

(*1*) CMS determines the number of points accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued under § 460.19(c)(3) during the performance period counts for 6 points.

(*ii*) Each warning letter issued under § 460.19(c)(2) during the performance period counts for 3 points.

(*iii*) Each notice of noncompliance issued under § 460.19(c)(1) during the performance period counts for 1 point.

(*2*) CMS adds all the point values for each PACE organization's program agreement to determine if the 13-point threshold described in paragraph (c)(1)(i)(D) of this section has been reached.

(ii) CMS may deny an application submitted by an organization that does not hold a PACE program agreement at the time of the submission if the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (c)(1)(i) of this section. This paragraph does not apply to a parent organization that completed the acquisition of a subsidiary that meets the criteria for denial within the 24 months preceding the application submission deadline.

(2) [Reserved]

(d) If CMS has terminated a PACE program agreement under § 460.50, or did not renew a PACE program agreement, and that termination or non-renewal took effect within the 38 months preceding the submission of an initial or expansion PACE application from the same organization, CMS may deny the application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant currently meets all of the requirements of this part.

* * * * *

98. Section 460.19 is added to read as follows:

§ 460.19 Issuance of compliance actions for failure to comply with the terms of the PACE program agreement.

(a) CMS may take compliance actions as described in paragraph (c)(1) of this section if CMS determines that the PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and a State administering agency.

(1) CMS may determine that a PACE organization is out of compliance with requirements when the organization fails to meet performance standards articulated in sections 1894 and 1934 of the Social Security Act and regulations in this chapter.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an PACE organization is out of compliance when its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

(b) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(1) The nature of the conduct.

(2) The degree of culpability of the PACE organization.

(3) The actual or potential adverse effect on beneficiaries which resulted or could have resulted from the conduct of the PACE organization.

(4) The history of prior offenses by the PACE organization or its related entities.

(5) Whether the noncompliance was self-reported.

(6) Other factors which relate to the impact of the underlying noncompliance or to the PACE organization's inadequate oversight of the operations that contributed to the noncompliance.

(c) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(1) *Notice of noncompliance.* A notice of noncompliance may be issued for any failure to comply with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section.

(2) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(3) *Corrective action plan.* (i) Corrective action plans are issued for particularly serious or continued noncompliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(ii) CMS issues a corrective action plan if CMS determines that the PACE organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

99. Section 460.20 is amended by redesignating paragraphs (c) through (e) as paragraphs (d) through (f) and adding new paragraph (c).

The addition reads as follows:

§ 460.20 Notice of CMS determination.

* * * * *

(c) *Incomplete application due to the lack of required State assurances documentation*. An application that, upon submission, is determined to be incomplete under § 460.12(b)(3) will be withdrawn by CMS and the applicant will be notified accordingly. The applicant is not entitled to a fair hearing when CMS withdraws an incomplete application on this basis.

* * * * *

100. Section 460.40 is amended by revising paragraph (b) to read as follow:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(b) If CMS or the State administering agency makes a determination under § 460.50 that could lead to termination of a PACE program agreement, CMS may impose any of the sanctions specified at §§ 460.42 and 460.46. If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administrating agency has to

determine that the circumstances in 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension.

101. Section 460.64 is amended by revising paragraph (a)(5) and adding paragraph (a)(6) to read as follows:

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) * * *

(5) Be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis.

(i) Staff must be cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice, unless:

(A) The PACE organization conducts an individual risk assessment that meets the conditions specified in paragraph (a)(5)(iii) of this section, and

(B) The results of the risk assessment indicate the individual does not require a physical examination for medical clearance.

(ii) As part of the initial physical examination, staff must be determined to be free of active Tuberculosis disease.

(iii) If the PACE organization conducts a risk assessment on an individual under paragraphs (a)(5)(i)(A) and (B) of this section:

(A) Policies and procedures for conducting a risk assessment on each individual with direct participant contact must be based on accepted professional standards of care.

(B) The PACE organization's risk assessment must identify when a physical examination is required based on the results of the assessment.

(C) The results of the risk assessment must be reviewed by a registered nurse, physician, nurse practitioner, or physician assistant.

(D) At a minimum, the risk assessment must:

(*1*) Assess whether staff have been exposed to or have any symptoms of the following diseases: COVID-19, Diphtheria, Influenza, Measles, Meningitis, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Rubella, Streptococcal Infection, Varicella Zoster Virus, and any other infectious diseases noted as a potential threat to public health by the CDC.

(*2*) Determine if staff are free of active Tuberculosis during the initial risk assessment.

(6) Have all immunizations up-to-date before engaging in direct participant contact, including, at a minimum, the vaccination requirements in § 460.74.

* * * * *

102. Section 460.70 is amended by revising paragraph (a) to read as follows:

§ 460.70 Contracted services.

(a) *General rule*. The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, including, at a minimum, the medical specialties identified in paragraph (a)(1) of this section. The PACE organization does not need to have a written contract with entities that provide emergency services as described in § 460.100.

(1) At a minimum, except as noted in paragraph (a)(4) of this section, PACE organizations must have contracts in place for the following medical specialties:

(i) Anesthesiology.

(ii) Audiology.

(iii) Cardiology.

(iv) Dentistry.

(v) Dermatology.

(vi) Gastroenterology.

(vii) Gynecology.

(viii) Internal Medicine.

(ix) Nephrology.

(x) Oncology.

(xi) Ophthalmology.

(xii) Oral surgery.

(xiii) Orthopedic surgery.

(xiv) Otorhinolaryngology.

(xv) Plastic surgery.

(xvi) Pharmacy consulting services.

(xvii) Podiatry.

(xviii) Psychiatry.

(xix) Pulmonology.

(xx) Radiology.

(xxi) Rheumatology.

(xxii) General Surgery.

(xxiii) Thoracic and vascular surgery.

(xxiii) Urology.

(2) Contracts with medical specialists must be executed prior to enrollment of participants and must be maintained on an ongoing basis to ensure participants receive appropriate and timely access to all medically necessary care and services.

(3) A PACE organization is responsible for making all reasonable and timely attempts to contract with medical specialists. If at any time a PACE organization is unable to directly contract or maintain a contract with a specific specialty, the PACE organization must:

(i) Ensure care and services that would otherwise be provided to participants by a contracted specialist are provided and that the participant's needs are met through a different mechanism to include hospitalization, and

(ii) Promptly report the contracting issue to CMS and the SAA, including the attempts made to contract, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary services.

(4) A PACE organization is not required to have a contract with a particular medical specialty if the PACE organization directly employs one or more individuals prior to contracting who are legally authorized, and if applicable, board certified in the participant medical specialty.

* * * * *

103. Section 460.71 is amended by—

a. Revising paragraph (b)(4);

b. Redesignating paragraph (b)(5) and (6) as paragraphs (b)(6) and (7), respectively; and

c. Adding new paragraph (b)(5).

The revision and addition read as follow:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) * * *

(4) Be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis as required under § 460.64(a)(5).

(5) Have all immunizations up-to-date before engaging in direct participant contact, including, at a minimum, the vaccine requirements identified in § 460.74.

* * * * *

104. Section 460.98 is amended by:

a. Removing paragraph (b)(4);

b. Redesignating paragraph (b)(5) as paragraph (b)(4).

c. Redesignating paragraphs (c) through (e) as paragraphs (d) through (f), respectively;

d. Adding new paragraph (c);

The addition reads as follows:

§ 460.98 Service delivery.

* * * * *

(c) *Timeframes for arranging and providing services*—(1) *Medications*. The PACE organization must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication.

(2) *All other services*. The PACE organization must arrange or schedule the delivery of interdisciplinary team approved services, other than medications, as identified in paragraph (c)(2)(i) of this section, as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the interdisciplinary team or member of the interdisciplinary team first approves the service, except as identified in paragraph (c)(3) of this section.

(i) Interdisciplinary team approved services include:

(A) Services approved by the full interdisciplinary team.

(B) Services approved by a member of the interdisciplinary team.

(C) Services ordered by a member of the interdisciplinary team.

(D) Care planned services.

(ii) [Reserved]

(3) *Routine or preventative services*. Routine or preventive services are excluded from the requirement in paragraph (c)(2) of this section when all of the following requirements are met:

(i) The PACE organization documents that they were unable to schedule the appointment due to circumstances beyond the control of the PACE organization.

(ii) The participant does not have a change in status that requires the service to be provided more quickly.

(iii) The PACE organization provides the service as expeditiously as the participant's condition requires.

(4) *Providing approved services*. Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs.

* * * * *

105. Section 460.102 is amended by revising paragraph (d)(1) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *.

(1) The interdisciplinary team is responsible for the following for each participant:

(i) *Assessments and plan of care*. The initial assessment, periodic reassessments, and plan of care.

(ii) *Coordination of care*. Coordination and implementation of 24-hour care delivery that meets participant needs across all care settings, including but not limited to:

(A) Ordering, approving, or authorizing all necessary care.

(B) Communicating all necessary care and relevant instructions for care.

(C) Ensuring care is implemented as it was ordered, approved, or authorized by the IDT.

(D) Monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs.

(E) Promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant.

(iii) *Documenting recommended services*. Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(iv) *Consideration of recommended services*. The interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists. Specifically, the interdisciplinary team must ensure the following requirements are met:

(A) The appropriate member(s) of the interdisciplinary team must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs within 24 hours from the time of the participant's discharge.

(B) The appropriate member(s) of the interdisciplinary team must review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 5 calendar days from the date the recommendation was made.

(C) If recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c).

* * * * *

106. Section 460.104 is amended by revising paragraph (e) to read as follows:

§ 460.104 Participant assessments.

* * * * *

(e) *Changes to plan of care*. When the interdisciplinary team conducts semiannual or unscheduled reassessments, the interdisciplinary team must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments.

* * * * *

107. Section 460.106 is revised to read as follows:

§ 460.106 Plan of care.

(a) *Basic requirement*. The interdisciplinary team members specified in § 460.102(b) must develop, evaluate, and if necessary revise a comprehensive person-centered plan of care for each participant. Each plan of care must take into consideration the most current assessment findings and must identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being.

(b) *Timeframes for developing, evaluating, and revising plan of care*—(1) *Initial plan of care*. The interdisciplinary team must complete the initial plan of care within 30 calendar days of the participant's date of enrollment.

(2) *Semi-annual plan of care evaluation*. At least once every 180 calendar days the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to each participant's plan of care.

(3) *Change in participant's status*. (i) Except as specified in paragraph (b)(3)(ii) of this section, the interdisciplinary team must complete a re-evaluation of, and if necessary, revisions to a participant's plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status, or more expeditiously if the participant's condition requires. For purposes of this section, a "change in participant's status" means a major decline or improvement in a participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status, and requires interdisciplinary team review or revision of the care plan, or both.

(ii) If a participant is hospitalized within 14 calendar days of the change in participant status, the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to

the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital.

(c) *Content of plan of care*. At a minimum, each plan of care must meet the following requirements:

(1) Identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring. At a minimum, the care plan must address the following factors:

(i) Vision;

(ii) Hearing;

(iii) Dentition;

(iv) Skin integrity;

(v) Mobility;

(vi) Physical functioning, including activities of daily living;

(vii) Pain management;

(viii) Nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs;

(ix) The participant's ability to live safely in the community, including the safety of their home environment;

(x) Home care;

(xi) Center attendance;

(xii) Transportation; and

(xiii) Communication, including any identified language barriers.

(2) Identify each intervention (the care and services) needed to meet each medical, physical, emotional, and social needs, except: the plan of care does not have to identify the

medications needed to meet the participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record;

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify how each intervention will be implemented, including a timeframe for implementation.

(5) Identify a measurable goal for each intervention.

(6) Identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified.

(7) The participant's preferences and goals of care.

(d) *Implementation of the plan of care*. (1) The team must continuously implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or contractors, across all care settings.

(2) The team must continuously evaluate and monitor the participant's medical, physical, emotional, and social needs as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other employees or contractors.

(e) *Participant and caregiver involvement in plan of care*. (1) The interdisciplinary team must develop, evaluate and revise each plan of care in collaboration with the participant, the participant's caregiver, or both.

(2) The interdisciplinary team must review and discuss each plan of care with the participant and/or the participant's caregiver before the plan of care is completed to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation*. The team must establish and implement a process to document and maintain records related to all requirements for plans of care, in the participant's medical record,

and ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

108. Section 460.112 is amended by —

a. Removing paragraph (d);

b. Redesignating paragraphs (a) through (c) as paragraphs (b) through (d);

c. Adding new paragraph (a);

d. Adding paragraph (b)(8);

e. Revising newly redesignated paragraph (c) introductory text and paragraph (e)(1);

f. Adding paragraph (c)(5);

g. Revising paragraph (e)(1);

g. Redesignating paragraphs (e)(2) through (6) as (e)(3) through (7);

h. Adding new paragraph (e)(2);

i. Revising the paragraph (g) subject heading;

j. Revising paragraph (g)(2); and

k. Adding paragraph (g)(3).

The revisions and additions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Right to treatment*. Each participant has the right to appropriate and timely treatment for their health conditions, including the right to:

(1) Receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being; and

(2) Access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(b) * * *

(8) To have all information regarding PACE services and treatment options explained in a culturally competent manner.

(c) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health decisions. A participant has the right to have all information in this section shared with their designated representative. Specifically, each participant has the following rights:

* * * * *

(5) To be fully informed of the following, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services:

(i) A description of the PACE organization's palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving.

(ii) Whether palliative care, comfort care, or end-of-life care services (as applicable) will be provided in addition to or in lieu of the care the participant is currently receiving.

(iii) Identify all services that will be impacted and provide a detailed explanation of how the services will be impacted if the participant and/or designated representative elects to initiate palliative care, comfort care, or end-of-life care, including but not limited to the following types of services.

(A) Physician services, including specialist services.

(B) Hospital services.

(C) Long-term care services.

(D) Nursing services.

(E) Social services.

(F) Dietary services.

(G) Transportation.

(H) Home care.

(I) Therapy, including physical, occupation, and speech therapy.

(J) Behavioral health.

(K) Diagnostic testing, including imaging and laboratory services.

(L) Medications.

(M) Preventative healthcare services.

(N) PACE center attendance.

(iv) The right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason, either verbally or in writing.

* * * * *

(e) * * *

(1) To make health care decisions, including the right to:

(i) Have all treatment options fully explained;

(ii) Refuse any and all care and services; and

(iii) Be informed of the consequences their decisions may have on their health and/or psychosocial status.

(2) To fully understand the PACE organization's palliative care, comfort care, and end-of-life care services. Specifically, the PACE organization must do all of the following before palliative care, comfort care, or end-of-life care services can be initiated:

(i) Fully explain the applicable treatment options;

(ii) Provide the participant with written information about their treatment options, in accordance with paragraph (c)(5) of this section.

(iii) Obtain written consent from the participant or designated representative prior to initiating palliative care, comfort care, or end-of-life care.

* * * * *

(g) *Complaints, requests, and appeals*. * * *

(2) To request services from the PACE organizations, its employees, or contractors through the process described in § 460.121.

(3) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122.

109. Section 460.120 is revised to read as follow:

§ 460.120 Grievance process.

(a) *Written procedures*. A PACE organization must have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances in accordance with the requirements in this part.

(b) *Definition of grievance*. For purposes of this part, a grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant.

(c) *Grievance process notification to participants*. Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process in understandable language, including:

(1) A participant or other individual specified in paragraph (d) of this section has the right to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal.

(2) A Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services.

(3) The requirements under paragraphs (b) and (d) through (k) of this section.

(d) *Who can submit a grievance*. Any of the following individuals can submit a grievance:

(1) The participant;

(2) The participant's family member;

(3) The participant's designated representative; or

(4) The participant's caregiver.

(e) *Methods for submitting a grievance*. (1) Any individual as permitted under paragraph (d) of this section may file a grievance with the PACE organization either orally or in writing.

(2) The PACE organization may not require a written grievance to be submitted on a specific form.

(3) A grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants.

(f) *Conducting an investigation*. The PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known.

(g) *Grievance resolution and notification timeframes*. (1) The PACE organization must take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance.

(2) The PACE organization must notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with paragraph (g)(1) of this section.

(h) *Expedited grievances*. The PACE organization must resolve and notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 24 hours after the time the PACE organization receives the oral or written grievance if the nature of the grievance could have an imminent and significant impact on the health or safety of the participant.

(i) *Grievance resolution notification*. The PACE organization must inform the individual who submitted the grievance of the resolution as follows:

(1) Either orally or in writing, based on the individual's preference for notification, except for grievances identified in paragraph (i)(3) of this section.

(2) At a minimum, oral or written notification of grievance resolutions must include the following, if applicable:

(i) A summary statement of the participant's grievance including all distinct issues.

(ii) For each distinct issue that requires an investigation, the steps taken to investigate the issue and a summary of the pertinent findings or conclusions regarding the concerns for each issue.

(iii) For a grievance that requires corrective action, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur.

(3) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must describe the right of a Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint.

(4) The PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive the notification, and the PACE organization has documented this request in writing. The PACE organization is still responsible for paragraphs (i)(1) through (3) of this section.

(j) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(k) *Maintaining confidentiality of grievances*. The PACE organization must develop and implement procedures to maintain the confidentiality of a grievance, including protecting the identity of all individuals involved in the grievance from other employees and contractors when appropriate.

(l) *Recordkeeping*. The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of paragraph (k) of this section,, must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

(m) *Analyzing grievance information.* The PACE organization must aggregate and analyze the information collected under paragraph (l) of this section for purposes of its internal quality improvement program.

§ 460.121 [Amended]

110. Section 460.121 is amended in paragraph (i)(2) by adding the phrase "either orally or" after the phrase "their designated representative".

111. Section 460.198 is added to subpart K to read as follows:

§ 460.198 Disclosure of compliance deficiencies.

CMS may require a PACE organization to disclose to its PACE participants or potential PACE participants, the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS.

112. Section 460.200 is amended by revising paragraph (d)(2) to read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(d) * * *

(2) Maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the

communications relate to a participant's care, health, or safety including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's, care, health, or safety.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

* * * * *

§ 460.202 [Amended]

113. Section 460.202 is amended in paragraph (b) by removing the last sentence.

114. Section 460.210 is amended by revising paragraph (b)(6) to read as follows:

§ 460.210 Medical records.

* * * * *

(b) * * *

(6) Original documentation, or an unaltered electronic copy, of any written communication as described in § 460.200(d)(2) must be maintained in the participant's medical record unless the following requirements are met:

(i) The medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication,

(ii) Original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and

(iii) Original documentation of the communication is available to CMS and the SAA upon request.

* * * * *

Title 45

PART 170-- HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

115. 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.

116. Section 170.205 is amended by revising paragraphs (b)(1) and (2) and adding paragraph (c) to read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(b) * * *

(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, 2025.

(2) *Standard*. NCPDP SCRIPT Standard, Implementation Guide, Version 2022011 (incorporated by reference in § 170.299).

(c) *Real-Time Prescription Benefit* —(1) *Standard*. NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12 (incorporated by reference in § 170.299).

(2) [Reserved]

* * * * *

117. Section 170.299 is amended by revising paragraphs (a) and (k) to read as follows:

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services (HHS) must publish a document in the Federal Register and the material must be available to the

public. All approved incorporation by reference (IBR) material is available for inspection at the HHS and at the National Archives and Records Administration (NARA). Contact HHS at: U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW., Washington, DC 20201; call ahead to arrange for inspection at 202-690-7151. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may be obtained from the sources in the following paragraphs of this section.

* * * * *

(k) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; phone (480) 477-1000; fax: (480) 767-1042: website: www.ncpdp.org. (1) 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 2022011, January 2022, (Approval Date for ANSI: December 2, 2021), IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12, October 2021 (Approval Date for ANSI: September 27, 2021), IBR approved for § 170.205(c).

* * * * *

Dated: December 7, 2022

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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