CMS Final Rule on 2025 Policy and Technical Changes to Medicare Advantage and Medicare Part D

On April 4th, CMS released the Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications Final Rule. Among its provisions, the rule finalizes changes related to Star Ratings, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans (D-SNPs), utilization management, network adequacy, and other programmatic areas. **The summary below does not reflect a complete summary of the provisions of the rule. Rather, it includes a chosen subset of sections most relevant.**

NOTE: Page numbers refer to the pdf page numbers in the unofficial published inspection document made available on the federal register prior to the official publication of the rule.

Contents

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

A. Definition of Network-Based Plan (§§ 422.2 and 422.114) (section II.A, pg 23-24)

Finalized Changes
CMS finalized as proposed to relocate the definition of network-based plan from § 422.114(a)(3)(ii) to the definitions section in § 422.2, making the current cross reference at § 422.116(a)(1)(i) correct. Additionally, language specifying the network requirement for private-fee-for-service (PFFS) plans will continue to be included in the relevant provision at § 422.114(a)(3)(ii).

Background/Rationale
CMS believes that moving the definition of network-based plan will make the definition more readily accessible and applicable beyond the context of PFFS plans. Initially established without network requirements, PFFS plans were later mandated to have networks if operating alongside two or more network-based plans, therefore the reorganization aims to ensure consistency and clarity within the regulations. CMS received no comments on the proposal to move the definition.

B. Past Performance (section II.B, pg 24-27)

Finalized Changes
CMS finalized as proposed to revise §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) to change "Was subject to the imposition of an intermediate sanction" to "Was under an intermediate sanction" to reflect instances where sanctions remain active across consecutive review periods.

CMS finalized as proposed to incorporate federal bankruptcy proceedings as a basis for application denials due to past performance, by changing the text to "Filed for or is currently in federal or state bankruptcy proceedings" from "Filed for or is currently in State bankruptcy proceedings," at § 422.502(b)(1)(i)(C) and "Filed for or is currently under state bankruptcy proceedings" at § 423.503(b)(1)(i)(C) to include both federal and state bankruptcy proceedings.

CMS finalized as proposed to update references from § 422.504(b)(14) to the correct reference at § 422.504(a)(14), and removing duplications in the regulation text at § 422.502(b)(1)(i)(A) and (B).

Background/Rationale
CMS believes that revising the language regarding the basis for application denials due to intermediate sanctions will clarify a scenario where Medicare Advantage (MA) organizations and Part D sponsors may have a sanction imposed during one 12-month past performance review period, which remains effective for all or part of the subsequent 12-month review period. The change reflects the intent to deny applications from MA organizations and Part D sponsors if they have an active sanction during the relevant 12-month review period. This intent was previously established in the January 2021 final rule.

CMS believes that codifying state bankruptcy as a basis for application denial for the past performance of Medicare Advantage (MA) or Part D sponsors will revise regulations to enable the denial of applications from MA organizations or Part D sponsors involved in state or federal bankruptcy proceedings based on past performance, aligning with the best interests of the programs and the beneficiaries they serve.

Several commenters offered support for the proposed changes and no commenters opposed the changes.

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

A. Part D Medication Therapy Management (MTM) Program (section III.E, page 65-104

1. MTM Eligibility Criteria (65 – 100)

Finalized Changes:
CMS finalized significant adjustments to the Medication Therapy Management (MTM) program eligibility criteria, aiming to address disparities in access and enhance the program's effectiveness. These changes include requiring Part D sponsors to target beneficiaries with multiple chronic diseases, codifying ten core chronic diseases, including HIV/AIDS, and allowing sponsors flexibility to target additional chronic diseases. Additionally, CMS has retained the maximum number of covered Part D drugs required for eligibility at eight, while granting sponsors the flexibility to set a lower threshold between two- and eight-Part D drugs. Furthermore, sponsors are now required to include all Part D maintenance drugs in their targeting criteria, with minor modifications to allow flexibility but not limiting the inclusion of Part D maintenance drugs to specific drug classes. Lastly, CMS has set the MTM cost threshold at the average cost of eight generic drugs, calculated based on the average daily cost of a

generic drug using specified PDE data. These finalized changes aim to balance eligibility and program size while addressing specific issues identified in the Part D MTM program. Additionally, CMS has updated the MTM Program Completion Rate for Comprehensive Medication Review (CMR) measure to align with revised targeting criteria and will reintroduce it as a new measure to the Star Ratings program no earlier than the 2027 measurement year. The eligibility criteria now require Part D sponsors to target all at-risk beneficiaries (ARBs) in their Part D drug management program (DMP) for MTM enrollment.

Background/Rationale:
Since January 1, 2022, all Part D sponsors have been mandated to implement an MTM program targeting beneficiaries with multiple chronic diseases and high medication usage, as per Section 1860D–4(c)(2)(A)(ii)(II) of the Act. However, CMS observed a decline in MTM eligibility rates alongside increasing convergence among sponsors towards restrictive targeting criteria. These criteria, allowing sponsors flexibility in establishing MTM eligibility, have led to limited access for clinically high-risk beneficiaries. An analysis revealed disparities in eligibility due to high cost thresholds and restrictive plan criteria. Consequently, CMS proposed changes to the eligibility criteria, aiming to broaden access and ensure beneficiaries with complex drug regimens benefit from MTM.

Comments received on the proposed changes highlighted the value of MTM services in improving health outcomes, reducing costs, and enhancing patient empowerment. Supporters emphasized the potential for cost savings and improved medication adherence through MTM interventions. They also underscored the need to target underserved populations and address disparities in access. However, some commenters expressed concerns about the financial burden and resource constraints associated with expanding the MTM program. They feared increased premiums, administrative costs, and potential compromises in program quality.

In response to these comments, CMS acknowledged the challenges posed by the proposed expansion and made modifications to mitigate cost and resource burdens while ensuring the delivery of high-value MTM programs. The finalized changes aim to maintain program effectiveness, promote equity in access, and alleviate staffing concerns raised by commenters. CMS believes that these adjustments strike a balance between expanding access to MTM services and managing program size and resources effectively, thus fostering improved medication management for Medicare beneficiaries.

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

Finalized Changes
CMS finalized the definition of "unable to accept an offer to participate" in a Comprehensive Medication Review (CMR) as proposed at § 423.153(d)(1)(vii)(B)(2) to specify that a beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment. This clarification ensures consistency with CMS's previous guidance, which considers cognitive impairment as the criterion for inability to participate in a CMR.

Background/Rationale
Comments were made about the proposal, expressing support as well as concerns regarding beneficiaries' ability to involve caregivers or family members in the CMR process, citing instances such

as hearing impairment or participation in long-term care facilities. CMS acknowledged these concerns, emphasizing that the rule codifies the definition of "unable to participate" due to cognitive impairment, distinct from a beneficiary's choice to involve others in the CMR. CMS reminded plan sponsors to implement safeguards against discrimination and ensure accessibility in MTM services, referencing relevant federal regulations. Despite the comments, CMS finalized the proposed definition to maintain consistency and clarity in CMR eligibility criteria.

3. Requirement for In Person Synchronous Telehealth Consultation

Finalized Changes
CMS finalized the proposed revisions to § 423.153(d)(1)(vii)(B)(1)(i) without modification, requiring that a Comprehensive Medication Review (CMR) must be performed either in person or via synchronous telehealth. This clarification ensures that the CMR includes an interactive consultation conducted in real-time, regardless of the mode of delivery.

Background/Rationale
Comments received expressed support for clarifying the regulatory language on the use of telehealth, with some conditionally supporting the proposal based on including a telephone option. Concerns were raised about lower engagement levels due to preferences for remote interactions and challenges in reaching beneficiaries via phone. CMS acknowledged these concerns, confirming that telephonic communication meets the definition of synchronous telehealth and emphasizing the importance of offering multiple engagement methods. Despite the comments, CMS finalized the proposed revisions to maintain consistency and clarity in CMR delivery requirements.

B. Application of 2-Year Ban on Reentering the Part D Program Following Non-renewal (§§ 423.507 and 423.508) (Section III.G, page 109-112)

Finalized Changes
CMS finalized as proposed the following modifications to § 423.507(a):

- Revising paragraph (3) to clarify that it pertains to PDP sponsors' ineligibility to enter into a new contract for 2 years.
- Redesignating paragraph (a)(3) as new paragraph (a)(3)(i) to address the 2-year contracting ban following non-renewal of a PDP contract.
- Adding language to new paragraph (a)(3)(i) stating that CMS cannot enter into a new contract in the PDP region(s) served by the non-renewing contract.
- Introducing new paragraph (a)(3)(ii) to authorize CMS to make organizations that non-renew all their plan benefit packages (PBPs) in a PDP region ineligible to have plan bids approved again in that region for 2 years.
- Adding new paragraph (a)(3)(iii) to exempt new Employer Group Waiver Plan (EGWP) PBPs from the 2-year ban.

CMS finalized as proposed at § 423.508, adding at paragraph (e) to specify 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.

Background/Rationale
CMS received many comments offering general support for the proposed provisions and agreed with exempting EGWP plans from the 2-year ban following nonrenewal or mutual termination. Additionally, they requested an exemption for PDP PBPs and contracts terminated as part of a consolidation of plans and contracts after an acquisition. CMS believed no modification of the proposed change was necessary. They argued that the termination of a PDP contract as part of a consolidation wouldn't trigger the 2-year ban as long as the surviving contract continued to offer PDP PBPs in the affected regions. CMS explained that consolidations often occur after the acquisition of a sponsor by a parent organization to comply with the limit on the number of PDP PBPs per region. As long as the contract into which the plans are consolidated continues to offer PDP PBPs in the affected region(s), the sponsor or its parent organization isn't considered as exiting the region and thus wouldn't be subject to the 2-year ban on reentering the region.

C. Crosswalk Requirements for Prescription Drug Plans (§ 423.530) (Section III.H, page 113-127)

Finalized Changes
CMS finalized as proposed with minor grammatical and formatting changes at §423.530(a)(1) defining plan crosswalk as the movement of enrollees from one PDP PBP to another, and at §423.530(a)(2)(i)-(iii) adopting the crosswalk prohibitions in current CMS subregulatory guidance including barring crosswalks between PBPs in different PDP contracts, preventing the splitting of enrollee enrollment, and prohibiting crosswalks from basic coverage PBPs to those offering enhanced alternatives.

CMS finalized as proposed to continue current policy which prohibits PDP contracts from offering more than one PBP offering basic coverage in a region under § 423.265(b)(2). CMS finalized at § 423.530(a)(3) requiring sponsors seeking crosswalks to comply with rules in §§ 423.506 and 423.507 governing renewals and non-renewals, respectively. CMS also finalized 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, and at § 423.530(a)(5) enrollees in employer group health or waiver PBPs are allowed to be transferred between PBPs according to the usual process for enrollment in such plans.

CMS finalized as proposed with minor grammatical and formatting changes at § 423.530(b)(1) and (2) requiring enrollees in PDP PBPs that are renewing to be transferred into the same PBP for the following contract year.

CMS finalized as proposed with minor grammatical and formatting changes the following at § 423.530(c):

- Classifying consolidated renewal and contract consolidation crosswalks as "crosswalk exceptions" and define terms such as "consolidated renewals" and "contract consolidations" in accordance with current policy outlined in Section IV.AD.2. of the December 2022 proposed rule.
- At § 423.530(c)(1)(i)-(vii), requiring maintaining the same plan ID for the upcoming contract year, consolidating PBPs under the same PDP contract, ensuring that a PBP offering basic prescription drug coverage cannot be discontinued if other plans are still offered in the service area, and allowing enrollment from PBPs offering enhanced alternative coverage to be crosswalked into either enhanced alternative or basic prescription drug coverage.

- At § 423.530(c)(1), allowing plan crosswalks in consolidated renewal scenarios.
- At § 423.530(c)(1)(v) and § 423.530(c)(2)(v), require enrollees from non-renewing PBPs offering enhanced alternative coverage to be crosswalked into the PBP that will result in the lowest premium increase.
- At § 423.530(c)(1)(vi) and § 423.530(c)(2)(vi), prohibit plan crosswalks if the increase in premium would exceed 100%, unless the dollar amount of the increase is less than the base beneficiary premium compared to the current year premium for the non-renewing PBP.
- At § 423.530(c)(1)(vii), prohibit sponsors failing to request and receive a plan crosswalk exception from offering a new enhanced alternative PBP in the same service area for the following contract year.
- At § 423.530(c)(2)(i)–(iv), require that in contract consolidations, the non-renewing PDP contract and the surviving contract must be held by the same legal entity or entities with the same parent organization, with crosswalked enrollment allowed between PBPs offering the same type of prescription drug coverage and from PBPs offering enhanced alternative coverage to those offering basic coverage.

CMS finalized as proposed with minor grammatical and formatting changes at § 423.530(d) to codify procedures for submitting plan crosswalks and exceptions, requiring Part D sponsors to submit all mandatory plan crosswalks through the bid submission process in HPMS by the bid submission deadline, and all plan crosswalk exceptions by the deadline announced annually by CMS, with CMS verifying and approving exception requests meeting regulatory requirements to ensure proper allocation of PBP enrollment.

Background/Rationale

Comments on the proposed changes included requests to consider factors beyond total premiums when determining crosswalks, concerns about beneficiaries' understanding of changes to their Part D benefits, requests for a special election period for beneficiaries subject to crosswalks, and concerns about the impact of premium stabilization provisions from the Inflation Reduction Act of 2022 (IRA). CMS responded by acknowledging concerns but emphasized the complexity of considering other factors and the stability of premiums.

Additionally, CMS addressed concerns about delays in implementing the crosswalk provisions, noting that premium stabilization provisions from the IRA had already gone into effect for plan year 2024, negating the need for further delay based on those concerns. CMS decided to delay implementation of the crosswalk provisions until January 1, 2026, to allow time for necessary system updates, alleviating potential burdens during the adjustment period. CMS also clarified the interpretation of comparing premium increases to the base beneficiary premium. CMS also discussed the rationale behind prohibiting certain crosswalks, recognizing that formulary structure, cost sharing, and network composition are significant factors, CMS emphasized the difficulty in practically assessing these elements compared to premiums, which are uniform for all beneficiaries. CMS declined to address requests related to the Prescription Drug Hierarchical Condition Category (Rx-HCC) Risk Adjustment Model. CMS finalized the plan crosswalk provisions as proposed with minor grammatical and formatting changes and a delayed effective date from January 1, 2025 to January 1, 2026.

D. Expanding Network Adequacy Requirements for Behavioral Health (Section III.K, page 133-153)

Finalized Changes

CMS finalized as proposed at § 422.116(b) adding to the list of provider specialties subject to specific time and distance requirements for network adequacy evaluations at § 422.116(d)(2).

CMS finalized with modifications extending adding Outpatient Behavioral Health as a new facility-specialty in § 422.116(b)(2) and incorporating time and distance requirements in § 422.116(d)(2). The new combined behavioral health specialty type can include marriage and family therapists (MFT), mental health counselors (MHC), Opioid Treatment Programs (OTPs), Community Mental Health Centers, and those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services, including, but not limited to, psychotherapy or prescription of medication for substance use disorders: physician assistants (PA), nurse practitioners (NP), and clinical nurse specialists (CNS); addiction medicine physicians; or outpatient mental health and substance use treatment facilities. The following modification was made based on comments received:

- At § 422.116(b)(2)(xiv) establishing specific criteria that MA organizations must use to determine when an NP, PA, or CNS can be considered part of a network to meet the Outpatient Behavioral Health network adequacy standard.

CMS finalized as proposed allowing MA organizations to include contracted individual practitioners, group practices, or facilities that are applicable under this specialty type (Outpatient Behavioral Health) on their facility Health Services Delivery (HSD) tables, while prohibiting MA organizations from submitting a single provider for purposes of meeting the Outpatient Behavioral Health requirement if they have already submitted that provider under another specialty.

CMS finalized as proposed base time and distance standards in each county type for the new specialty type as follows:

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

CMS finalized as proposed adding the new Outpatient Behavioral Health facility-specialty type to the list at § 422.116(d)(5) of the specialty types that will receive a 10-percentage point credit 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.

Background/Rationale

Many commenters supported CMS' proposal to improve behavioral health network adequacy standards in MA plans. In response to concerns about consolidating mental health (MH) and substance use disorder (SUD) specialties into a single category, CMS acknowledged stakeholders' worries but

asserted that meaningful standards can be established under this combined approach. While recognizing the need for future rulemaking to address specific standards for each specialty, CMS emphasized the feasibility of setting adequate standards for both MH and SUD within the proposed framework.

Regarding the extension of telehealth credit for behavioral health services, CMS noted support from commenters but acknowledged varied opinions on the appropriate percentage and concerns about over-reliance on telehealth. CMS reaffirmed the extension of telehealth credit while emphasizing that telehealth should not replace in-person care. CMS committed to monitoring the effectiveness of telehealth services and remains open to potential adjustments based on evidence and stakeholder feedback.

Some commenters raised concerns about the inclusion of Nurse Practitioners (NPs), Physician Assistants (PAs), and Clinical Nurse Specialists (CNSs) in network adequacy standards. In response CMS finalized specific criteria for their inclusion such that MA organizations must independently verify that the provider has furnished or will furnish certain services to 20 patients within a recent 12-month period, using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data. In addition, MA organizations must provide information related to psychiatry or addiction medicine specialized training and ensure that the provider is listed as a psychiatry or addiction medicine NP, PA, or CNS on public-facing websites. These criteria aim to address concerns about the potential inclusion of inexperienced or unqualified providers, ensuring that only those with the necessary expertise are counted towards network adequacy.

Responding to requests for clarity on qualifications for Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs), CMS pointed to definitions in the Consolidated Appropriations Act and asserted that MA organizations are responsible for ensuring compliance with these qualifications. CMS directed stakeholders to existing regulations for Medicare-covered MFT and MHC services. In addressing concerns about providers with multiple credentials, CMS clarified that providers can be counted in multiple specialties if they meet the requirements for each specialty. Regarding requests to postpone the implementation of the Outpatient Behavioral Health network adequacy standard until 2026, CMS reiterated the expectation for existing network preparation and believed that the applicability date of January 1, 2025, of this final rule, provides sufficient time for organizations to prepare to include these provider types for the formal network adequacy evaluations conducted by CMS under § 422.116 beginning in 2025.

E. Improvements to Drug Management Programs (§§ 423.100 and 423.153) (section III.L, page 154-167)

1. Definition of Exempted Beneficiary § 423.100

Finalized Changes

CMS finalized as proposed amending the regulatory definition of "exempted beneficiary" at § 423.100 by replacing the reference to “active cancer-related pain” with “cancer-related pain”.

Background/Rationale

Commenters generally supported the proposed expansion of the definition of "exempted beneficiary" to include enrollees being treated for cancer-related pain, encompassing active cancer treatment, cancer survivors with chronic pain, and those under cancer surveillance. Concerns were raised about potentially including individuals not experiencing cancer-related pain, but CMS clarified that the proposal's impact would be minimal and maintained that exempted beneficiaries must be excluded from DMPs despite meeting other criteria. Additionally, commenters emphasized the importance of clear documentation and transitional processes for identifying exempted beneficiaries. Suggestions were made for establishing clinical documentation codes and providing guidance on case management. CMS agreed to share exemption codes in the OMS reporting in the technical user guide and consider how best to update future OMS reporting for clarity.

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

Finalized Changes

CMS finalized as proposed redesignating existing § 423.153(f)(8)(ii) as § 423.153(f)(8)(iii) and revising the text at § 423.153(f)(8)(ii) to specify that, for such exempted beneficiaries, the sponsor must provide the alternate second notice within 3 days of determining the beneficiary is exempt, even if that occurs less than 30 days from the date of the initial notice.

CMS finalized as proposed adding at § 423.153(f)(8)(i)(A) a window of up to 3 days to allow for printing and mailing the second notice or alternate second notice.

Background/Rationale

Commenters widely supported the proposal to eliminate the 30-day waiting period for sending an alternate second notice to exempted beneficiaries after receiving an initial notice. They viewed the change as effective and reasonable, aimed at preventing unnecessary burden and treatment interruptions for exempted beneficiaries. No opposition was voiced against the proposal. Additionally, support was expressed for discontinuing the use of the Part D DMP Retraction Notice for Exempted Beneficiaries, as it would no longer be necessary under the proposed change. CMS acknowledged the support from commenters and finalized the provision as proposed.

Several comments were received regarding the proposed timeframe for providing the second notice or alternate second notice to beneficiaries after a determination is made, all expressing support for the proposal but with varying opinions on the suggested timeframe. Most commenters emphasized the importance of notifying beneficiaries promptly about DMP determinations. Some commenters suggested allowing more than 3 days for sponsors to provide the notice, proposing timelines of up to 4 days, 5 business days, or 7 calendar days, citing concerns about practicality, particularly regarding weekends and holidays. CMS disagreed with extending the timeframe, stressing the significance of timely notification and highlighting existing precedent for a 3-day window for written notices in other Part D requirements. CMS clarified that the proposed 3-day window refers to calendar days and intends for sponsors to issue the notice within 3 days of making the determination, not necessarily for beneficiaries to receive it within that timeframe. CMS will update the DMP guidance to provide these clarifications. Overall, CMS maintains that the proposed change allows sufficient time for sponsors to print and mail the notices while ensuring timely communication of DMP limitations to beneficiaries.

F. Codification of Complaints Resolution Timelines and Other Requirements Related to the Complaints Tracking Module (CTM) (42 CFR §§ 417.472(l), 422.125, 423.129, and 460.119) (section III.M, page 179-196)

Finalized Changes

CMS finalized the proposed changes at §§ 422.504(a)(15) and 423.505(b)(22) that MA and Part D plans and PACE organizations to codify existing guidance for the timeliness of complaint resolution and to address and resolve complaints in the Complaints Tracking Module (CTM). These changes were largely finalized as proposed, with four modifications: changing the requirement to make contact to a requirement to attempt contact; adding language that permits the extension of time to resolve non-immediate need and non-urgent complaints that also qualify as non-expedited grievances in a manner consistent with the extension permitted for grievances; adding language that requires organization to adhere to the shortest timeframe required by regulation for CTM complaints and grievances when a compliant qualifies as a grievance; and requiring organizations contact complainants within 7 calendar days rather than 3 calendar days.

Background/Rationale

Many commentors were supportive of the rule and CMS's efforts to establish standards related to CTS timeliness and accountability. A few commenters suggested increasing the transparency and accountability for CTM complaints by making them publicly available on Medicare Plan Finder or another website. CMS noted they will consider these suggestions for future rulemaking.

One commentor recommended CMS clarify which complaints should be treated as appeals or grievances, and thus subject to different regulatory requirements and timelines. CMS noted that complaints should only be treated as appeals or grievances when they meet those regulatory definitions. However, CMS noted that because existing regulations permit extensions for MA and Part D appeals and grievances, they do not want to penalize organizations for extending the resolution of non-immediate need and non-urgent CTM complaint that meets the definitions of an appeal or grievance. Therefore, they are adding new paragraph (4) to §§ 422.125(b) and 423.129(b) to allow organizations to extend the timeline to respond to a CTM complaint if the complaint is also a grievance within the scope of §§ 422.564, 422.630 or 423.564 and if it meets the requirements for an extension of time under §§ 422.564(e)(2), 422.630(e)(2), or 423.564(e)(2) as applicable.

CMS also acknowledged the potential conflict between resolution timelines for immediate need/urgent complaints and grievances that meet the definition of "expedited grievances" under §§ 422.564(f), 422.630(d), and 423.564(f) for MA and Part D, and PACE service determination requests and expedited appeals under §§ 460.121(i) and 460.122(f)(2). To prevent organizations from being able to take longer to resolve these expedited grievances, requests, or appeal, CMS is adding a new paragraph (5) to §§ 422.125(b) and 423.129(b) to make clear that organizations must comply with the shortest applicable timeframe for resolving a CTM complaint when the complaint also qualifies as a grievance, PACE service determination request, or PACE appeal.

Some commenters recommend that CMS clarify whether organizations would be required to actually make contact with beneficiaries within the required timelines or to attempt to contact the beneficiaries,

as well as the means by which the organization may make contact. CMS modified the proposed regulations at §§ 422.125(c) and 423.129(c) to clarify that organizations attempt to make contact with individuals filing complaints in the CTM within the specified timeframe. CMS also noted that plans have many ways to contact beneficiaries, and they expect organizations to attempt to contact complainants by the most expeditious means available, and generally use the same contact method used by the complainant to submit their complaint. However, CMS is not codifying this expectation at this time, as it is generally an accepted practice among plans.

Several commentors requested greater flexibility in timeframes for resolving CTM complaints and reaching out to complainants. CMS recognizes the challenge plans may experience in meeting a 3-calendar day timeframe for reaching out to beneficiaries, and therefore are modifying the timeline. §§ 422.125(c) and 423.129(c) require organizations to attempt to contact the complainant filing non-immediate need complaints within 7 calendar days of the organization being assigned the complaint from the CTM.

G. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products (§§ 423.4, 423.100, 423.104, 423.120, 423.128, and 423.578) (section III.N, page 198-249)

Finalized Changes
CMS finalized changes encompassing several key aspects related to formulary changes and notifications for Medicare Part D plans.

Firstly, the regulations address the requirements for Part D sponsors to obtain approval for negative formulary changes, ensuring compliance with Section 1860D–11(e)(2) of the Act, codifying existing practices, and introducing definitions for various types of formulary changes, including maintenance changes, non-maintenance changes, and immediate negative formulary changes. Notably, exceptions are provided for immediate substitutions, such as generic substitutions and market withdrawals, allowing Part D sponsors to make these changes without prior CMS approval under certain conditions, with advance general notice and specific notice to affected enrollees required. Additionally, the regulations streamline and align the requirements for notice of formulary changes, specifying the timing and content of notifications to CMS, specified entities, and affected enrollees. Furthermore, changes related to the Inflation Reduction Act of 2022 are finalized, requiring Part D sponsors to include selected drugs with maximum fair prices on their formularies starting in 2026 and clarifying the process for removing such drugs from formularies. Overall, the finalized changes aim to enhance transparency, efficiency, and accessibility within the Medicare Part D program, ensuring beneficiaries receive timely information about formulary changes and access to necessary medications.

Background/Rationale
The finalized changes stem from a series of rulemaking initiatives, with the December 2022 proposal outlining revisions to approval processes and notice requirements for formulary changes. Subsequent to receiving comments, the November 2023 proposal incorporated adjustments, particularly regarding the treatment of biosimilar biological products and flexibility in timing requirements for certain substitutions. These proposals align with broader objectives, including increasing access to biosimilar biological products and promoting competition in the healthcare market, as highlighted in Executive Order 14306. The regulatory process involved soliciting feedback from stakeholders, including

commenters expressing differing perspectives on various aspects of the proposed changes. Ultimately, the finalized regulations aim to strike a balance between ensuring the efficiency of Part D plans' formulary management and safeguarding the interests of enrollees and other stakeholders in the healthcare ecosystem.

Key themes raised by commenters were concerns regarding the advance direct notice period for maintenance changes involving biosimilar biological products, with suggestions to extend it to 60 or 90 days due to patient access and familiarity issues. Additionally, commenters proposed sharing cost-saving benefits with enrollees and emphasized the importance of education and information dissemination about biosimilar biological products to reduce confusion among patients and healthcare professionals. Some commenters also expressed worries about increased administrative burdens on pharmacists due to immediate substitutions of interchangeable biological products and suggested aligning regulations with international policies.

CMS responded to commenters by maintaining the 30-day advance direct notice period, citing trust in FDA evaluations and consistency with longstanding policy. They disagreed with requiring biosimilar biological products to be placed on lower cost-sharing tiers and committed to updating educational resources and investigating options for identifying these products on Medicare Plan Finder. CMS also clarified that state laws govern pharmacy-level substitutions and argued that their proposal aims to prevent enrollees from facing issues at the pharmacy counter. They emphasized that their policies are informed by FDA regulations and are independent of policies in other countries, ultimately finalizing regulation text changes while maintaining their proposed policies regarding biosimilar biological products in the Medicare Part D program.

H. Parallel Marketing and Enrollment Sanctions Following a Contract Termination (§§ 422.510(e) and 423.509(f)) (section III.M, page 250-252)

Finalized Changes
CMS finalized its proposal to add paragraph (e) to § 422.510 and paragraph (f) to § 423.509, which details marketing and enrollment sanctions will automatically take effect after a termination is imposed. Additionally, this finalized proposal states that the marketing and enrollment sanctions will go into effect 15 days after CMS issues a contract termination notice.

CMS also finalized its proposal at paragraph (e)(2) of § 422.510 and paragraph (f)(2) of § 423.509, that MA organizations and Part D sponsors would continue to be afforded the same appeals rights and procedures specific to contract terminations; however, there would not be a separate appeal for the sanction.

CMS also finalized its proposal that if an MA organization or Part D sponsor appeals the contract termination, the marketing and enrollment sanctions would not be stayed pending the appeal. Lastly, CMS is finalized its proposal that the sanction would remain in effect until the effective date of termination, or if the termination decision is overturned on appeal until the final decision to overturn the termination is made by the hearing officer.

All these changes are finalized without modification and will be effective starting in contract year 2025.

Background/Rationale
If CMS terminates an MA organization or Part D sponsor contract(s) during the plan year, the termination is not effective until January 1st of the following year. This means the MA organization or Part D sponsor could potentially continue to market and enroll eligible beneficiaries into plans under the terminating contract(s) unless CMS imposes separate marketing and enrollment sanctions on the terminating contract(s). A terminating contract that continues to market to and enroll eligible beneficiaries would cause confusion and disruption for beneficiaries who enroll between the termination action and the January 1st effective date of the termination.

Several commenters expressed their support for these changes.

I. Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310) (section III.Q, page 274-298)

Finalized Changes
CMS finalized its proposal to add "and Medicaid program" to the current MA encounter data use purposes codified at § 422.310(f)(1)(vi) and (vii). These additions would enable CMS to use the data and release it for evaluation and analysis and program administration for Medicare, Medicaid, or Medicare and Medicaid combined purposes. Under these changes, a state receiving MA encounter data for care coordination may disclose MA encounter data to Medicaid-managed care plans to coordinate services for enrolled dually eligible individuals. This change is being made without modifications and will be effective beginning in the contract year 2025.

CMS also finalized its proposal to add a new subsection § 422.310(f)(3)(v) to allow for MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before reconciliation is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii). This change is being made without modifications and will be effective beginning in the contract year 2025.

Background/Rationale
CMS received several comments in support of CMS sharing MA encounter data with states prior to reconciliation for quality review and improvement use.

These final rule changes related to the disclosure of MA encounter data are focused on expanding allowable disclosures of these data to support not only the Medicare program or Medicare-Medicaid demonstrations, but also the Medicaid program in the interest of improving care for individuals who are eligible for Medicaid. Further, CMS believes these finalized changes regarding disclosures would improve States' abilities to understand and improve care provided to dually eligible individuals. For example, CMS notes that access to MA encounter data could support States' analysis of geographic trends to create targeted community outreach and education, including identification of geographic areas with higher rates of dementia, diabetes, or emergency room visit overutilization and evaluation of current Medicaid initiatives, including tracking efficacy of opioid overuse and misuse programs by monitoring service utilization for those with opioid dependency, evaluating appropriate and

inappropriate use of antibiotic and psychotropic medications, and analyzing deaths among individuals with opioid use disorder.

J. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process (section III.T, page 299-309)

Finalized Changes
CMS finalized its proposal to delete § 422.311(c)(5)(ii)(C), which requires MA organizations requesting both a medical record review determination appeal and payment error calculation appeal to file their written requests for both appeals within 60 days of the issuance of the RADV audit report before the reconsideration level of administrative appeal.

CMS finalized its proposal to amend § 422.311(c)(5)(iii) by providing that MA organizations who request a medical record review determination appeal may only request a payment error calculation appeal after the completion of the medical record review determination administrative RADV appeal process. At § 422.311(c)(5)(ii)(B), CMS is also finalizing its proposal to specify that MA organizations will forgo their medical record review determination appeal if they choose to only file a payment error calculation appeal.

CMS finalized its proposal at § 422.311(c)(5)(iii)(A) and (B) to specify that this process is complete when the medical record review determination appeals process has been exhausted through the three levels of appeal, or when the MA organization does not timely request a medical record review determination appeal during either the hearing officer or CMS Administer review stages.

CMS finalized its proposal at § 422.311(c)(5)(iii)(B) that an MA organization whose medical record review determination appeal has been completed, has 60 days from the issuance of a revised RADV audit report to file a written payment error calculation appeal, and clarifies that an MA organization's request for medical record review determination reconsideration must specify all audited HCCs from an audit report that they wish to dispute. CMS also revised § 422.311(c)(6)(i)(A) to clarify an MA organization's request must specify any and all audited HCCs from an audit report that the MA organization wishes to dispute.

CMS finalized its proposal to revise § 422.311(c)(6)(iv)(B) to clarify that the reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at § 422.311(c)(7)(x). CMS is also finalizing its proposal to add § 422.311(c)(6)(v) to clarify that the reconsideration official's written decision will not lead to the issuance of a revised audit report until the decision is considered final in accordance with § 422.311(c)(6)(iv)(B).

CMS finalized its proposal to clarify at revised § 422.311(c)(7)(ix) that if the hearing officer's decision is considered final, the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports for the specific MA contract audit.

Additionally, CMS is finalizing its proposal to revise § 422.311(c)(8)(iii) to add the requirement that if the CMS Administrator doesn't decline to review within 90 days of the receipt of either the MA organization

or CMS's timely request for review, the hearing officer's decision becomes final. Providing further clarification that CMS and the MA organization may submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision.

At § 422.311(c)(8)(v), CMS finalized its proposal to clarify the requirement of the Administrator to render a final decision in writing within 60 days of issuing the acknowledgment the acknowledgement notice, as determined by the date on which the final decision is made, not the date it is delivered to parties. Further, at § 422.311(c)(8)(vi) CMS is clarifying the scenarios in which the hearing officer's decision becomes final after a request for Administrator review has been made.

CMS finalized its proposal to add new § 422.311(c)(8)(vii) which states that once the Administrator's decision is considered final, the Secretary will recirculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior reports.

Additionally, CMS finalized its proposal to add § 422.311(c)(9) to specify what actions constitute final agency action. They specify that in cases when a MA organization appeals a payment error calculation after an MRRD appeal has completed the administrative appeals process, the MRRD payment error calculation final decisions will not be considered final agency action until the related payment error calculation appeal has been completed though the administrative appeals process and a final revised audit report has been issued.

CMS also finalized its proposal to revise § 422.311(a) to remove the word "annually" for clarity, as the Secretary may conduct RADV audits on differing cadences between the CMS and HHS-OIG RADV audits.

CMS is finalizing all of the above proposals without modification and with an effective date of contract year 2025.

Background/Rationale
CMS believes that clarifying and simplifying the regulatory text will create consistency in RADV payment calculations and the process that follows it—stating that previous language addressed possibilities in multiple ways, CMS believes these changes will alleviate administrative burden on both CMS and MA organizations. In addition to the above, CMS wishes to clarify what actions related to the RADV audit appeals process constitute final agency action and believe that these rule changes will clarify the requirements for a final decision to be provided in the RADV process.

CMS further believes these rule changes will clarify the proposals surrounding an MA organization forgoing their medical record review determination appeal and being able to permit an MA organization to submitting only one medical record review determination reconsideration request per audited contract. Additionally, CMS believes that issues surrounding the audit report will be revised to create more efficient clarifications on the process.

CMS received several comments that were beyond the scope of the proposed rule. Commenters sought additional clarification and made recommendations related to the underlying risk adjustment payment model, aspects of the RADV audit methodology related to sampling and extrapolation, and the need for monetary penalties to be applied to providers or other actors that contributed to a negative RADV finding.

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

A. Part C and Part D Midyear Benefit Changes (§§ 422.254, 423.265) (section IV.A, page 310-318)

Finalized Changes
CMS finalized the proposed provisions at §§ 422.254(a)(5) and 423.265(b)(5) to use the term "midyear benefit changes" and 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 of each year for the following contract year and until the end of the applicable contract year. CMS is finalizing these changes with only minor modifications to clarify the text.

Background/Rationale
CMS generally received positive or neutral comments on the proposal, which did not differentiate between the MA or Part D provisions. A few commenters recommended allowing plans to make mid-year benefit changes to improve their benefit packages or when new products (e.g. FDA-approved drugs) enter the market. CMS disagreed with these comments, noting that changes in bid-level cost sharing or benefits after bids have been submitted could undermine the integrity of the bidding system, disincentivize plans from submitting complete and accurate bids on time, provide competitive advantages to plans that make such changes, undermine CMS's ability to provide accurate comparative information to beneficiaries about plan benefits and costs, and potentially violate the uniform benefit requirements. They also note that plans are already allowed to update their formularies when new products enter the market.

B. Failure to Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts (§§ 423.293 and 423.294) (section IV.AA, page 319-330)

Finalized Changes
CMS finalized the changes to §§ 423.293 and 423.294 as proposed to require Part D sponsors to refund incorrect collections of premiums and cost sharing, recover underpayments of premiums and cost sharing, and to apply a de minimis amount, currently $2, that the Part D would not be required to issue a refund or recovery notice. CMS only made minor grammatical and formatting changes.

Background/Rationale
CMS received some positive and negative comments on the proposed de minimis amount for incorrect collections of Part D premiums and cost sharing. Some commenters recommend ensuring the proposal is mandatory across all plans to minimize enrollee confusion, while others believed mandatory application would deprive plans of existing flexibilities to set their own financial thresholds that are appropriate for collection. CMS clarified that Part D sponsors were not previously given flexibility and

failure to attempt to collect premiums and cost-sharing is interpreted as a violation of the uniform benefit requirement. They also believe that implementing the de minimis option will have minimal financial impact on enrollees and will minimize burden on enrollees and plans. Therefore, they are finalizing at § 423.294(b) and (c)(1) that it is not mandatory for Part D sponsors to collect or refund amounts below the de minimis threshold established in the regulation.

C. Standards for Determining Whether Special Supplemental Benefits for the Chronically Ill (SSBCI) have a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (section IV.C, page 331-365)

Finalized Changes

CMS is finalizing their proposals § 422.102(f), largely as proposed, with three major modifications. CMS has modified the requirements at § 422.102(f)(3)(ii) for MA organizations to establish, by the date on which it submits its bid, a comprehensive bibliography of relevant acceptable evidence related to the item or service the MA organization would offer as an SSBCI during the applicable coverage year. Plans are no longer required to incorporate all available evidence generated in the past 10 years, but a comprehensive list that incorporates all relevant and acceptable evidence, including negative evidence. CMS is finalizing paragraph (f)(4)(iv) (redesignated from existing paragraph (f)(3)(iv) with changes to require MA plans to document both approvals and denials of SSBCI eligibility. CMS is also adding new paragraph (f)(4)(v) as part of the changes they are finalizing to § 422.102(f). New paragraph (f)(4)(v) requires that an MA plan offering SSBCI must maintain without modification for the full coverage year for the SSBCI offered, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, and the specific objective criteria used by an MA plan as part of SSBCI eligibility determinations.

Background/Rationale

Commenters were generally supportive of these proposals. Some commenters expressed concern with the requirement that plans provide “all relevant acceptable evidence” and suggested alternatives that would allow plans to demonstrate good faith effort in collecting evidence in order to not stifle innovation or limit SSBCI offerings. CMS recognized that some commonly offered or generally agreed upon benefits may have a large body of evidence generated over the past 10 years, and that it may be unrealistic to require plans to collect all such evidence. Therefore, CMS is modifying their proposed language at § 422.102 (f)(3)(ii) to require plans to include in their bibliographies “a comprehensive list" of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered. They proposed requiring plans to include “all relevant acceptable evidence” in these bibliographies. CMS notes that plans still must demonstrate genuine effort to be thorough and inclusive of evidence related to SSBCI offered, including negative evidence.

Several commenters requested that the implementation of the evidence collection requirements until calendar year 2026 or bidding for CY 2026. CMS believes plans should already have evidence to show their benefit offerings have reasonable expectation of improving or maintaining the health or overall

function of chronically ill enrollees, and the new standard will not pose an undue burden. Consequently, CMS is finalizing these changes beginning after January 1, 2025, as proposed.

Several commenters requested that CMS provide additional flexibility in the types of evidence incorporated into the bibliographies, beyond clinical studies. They believed this burden of evidence would be particularly burdensome for MA Special Needs Plans (SNPs). CMS disagreed with these comments, noting that they require a broad scope of relevant and acceptable, including research published in peer-reviewed journals, case studies, federal policies/reports, and internal analyses. They finalized these requirements as proposed but may consider refining the standard in future rulemaking. Commenters were generally supportive of CMS's proposal to have plans document SSBCI eligibility denials, and also recommended that CMS collect information on approvals to gain a more complete and comprehensive understanding of how plans are implementing SSBCI coverage. CMS concurred with this recommendation and finalized this section with this additional requirement.

Commenters had differing views on whether or not plans should be allowed to change SSBCI eligibility requirements mid-year at all, if the changes would expand access, and the potential impacts to plan flexibility and enrollee confusion. CMS appreciated the feedback and agreed with prioritizing minimizing beneficiary confusion and disruptions in access to SSBCI. Therefore, they added new paragraph (f)(4)(v) to the finalized rule to require plans to maintain coverage without modification for the full year. However, they are not prohibiting plans from changing their utilization management policies related to SSBCI during the coverage year at this time.

D. Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111(l) and 422.2267(e)(42)) (section IV.D, page 366-380)

Finalized Changes
CMS finalized § 422.111(l) (requiring the Mid-year Notice to be sent and the timing) and § 422.2267(e)(42) (the content requirements for the Mid-Year Notice) as proposed, with a modification to clarify that supplemental benefits in the form of cost-sharing reductions are excluded from the notice.

Background/Rationale
Several commenters expressed concern that a single annual, mid-year notice would be insufficient to meet enrollees' needs and suggested numerous alternatives. CMS is not implementing changes to the timing or frequency of notice, because they believe the EOC should be the appropriate communication for informing beneficiaries of all supplemental benefits offered under a particular plan. CMS was concerned that monthly or quarterly reminders may become burdensome and less effective.

Additionally, several commenters highlighted the potential for enrollees to become confused, frustrated, and ultimately dissatisfied with their plans because they are ineligible to use a particular benefit. An example provided was meal delivery being available only post-surgery. CMS noted that plans are required to provide clear and accurate descriptions of the supplemental benefits, including whether a benefit is available under limited circumstances. CMS also feels the risk of confusion or frustration are outweighed by the benefits of informing enrollees about useful supplemental benefits.

Some commenters were concerned about plans' ability to offer "real-time" information in the notice, as the organizations that furnish these services (e.g. community-based organizations, providers) may

have limited resources and may lack sophisticated software system to facilitate real-time data sharing. CMS understood these concerns and clarified that they consider information that is up to date as of June 30 of the plan year satisfactory.

E. Annual Health Equity Analysis of Utilization Management Policies and Procedures (section IV.N, page 381-407)

Finalized Changes

Health Equity Representation on UM Committee
CMS finalized their proposal to add health equity-related requirements to § 422.137. First, the Agency proposes to require that beginning January 1, 2025, the Utilization Management (UM) committee must include at least one member with expertise in health equity. They are finalizing that health equity expertise include educational degrees or credentials with an emphasis on health equity, experience conducting studies identifying disparities amongst different population groups, experience leading organization-wide policies, programs, or services to achieve health equity, or experience leading advocacy efforts to achieve health equity.

Health Equity Analysis of the Use of Prior Authorization
CMS finalized their proposal to add a requirement at § 422.137(d)(6) that the UM committee must conduct an annual health equity analysis of the use of prior authorization with two provisions. CMS is not finalizing use of the repetitive phrase "but is not limited to" in the sentence that provides the non-exhaustive list of examples of expertise in health equity. Second, they are finalizing a clarification in § 422.137(d)(6)(iii) that the data used for the health equity analysis and reporting excludes data on drugs as defined in § 422.119(b)(1)(v).

CMS finalized that the member of the UM committee, who has health equity expertise, must approve the final report of the analysis before it is posted on the plan's publicly available website. The finalized analysis would examine the impact of prior authorization at the plan level, on enrollees with one or more of the following social risk factors (SRF): (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems. CMS finalized that this analysis must be posted on the plan's publicly available website and easily accessible to the general public.

The finalized analysis must use the following metrics, calculated for enrollees with the specified SRFs, and for enrollees without the specified SRFs, from the prior contract year, to conduct the analysis:

- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

Background/Rationale

Health Equity Representation on UM Committee
Nearly all commenters supported the proposal to add a member to the utilization management committee with expertise in health equity. A majority of commenters also supported the proposed definition of expertise in health equity. Commenters expressed gratitude for CMS's recognition that there is not currently a widely accepted definition of what qualifies as "expertise in health equity," and that the proposed non-exhaustive list provides adequate flexibility and acknowledges the varied experiences and qualifications that could comprise health equity expertise.

Some commenters suggested that CMS include additional specificity in the definition of expertise in health expertise, such as clinical experience practicing in underserved and marginalized communities, as well as lived, community, and professional experience in addition to academic training. Other commenters suggested that the individual be a physician. CMS noted that at this time, they do not believe adding the additional examples suggested by commenters of expertise in health equity to the non-exhaustive list in the regulation would necessarily add clarity, and they believe there is value in leaving some flexibility for MA organizations to determine what qualifies as expertise in health equity.

Health Equity Analysis of the Use of Prior Authorization
Commenters generally expressed support for the goal to advance health equity, increase transparency around the use of prior authorization, and ensure enrollees have timely access to medically necessary and clinically appropriate care. Some commenters encouraged CMS to continue advancing broader policy efforts to advance health equity goals and expressed concern that the proposed analysis will not actually advance health equity or help identify gaps in health equity. A few commenters indicated the analysis could be helpful in assisting researchers to develop tools and conduct studies to further inform the public. Some commenters indicated that the UM committee may not be the best entity to conduct this analysis.

CMS noted that the goal of this proposal is to ensure that all utilization management policies and procedures are reviewed from a health equity perspective, and to establish baseline data by beginning to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified social risk factors.

Some commenters indicated that prior authorization denial rates are not necessarily attributable to or correlated with an enrollee's social risk factor status. Commenters expressed concern about the proposed methodology and the practical utility of the data in its proposed form, and concerns about the potential for this information to mischaracterize plan activities or inadvertently mislead enrollees.

CMS noted that since they currently do not have any information that compares data for enrollees with the specified SRFs to those without the specified SRFs, CMS continues to believe that this analysis is an important first step in looking deeper into the use of prior authorization and its potential effects on enrollees.

IV. Enrollment and Appeals

A. Part D Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members (§§ 423.32 and 423.36) (section V.N page 453-455)

Finalized Changes

CMS finalized as proposed a new provision at §§ 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.

Background/Rationale

CMS's 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.

B. Revise Initial Coverage Election Period Timeframe to Coordinate with A/B Enrollment (§§ 423.32 and 423.36) (section V.P, page 457-464)

Finalized Changes

CMS finalized as proposed a provision in § 422.62(a)(1)(i) that an individual would have an opportunity to enroll in an MA plan (with or without drug coverage) using their ICEP until the last day of the second month after the month in which they are first entitled to Part A and enrolled in Part B.

Background/Rationale

CMS believes that extending the timeframe for the ICEP under § 422.62(a)(1)(i) would provide beneficiaries that are new to Medicare additional time to decide if they want to receive their coverage through an MA plan. All commenters supported the proposed policy.

C. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for NonHospital Provider Services (§ 422.626) (section V.Q, page 465-475)

Finalized Changes
CMS finalized as proposed a provision to revise § 422.626(a)(2) to specify that if an enrollee makes an untimely request for a fast-track appeal, the QIO will accept the request and perform the appeal. CMS also specified that the IRE decision timeframe in § 422.626(d)(5) and the financial liability provision in § 422.626(b) would not apply. Secondly, CMS finalized as proposed to remove the provision at § 422.626(a)(3) that prevents enrollees from appealing to the QIO if they end their covered services on or before the date on their termination notice, even in instances of timely requests for fast-track appeals.

Background/Rationale
These finalized changes would bring the MA program further into alignment with Original Medicare regulations and procedures for the parallel appeals process. This proposed expedited coverage appeals process would afford enrollees in MA plans access to similar procedures for fast-track appeals as for beneficiaries in Original Medicare in the parallel process. Nearly all commenters expressed support for the finalized provisions.

D. Amendments to Part C and Part D Reporting Requirements (§§ 422.516 and 423.514) (section V.R, page 476-483)

Finalized Changes
CMS finalized as proposed a provision to strike the term "statistics," as well as the words "and other," with the understanding that the broader term "information" which is already at § 422.516(a), includes statistics, Part C data, and information on plan administration. In a conforming proposal to amend § 423.514(a), CMS finalized a provision to strike the term "statistics" and add "information."

Additionally, CMS proposed to amend §§ 422.516(a)(2) and 423.514(a)(2) to make an affirmative change regarding CMS's collection of information related to what occurs from beginning to end when beneficiaries seek to get coverage from their Medicare health and drug plans for specific services. Specifically, CMS proposed to amend both sections to read, "The procedures related to and utilization of its services and items" to clarify that these regulations authorize reporting and data collection about MA organizations and Part D plan sponsor procedures related to coverage, utilization in the aggregate, and beneficiary-level utilization, including the steps beneficiaries may need to take to access covered benefits. CMS finalized these provisions as proposed, with a minor modification at § 422.516(a) to replace the term "doctor-patient relationship" with "provider-patient relationship."

Background/Rationale
Most comments supported the proposed provisions. Many commenters recommended CMS collect data elements for specific areas of interest, including data related to enrollee's cost-sharing for Part D medications, disease modification trends, multiple sclerosis diagnoses and enrollee demographics, plan referrals to specialists (e.g., neurologists), End-Stage Renal Disease (ESRD) services, social determinants of health (e.g., access to transportation, food insecurity, need for rental/utility assistance), plan use of prior authorization in specific settings, length of stays in post-acute care facilities,

rehospitalization rates, qualifications of plan organization determination and appeal reviewers, plan use of algorithm and artificial intelligence when making coverage determinations, Medicaid coverage, pharmacy benefit managers, point-of-sale coverage decisions, service-level initial determinations, and initial determination denial rationale.

E. Amendments to Establish Consistency in Part C and Part D Timeframes for Filing an Appeal Based on Receipt of the Written Decision (§§ 422.582, 422.584, 422.633, 423.582, 423.584, and 423.600) (section V.S, page 484-489)

Finalized Changes

CMS finalized as proposed a provision to revise §§ 422.582(b), 422.633(d)(1)(i), 423.582(b), and 423.600(a) to state that a request for a Part C reconsideration, Part D redetermination, Part D at-risk redeterminations and Part D IRE reconsiderations must be filed within 60 calendar days after receipt of the written determination notice. CMS also finalized as proposed a provision to add new §§ 422.582(b)(1), 422.633(d)(1)(i), and 423.582(b)(1), to provide that the date of receipt of the organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be 5 calendar days after the date of the written organization determination, integrated organization determination, coverage determination or at-risk determination, unless there is evidence to the contrary. In addition, CMS finalized as proposed to adopt this approach for plan and Part D IRE appeals in §§ 422.582(b), 422.633(d)(1), 423.582(b), 423.584 and 423.600(a).

CMs finalized as proposed a provision to add new §§ 422.582(b)(2), 422.633(d)(1)(ii), 423.582(b)(2) and 423.600(a) to provide that for purposes of meeting the 60 calendar day filing deadline, the appeal request is considered filed on the date it is received by the plan, plan-delegated entity or Part D IRE specified in the written organization determination, integrated organization determination, coverage determination, at-risk determination, or redetermination. In proposing new §§ 422.584(b)(3) and (4) and 423.584(b)(3) and (4), CMS also finalized as proposed to add the procedure and timeframe for filing expedited organization determinations and coverage determinations consistent with proposed requirements at §§ 422.582(b)(1) and (2) and 423.582(b)(1) and (2).

Background/Rationale

CMS believes these proposals will enhance consistency in the administrative appeals process and provide greater clarity on the timeframe for requesting an appeal and when an appeal request is considered received by the plan. Comments regarding the proposal were overwhelmingly supportive.

F. Authorized Representatives for Parts C/D Elections (§§ 422.60 and 423.32) (section V.T, page 490-494)

Finalized Changes

CMS finalized as proposed a provision to codify at paragraph (h)(1) of § 422.60 and (h)(1) of § 423.32 that authorized representatives will constitute the “beneficiary” or the “enrollee” for the purposes of making an election, meaning that CMS, MA organizations, and Part D sponsors will consider the authorized representative to be the beneficiary/enrollee during the election process. CMS’s proposal at

paragraph (h)(2) of § 422.60 and (h)(2) of § 423.32 clarified that authorized representatives under state law may include court-appointed legal guardians, durable powers of attorney for health care decisions and state surrogate consent laws as examples of those state law concepts that allow the authorized representative to make health care decisions on behalf of the individual. This proposal was also finalized as proposed.

Background/Rationale
Codifying this longstanding guidance provides plans, beneficiaries and their caregivers, and other interested parties clarity and transparency on the requirements when those purporting to be the representatives of the beneficiary attempt to make election decisions on their behalf. CMS proposed to codify this longstanding guidance in order to clarify the policy regarding the role of authorized representatives in the MA and Part D enrollment process, including the applicability of state law in this context. Comments expressed general support for the proposal.

G. Open Enrollment Period for Institutionalized Individuals (OEPI) End Date (§ 422.62(a)(4)) (section V.U, page 495-496)

Finalized Changes
CMS finalized as proposed a provision to codify at new subparagraph at § 422.62(a)(4)(ii) that the OEPI ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of "institutionalized" at § 422.2.

Background/Rationale
To provide transparency and stability for plans, beneficiaries and their caregivers, and other interested parties about this aspect of MA enrollment, CMS proposed in the November 2023 proposed rule to codify current sub-regulatory guidance that defines when the OEPI ends. Commenters supported the proposal.

H. Beneficiary Choice of C/D Effective Date if Eligible for More Than One Election Period (§§ 422.68 and 423.40) (section V.V, page 497-502)

Finalized Changes
To provide transparency and stability about the MA and Part D program for plans, beneficiaries, and other interested parties, CMS proposed at new §§ 422.68(g) and 423.40(f) that if the MA organization or Part D plan sponsor receives an enrollment or disenrollment request, determines the beneficiary is eligible for more than one election period and the election periods allow for more than one effective date, the MA organization or Part D plan sponsor must allow the beneficiary to choose the election period that results in the desired effective date. CMS also proposed at §§ 422.68(g)(1) and 423.40(f)(1) that the MA organization or Part D plan sponsor must attempt to contact the beneficiary and must document its attempt(s) to determine the beneficiary's choice.

In addition, CMS proposed at §§ 422.68(g)(2) and 423.40(f)(2) to require that the MA organization or Part D plan sponsor must use the proposed ranking of election periods to assign an election period if the beneficiary does not make a choice. Finally, CMS proposed at §§ 422.68(g)(3) and 423.40(f)(3) to require that if the MA organization or Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, they must assign an election period that results in the earliest disenrollment. All proposals were finalized without modifications.

Background/Rationale
This proposal represented the codification of longstanding MA and Part D sub-regulatory guidance. Commenters were generally supportive of the proposal as written, with some commenters noting that it reflects current practices and prioritizes beneficiary preference. Several commenters suggested updating Medicare.gov to allow individuals to indicate their desired effective date during online enrollments, which would alleviate plan burden in needing to contact individuals who are eligible for more than one election period.

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

A. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (§§ 422.2274(g) and 423.2274(g)) (section V.A page 503-529) (Rachel)

Finalized Changes
CMS finalized § 422.2274(g)(4) and 423.2274(g)(4) that will permit third part marketing organizations (TPMOs) to share personal beneficiary data with other TPMOs for marketing or enrollment purposes only if they first obtain express written consent from the relevant beneficiary, one-to-one from person to seller, through a clear and conspicuous disclosure. This aligns with the requirements in the FCC Secord Report and Order (FCC 23-107).

In the December 2022 proposed rule, CMS proposed that personal beneficiary data collected by a TPMO may not be distributed to other TPMOs. CMS asserted that when a beneficiary calls an entity based on an advertisement, the beneficiary is only expecting to connect with that entity, not to have return calls made to their home or receive calls from other entities. Considering the comments received on the proposed rule, CMS decided to finalize § 422.2274(g)(4) and 423.2274(g)(4) with revisions compared to the proposed rule, which will allow TPMOs to share personal beneficiary data with other TPMOs for marketing or enrollment purposes only if they first obtain express written consent from the relevant beneficiary.

Background/Rationale
CMS acknowledged that other agencies regulate certain types of information collection and sharing of personal information, such as the Department of Health and Human Services' Office of Civil Rights (OCR), the Federal Trade Commission (FTC), and the Federal Communications Commission (FCC). OCR administers and enforces the HIPAA Privacy Rule, which provides standards for the use and disclosure of protected health information by HIPAA covered entities and business associates. A covered entity is a

health care provider that conducts certain health care transactions electronically, a health plan, or a health care clearinghouse, while a business associate is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information. TPMOs have varying degrees of business and contractual arrangements with MA organizations and Part D sponsors and may or may not be considered business associates under the HIPPA Privacy Rule.

Further, in the Secord Report and Order (FCC 23-107), the FCC amended consent rules for robotexts and robocalls covered by the Telephone Consumer Protection Act (TCPA) and made it clear that texters and callers subject to the TCPA must obtain a consumer's prior express written consent when telemarketing via robocall or robotext and that requirement applies a single seller at a time. The rule also made it clear that the consumer's consent is not transferrable to another caller. The new FCC rules will apply to TPMOs operating in the MA and Part D marketplace that seek to contact Medicare beneficiaries with advertisements or telemarketing messages using an automatic telephone dialing system or artificial or prerecorded voice. The FTC also enforces rules and regulations that apply to TPMOs, such as the Telemarketing Sales Rule and Section 5 of the FTC Act, showing the broad swath of rules that TPMOs operated in the MA and Part D marketplace must comply with.

CMS received several comments that the proposal disregards a beneficiary's choice on whether to opt n to having their personal contact information shared. While some commenters were largely supportive of the total prohibition, many commenters believe that beneficiaries should be able to consent to having their information shared. Notably, a few commenters highlighted that the TPMOs should be able to share beneficiary contact information when the beneficiary knowingly consents and requests to have it shared, which would not be possible if the rule was finalized as proposed.

CMS shared that they agree with the commenters that beneficiaries should be able to consent to having their personal information shared in a clear and understandable way and have modified the proposed regulation text to provide for this option. In the final rule and based upon suggestions received in comments, CMS is codifying that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior written consent is given by the beneficiary. CMS codified that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure. They believe that beneficiaries have the right to share their personal data with whom they choose and should have the opportunity to fully understand with whom their personal data may be shared.

CMS also cited the numerous complaints, both through 1-800-Medicare, the new FCC Second Report and Order, as well as State Health Insurance Programs, testimony from health insurance administrators and executives, and advocacy groups noting that the overwhelming number of marketing calls beneficiaries receive from TPMOs are unwanted, confusing, and inhibit the beneficiary's ability to make an informed choice. Thus, CMS' final rule aims to limit when a beneficiary's personal data can be shared and ensures that they know who will be contacting them, which they believe will lower the number of complaints, be less overwhelming, and will result in beneficiaries having a more meaningful discussion with fewer agents.

CMS is codifying the regulation text in a way that is consistent with the one-to-one consent structure announced by the FCC in the Second Report and Order in order to make it simple for a TPMO to comply

with both rules. The FCC's Order requires a written agreement that bears the signature of the person called or texted that clearly and conspicuously authorizes no more than one identified seller and a written agreement that includes a disclosure informing the person signing that they are authorizing the seller to deliver or cause to be delivered to the signatory telemarketing calls or texts using an automatic telephone dialing system or a recorded voice. CMS believes that prior express written consent, one-to-one from person to seller, through a clear and conspicuous disclosure to share personal beneficiary data with another TPMO is a reasonable and less restrictive standard than a complete prohibition on the sharing of personal beneficiary data with other TPMOs.

B. Marketing and Communications Requirements for Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.2267) (section V.B page 530-561) (Rachel)

Finalized Changes

CMS finalized the SSBCI disclaimer requirements at § 422.2267(e)(34) with revisions compared to their proposal in the November 2023 proposed rule. They decided to change the reference in paragraph (e)(34)(ii) from "MA organization" to "applicable MA plan(s)" to clarify that the SSBCI the MA organization advertises must be clearly tied to the applicable MA plan or plans that offer that SSBCI. In addition, they finalized paragraph (e)(34)(iii) with a modification that clarifies that the disclaimer used by the MA organization must communicate that coverage depends on the enrollee being a "chronically ill enrollee" and on "the applicable MA plan's coverage criteria" for a specific SSBCI.

CMS finalized the regulation text regarding requirements for the chronic conditions list in the SSBCI disclaimer with revisions to address when only one type of SSBCI is mentioned and when multiple types of SSBCI are mentioned. When only one type of SSBCI is mentioned, the regulation addresses if the number of condition(s) is five or fewer, then the MA organization must list all condition(s), and if the number of conditions is more than five, then the MA organization must list the top five conditions. When multiple types of SSBCI are mentioned, the regulation addresses if the number of condition(s) is five or fewer, then the MA organization must list all condition(s) and if the number of condition(s) is more than five, then the MA organization must list the top five conditions.

Background/Rationale
The January 2021 final rule required MA organizations to comply with the SSBCI disclaimer, which requires MA organizations to convey that the benefits mentioned are a part of special supplemental benefits, convey that not all members will quality for these benefits, and include the model content in the material copy which mentions SSBCI benefits. Since MA organizations had over a year to implement their use of the SSBCI disclaimer at the time of the November 2023 proposed rule, CMS decided to reevaluate the implementation of the requirement at § 422.2267(e)(34).

In many instances, MA organizations have been found to use marketing to potentially misrepresent the benefit offered, often not presenting a clear picture of the benefit and limits on eligibility. Moreover, CMS has seen an increase in complaints related to marketing and misleading SSBCI ads among MA organizations. Thus, CMS highlighted that additional clarification of current requirements was appropriate. Specifically, requiring a more robust disclaimer with specific conditions listed would provide beneficiaries with more information to determine when a particular with SSBCI is appropriate for

their needs. In addition, it would reduce the potential for misleading information or misleading advertising.

CMS reviewed many comments that supported this proposal to strengthen and add more specific requirements to the SSBCI disclaimer in order to decrease misleading advertising and increase transparency for beneficiaries. A few commenters were concerned that the chronic conditions list would be difficult for MA organizations to implement and that it could lead to beneficiary confusion. Some commenters had concerns about how to implement the list of top five chronic conditions and how that list might impact beneficiaries, and requested CMS further clarify their expectations.

CMS believes that the clarifications they made regarding the requirements for the chronic conditions list in the SSBCI disclaimer, limit ambiguity for MA organizations, while simultaneously preserves their intention to ensure the SSBCI marketing and communications is transparent and not misleading for beneficiaries.

After considering the comments they received, CMS decided to finalize 422.2267(e)(34)(ii) with revisions compared to their proposal in the November 2023 proposed rule to add more specific requirements for when and how an MA organization must list up to five chronic conditions used to determine eligibility for SSBCI identified in marketing and communications materials. These requirements specify how an MA organization must structure its list of chronic conditions in the SSBCI disclaimer when only one type of SSBCI is mentioned and when multiple types of SSBCI are mentioned. CMS decided to change "MA organization" to "applicable MA plan" and requiring, where there are more than five eligible conditions, a note indicating that there are other eligible conditions not listed. They also decided to finalize language that ensures the specific coverage criteria of the MA plan that offers the SSBCI are referenced as additional eligible requirements. They decided to omit the phrase "items and services" to avoid any implication that SSBCI that are reductions in cost sharing are not included in the SSBCI disclaimer requirements. The SSBCI disclaimer is required for all marketing and communications materials that mention SSBCI of any type. The new SSBCI disclaimer requirements, as finalized, will apply to all contract year 2025 marketing and communications beginning October 1, 2024, and in subsequent years.

C. Agent Broker Compensation (section V.C page 562-595)

1. Limitations on Contract Terms

Finalized Changes
CMS is finalizing the proposed changes at § 422.2274(c)(13) to generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may directly or indirectly interfere with the agent's ability to objectively assess and recommend the plan that best fits the beneficiary. This will limit contract language that allows renewal based on rates of enrollment and marketing reimbursement rates based on enrollment quotas. This change was finalized with one modification to make clear that this requirement is applicable beginning with marketing and communications activities related to the 2025 contract year.

Background/Rationale
CMS received several comments asking for more explanation on what terms were prohibited. CMS has noted that they are relying on a "reasonableness standard," to determine which terms are within the

scope of the regulation. CMS will review contract terms as part of routine monitoring in addition to complaints and other methods of investigation to enforce this rule.

2. Compensation Rates

Finalized Changes
CMS is finalizing a proposed change to set a single agent and broker compensation rate for all plans for the contract year 2025 by the compensation rate requirements of § 422.2274(d)(1)-(3). CMS is also finalizing a rule to include administrative payments in the calculation of enrollment-based compensation. This change was finalized with one modification to include all payments tied to enrollment be included under compensation as defined by § 422.2274(a).

Background/Rationale
CMS received some comments expressing a struggle to comply given pressing deadlines for activities that brokers may already be engaged in. CMS has clarified that the updates will coincide with the beginning of marketing activities for the 2025 contract year.

3. Administrative Payments

Finalized Changes
CMS is finalizing to eliminate separate payment to agents and brokers for administrative services, beginning in contract year 2025 and forward. CMS is also finalizing at § 422.2274(a) to increase the flat rate compensation amount to a one-time increase of $100.

Background/Rationale
CMS received some comments requesting clarification on the timeline of the changes. CMS clarified that the rule takes effect October 1, 2024. CMS received other comments disagreeing with the proposal because many agents rely on administrative fees for "free," services that help agents and brokers do their jobs effectively. CMS understands and believes brokers will now be able to decide which services they find necessary to do their jobs. CMS also received comments that their proposed $31 increase was too low. CMS has adjusted this number to $100 as a result.

4. Agent Broker Compensation for Part D Plans

Finalized Changes
CMS is finalizing at § 423.2274 to apply all of the agent and broker compensation policies for the sale of MA plans to agents and brokers that market PDP plans.

Background/Rationale
CMS did not receive any comments.

VI. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.164, 422.166, 422.260, 423.184, and 423.186)

A. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184) (section VII.B page 598-625)

1. Measure Removals

Finalized Changes
CMS is finalizing to remove the Medication Reconciliation Post-Discharge ("MRP") measure from the Part C Star Ratings, beginning with the 2025 measurement year and 2027 Star Ratings.

Background/Rationale
CMS notes that it would be duplicative of the MRP component of the Transitions of Care (TRC) measure included beginning with the 2024 Star Ratings. CMS received comments showing support for this provision.

2. Measure Updates

Finalized Changes
CMS is finalizing to expand the age range for beneficiaries for Colorectal Cancer Screening to 45-75, for 2024 and the following measurement years.

CMS is also finalizing to return the Functional Status Assessment measure of the Care for Older Adults to the Star Ratings with one modification: the change will begin with the 2027 Star Ratings and the 2025 measurement period. The measure change for the COA—Functional Status Assessment measure is a substantive update under § 422.164(d)(2) because removal of a mechanism for positive performance on the measure may meaningfully impact the numerator. The updated measure was moved to the display page starting with the 2022 Star Ratings. With the updated specification, documentation of a complete functional status assessment must include: (1) notation that ADLs were assessed; (2) notation that IADLs were assessed; or (3) result of assessment using a standardized functional assessment tool.

CMS is also finalizing that the Medication Therapy management ("MTM") Program Completion Rate be removed from the Star Ratings for the 2025 and 2026 measurement years and return, at the earliest, in time for the 2029 Star Ratings, given the finalized changes to the MTM program.

Background/Rationale
CMS received a comment concerned that the expanded range for the Colorectal Cancer Screening would impact the measure rate. CMS believes the clinical recommendation for USPSTF is sufficient. CMS received other comments requesting clarification and a delay of the Functional Status Change and CMS has responded by changing the measurement periods. CMS received some comments about the MTM Program Completion Rate, recommending that CMS change the MTM program targeting criteria. CMS appreciated the comments but will not make changes in this section. CMS also received comments suggesting that they work with a measure steward to develop alternate measures for the success or impact of MTM services on health outcomes. CMS instead encouraged the industry to develop new measures for them to consider.

3. Measure Additions

Finalized Changes
CMS finalized adding three Part D measures to the 2026 Star Ratings: Concurrent Use of Opioids and Benzodiazepines ("COB"), Polypharmacy Use of Multiple Anticholinergic Medication in Older Adults ("Poly-ACH"), and Polypharmacy Use of Multiple Central Nervous System active Medications in Older Adults ("Poly-CNS"). These measures reflect the following performance:

- Concurrent Use of Opioids and Benzodiazepines (COB) (Part D)—analyzes the percentage of Medicare Part D beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines during the measurement period.
- Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of two or more unique anticholinergic medications during the measurement period.
- Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of three or more unique CNS-active medications during the measurement period.

Background/Rationale
Some comments did not support the inclusion of these measures. CMS believes clinical support, existing data, and recommendations from several subject-matter experts requires their inclusion. CMS also received comments that believed these measures would impose similar administrative burdens as formerly retired measurements. CMS believes plans and providers are already familiar and would not impose additional burdens. Several comments requested an exemption for Poly-ACH and Poly-CNS for those with mental health diagnoses given the typical treatment of multiple antipsychotics. CMS will continue to include these measurements according to recommendations.

B. Revising the Rule for Non-substantive Measure Updates (§§ 422.164(d) and 423.184(d)) (section VII.C page 625-628)

Finalized Changes
CMS finalized their proposal 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. They revised the regulation by adding that another example of a non-substantive change would include a new mode of data collection.

Background/Rationale
CMS received several comments supporting the proposal but there were also a few that opposed the proposed provision. Commenters stated that a new mode of data collection should be considered a substantive change. A couple of commenters were concerned that a change in survey modality would produce different survey results and that survey modality preferences differ by age groups, which may affect the population. CMS disagreed that changes to expand modes of data collection would be a substantive change to a measure. Notwithstanding an expansion of the modes of data collection, the denominator will remain the same. Expanding the modes of data collection will generally result in more data regarding performance on the measure. As a result, the measure will better reflect actual performance of the organization and provide more information to CMS and the public.

C. Weight of Measures with Substantive Updates (§§ 422.166(e)(2) and 423.186(e)(2)) (section VII.D page 628-630)

Finalized Changes

CMS finalized their proposal to adopt regulation text clarifying how they treat measures with substantive updates when they return to the Star Ratings program. Specifically, the Agency finalized their proposal to add language 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. They added a slight clarification that in subsequent years, a new or substantively updated measure will be assigned the weight associated with its category.

Background/Rationale

All commenters supported the proposal to clarify how CMS treats measures with substantive updates when they return to the Star Ratings program. Some commenters noted that this proposal would result in a phase-in approach reducing potential volatility, and it provides plans sufficient notice to familiarize themselves with a measure's updated specifications, assess potential impacts, and incorporate changes to internal processes if needed.

The first year (2028 Star Ratings) the updated medication adherence measures will be in the Star Ratings they will have a weight of 1, but then beginning with the following Star Ratings year, the weight will increase to 3, as these measures are categorized as intermediate outcome measures.

D. Data Integrity (§§ 422.164(g) and 423.184(g)) (section VII.E page 630-642)

Finalized Changes

References to Data Completeness

CMS finalized their proposal to revise the introductory language in § 422.164(g)(1)(iii) to remove references to the timeliness monitoring study and audits and replace them with references to data from MA organizations, the Independent Review Entity (IRE), or CMS administrative sources. They also finalized to modify § 422.164(g)(1)(iii)(A) to use data from MA organizations, the IRE, or CMS administrative sources to determine the completeness of the data at the IRE for the Part C appeals measures starting with the 2025 measurement year and 2027 Star Ratings.

Appeals to the IRE

CMS finalized their proposal to compare the total number of appeals received by the IRE, including all appeals regardless of their disposition (for example, including appeals that are dismissed for reasons other than the plan's agreement to cover the disputed services and withdrawn appeals), to the total number of appeals that were supposed to go to the IRE.

CMS also finalized their proposal to modify the calculation of the error rate at § 422.164(g)(1)(iii)(H) by taking 1 minus the quotient of the total number of cases received by the IRE and the total number of cases that were supposed to be sent to the IRE (Equation 1). CMS did include a modification to clarify

that the numerator is the total number of cases received by the IRE that should have been sent at § 422.164(g)(1)(iii)(H).

CMS finalized their proposal to remove and reserve § 422.164(g)(1)(iii)(J) because they intend to calculate the Part C error rate based on 12 months rather than a projected number of cases not forwarded to the IRE in a 3-month period as has historically been done with the TMP data. CMS also finalized their proposal to modify § 422.164(g)(1)(iii)(K)(2) so that the number of cases not forwarded to the IRE is at least 10 for the measurement year (that is, total number of cases that should have been forwarded to the IRE minus the total number of cases received by the IRE is at least 10 for the measurement year).

CMS also finalized their proposal at § 422.164(g)(1)(iii)(O) that the two Part C appeals measure Star Ratings be reduced to 1 star if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures. CMS finalized to update § 422.164(g)(1)(iii)(A)(2) to change the data source in the case of contract consolidations so that the data described in paragraph (g)(1)(iii)(A)(1) are combined for consumed and surviving contracts for the first year after consolidation.

Background/Rationale

References to Data Completeness
A few commenters recommended a transition year so Part C sponsors can get used to the new approach for scaled reductions. A commenter wanted additional time since they suggested that plans may need to put in additional efforts to ensure that they pass data validation for the Part C Reporting Requirements. However, CMS noted they do not believe that a transition year is needed since we would be using existing data collected at the contract level from MA organizations about the number of partially favorable reconsiderations.

Appeals to the IRE
CMS received a number of comments in support of their proposal to update the methodology for applying scaled reductions for the Part C appeals measures. A couple of commenters expressed strong support for this update, because it will help ensure data integrity by discouraging MA plans from not sending required appeals to the IRE to earn higher Star Ratings

E. Review of Sponsor's Data (§§ 422.164(h) and 423.184(h)) (section VII.F page 642-646)

Finalized Changes
CMS finalized their proposal that sponsors' requests for CMS review of administrative data must be received no later than the annual deadline set by CMS. Beginning with the 2025 measurement year (2027 Star Ratings), CMS finalized at §§ 422.164(h)(3) and 423.184(h)(3) that any requests by an MA organization or Part D sponsor to review its administrative data for Patient Safety measures be made by the annual deadline set by CMS for the applicable Star Ratings year.

For the 2025 measurement year (2027 Star Ratings) the deadline will be May 18, 2026. For subsequent years, CMS intends to announce the annual deadlines via the annual Advance Notice and Rate Announcement or by an HPMS memorandum.

Background/Rationale
Most commenters supported the proposal to set an annual deadline for MA organizations or Part D sponsors to request reviews of its administrative data for the Patient Safety measures. A few commenters supported the proposal but requested to move the deadline to mid-late June or have a phased-in approach to set multiple deadlines based on PDE dates of service to facilitate a complete review. CMS noted that the deadline was selected due to the time to complete the reviews and calculate the rates, and because the PDE data used to calculate the Patient Safety measures are generally complete by that point based on our analysis.

CMS received some suggestions to expand the administrative reviews to include other forms of payment outside of the Medicare PDEs for Patient Safety reports such as cash payment data, Veteran Affairs benefits, or other supplemental data. CMS noted that they do not accept PDEs for claims that were not submitted for processing and/or reimbursement under the plan by either a network pharmacy or enrollee as discussed in the May 11, 2012 HPMS memorandum, Prohibition on Submitting PDEs for non-Part D Prescriptions.

F. Categorical Adjustment Index (§§ 422.166(f)(2) and 423.186(f)(2)) (section VII.G page 646-649)

Finalized Changes
CMS finalized their proposal to calculate the percentage LIS/DE enrollees and percentage disabled enrollees used to determine the Categorical Adjustment Index (CAI) adjustment factor in the case of contract consolidations based on the combined contract enrollment from all contracts in the consolidation beginning with the 2027 Star Ratings. CMS finalized to modify §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) to calculate the percentage LIS/DE enrollees and the percentage disabled enrollees for the surviving contract for the first two years following a consolidation by combining the enrollment data for the month of December for the measurement period of the Star Ratings year across all contracts in the consolidation.

Background/Rationale
A commenter supported finalizing as proposed and another commenter appreciated CMS providing clarity on the calculation of the CAI. A commenter felt there are several benefits to the proposal but also raised some concerns. The commenter asked for clarification on how data from multiple contracts are weighted or integrated. CMS noted that data from the contracts involved in the consolidation are not weighed in the process they finalized. Rather the percentage of LIS/DE enrollees and the percentage of disabled enrollees will be calculated for the surviving contract of the consolidation based on all enrollees across all of the contracts involved in the consolidation.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3)) (section VII.G page 649-653)

Finalized Changes
For the first year following a consolidation, CMS finalized their proposal to add new paragraphs §§ 422.166(f)(3)(viii)(A) and 423.186(f)(3)(viii)(A) to assign the surviving contract of a consolidation the

enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using enrollment from July of the most recent measurement year used in calculating the HEI reward.

CMS finalized that contracts that do not meet the minimum percentage of enrollees with the specified SRF thresholds or the minimum performance threshold described at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) would have a reward value of zero used in calculating the enrollment-weighted mean reward. For the second year following a consolidation, CMS finalized at new paragraphs §§ 422.166(f)(3)(viii)(B) and 423.186(f)(3)(viii)(B) that, when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score would be combined across the contracts in the consolidation prior to calculating the HEI score. The HEI score for the surviving contract would then be used to calculate the HEI reward for the surviving contract following the methodology described in §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii).

CMS clarified that total contract enrollment from July of the most recent measurement year is used in calculating the enrollment weights in the first year following the consolidation.

Background/Rationale
Most commenters supported the proposal, and another commenter appreciated the additional clarity on how the HEI will be calculated across a broad range of situations. A commenter asked for additional clarification and examples of how the surviving contract's HEI reward would be calculated and combined across contracts noting that it is unclear how CMS intends to combine patient-level data "across contracts prior to calculating the HEI score". CMS noted that the methodology for combining data across contracts in the consolidation when calculating the HEI reward for the surviving contract will depend on which year the consolidation is in. In the first year following a consolidation, the HEI reward for the surviving contract will be calculated as the enrollment-weighted mean reward of the HEI rewards for all contracts in the consolidation using July enrollment from the most recent measurement year used in calculating the HEI.

In the second year following a consolidation, patient-level data for the measurement years used in calculating the HEI will be combined across contracts in the consolidation by assigning members from the consumed contract(s) to the surviving contract. These combined patient-level data will be used to calculate the HEI score and reward for the surviving contract, including the calculation of the percentage of enrollees with the specified SRFs for the surviving contract and the surviving contract's measure scores for the subset of enrollees with the specified SRFs following the methodology at §§ 422.166(f)(3) and 423.186(f)(3).

H. Quality Bonus Payment Appeal Rules (§ 422.260) (section VII.H page 653-664)

Finalized Changes
CMS finalized their proposal to revise the language at § 422.260(c)(2)(vii) to provide the CMS Administrator the opportunity to review and modify the hearing officer's decision within 10 business days of its issuance. CMS finalized that if the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding. Under this change, if the Administrator does review and modify the hearing officer's decision, a new decision will be issued as directed by the Administrator.

Background/Rationale
Commenters supported providing the Administrator the opportunity to review hearing officer decisions. A few asked for clarification of the criteria that trigger a review by the Administrator, including whether plans can request this review. CMS noted that the Administrator will have the discretion to review (or review and modify) all hearing officer decisions during the 10 business day period established in the regulation. This is not another appeal opportunity for MA organizations. Information about QBP appeals is communicated promptly via email.

VII. Improvements to Special Needs Plans

A. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2) (section VIII.A page 665-677)

Finalized Changes
CMS finalized definitions of the terms Facility-based Institutional special needs plan (FI-SNP), Hybrid Institutional special needs plan (HI-SNP), Institutional special needs plan (I-SNP), and Institutional-equivalent special needs plan (IE-SNP) at § 422.2 largely as proposed. In the definitions of FI-SNP, HI-SNP, and I-SNP, CMS slightly reorganized the definitions to improve their readability. CMS modified the definition of FI-SNP to more clearly provide how FI-SNPs must own or contract with institutions as described in the definition.

Lastly, CMS is revising the definition of FI-SNP by replacing "with the plan's county-based service area" with "in the plan's service area." In addition, CMS finalized revisions to § 422.101(f) to add a new paragraph (f)(2)(vi) as proposed to require the model of care for each I-SNP (regardless of the type of I-SNP) to ensure that contracts with long-term care institutions (listed in the definition of the term "institutionalized" in § 422.2) contain requirements allowing I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized.

Background/Rationale
A commenter sought clarification regarding the contracting requirements for Hybrid Institutional SNPs (HI-SNPs); specifically, the commenter asked that CMS clarify the requirement that HI-SNPs "must own or have a contractual arrangement with each institutionalized facility serving enrollees." CMS replied that I-SNPs have been able to successfully comply with this requirement to own or contract with the necessary institutions. However, CMS did adopt a slight clarification to the definition of FI-SNP, which will also apply to HI-SNPs, to use the phrase "in the plan's service area" Instead of the proposed phrase "within the plan's county-based service area." This revision better aligns with the definition of Service Area in 42 CFR 422.2 "Service area."

B. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (§ 422.101) (section VII.B page 677-701)

1. *Codification of Model of Care (MOC) Scoring Requirements for Special Needs Plans (SNPs) (677-685)*

Finalized Changes
CMS proposed to codify 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.

CMS also proposed at paragraph (f)(3)(iii)(A) to codify that an MOC for a C-SNP that receives a passing score is approved for 1 year. Additionally, CMS proposed at new paragraph (f)(3)(iii)(B), to codify different approval time limits for the MOCs of I-SNPs and D-SNPs, basing the approval period on the final score of the MOC on the aggregate minimum benchmark.

Lastly, CMS proposed a new paragraph (f)(3)(iii)(C) to provide an opportunity for a SNP to cure deficiencies in its MOC if the MOC fails to meet any minimum element benchmark or the aggregate minimum benchmark when reviewed and scored by NCQA. All provisions were finalized as proposed with minor grammatical and organizational changes.

Background/Rationale
CMS received several comments addressing the SNP Model of Care Element Matrix which reflects the content and evaluative criteria of the MOC. CMS will take these comments into consideration when renewing the next MOC Paperwork Reduction Act (PRA) package and for future rulemaking.

2. *Amending SNP MOCs after NCQA Approval (§ 422.101(f)(3)(iv)) (685-701)*

Finalized Changes
CMS finalized as proposed a provision stating 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 also finalized a provision stating that SNPs may submit updates and corrections to their NCQA-approved MOC between June 1st and November 30th of each calendar year or when CMS requires an off-cycle submission to ensure compliance with applicable law.

CMS finalized to codify a list of reasons for when a SNP must use an off-cycle submission of a revised MOC for review and approval. § 422.101(f)(3)(iv)(B) provided that an MA organization must submit updates or corrections to a SNP's MOC to reflect the following (found on page 689 of the final rule).

CMS finalized, § 422.101(f)(3)(iv)(D), that SNPs may not implement any changes to a MOC until NCQA has approved the changes. CMS also finalized to codify this policy at § 422.101(f)(3)(iv)(E), which provides that the successful revision of the MOC under proposed (f)(3)(iv) does not change the MOC's original period of approval original approval period (that is, 1-year or multi-year) by NCQA.

CMS finalized under § 422.101(f)(3)(iv)(F) to codify existing operational practices with respect to off-cycle submissions by C-SNPs. Specifically, CMS finalized to codify that C-SNPs are prohibited from submitting an off-cycle MOC submission except when CMS requires an offcycle submission to ensure

compliance with the applicable regulations. CMS also finalized, at § 422.101(f)(3)(iv)(G), to permit a single opportunity for a SNP to revise its offcycle submission to revise a MOC if there is a deficiency in the submission. CMS finalized 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).

CMS finalized 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. Excluding minor grammatical, technical, and organization modifications, all the provisions referenced above were finalized as proposed.

Background/Rationale
Although there were inadvertent differences in how the preamble of the proposed rule explained the proposed regulation text, CMS is finalizing the substance of the proposed policy for how off-cycle revisions to the MOCs of I-SNPs and D-SNPs could be requested and would be subject to review and approval before changes could be implemented.

C. Verification of Eligibility for C-SNPs (§ 422.52(f)) (section VIII.D page 729-743)

Finalized Changes

CMS is finalizing its proposal to codify existing guidance that the MA organization must contact the individual applicant's current physician, nurse practitioner, or physician's assistant to confirm that the chronic condition special needs program (C-SNP) enrollee has the specific severe or disabling chronic condition(s), as specified in § 422.52(f)(1). CMS also proposes that the physician must be the enrollee's existing provider, either a primary care physician or specialist treating their chronic condition(s) as outlined in § 422.52(f)(1)(i). CMS modified this final change to specify that an applicant's current health care provider, who may be a physician, nurse practitioner or physician's assistant, provides the verification of the applicant's chronic condition. This finalized change will go into effect in the Contract Year 2025.

CMS is finalizing its proposal, without modification, to add two new options for MA organizations to verify enrollees' conditions by either contacting the applicant's physician or office before enrollment or using a Pre-enrollment Qualification Assessment Tool (PQAT) prior to enrollment and subsequently obtain their physician's verification within the individual's first month of enrollment in the C-SNP. CMS is also proposing at new § 422.52(f)(1)(i) to require that the physician's verification must be in a form and manner authorized by CMS, such as a note or documented phone call with the physician or their office. This finalized change will go into effect in the Contract Year 2025.

CMS is finalizing its proposal at § 422.52(f)(1)(ii)(A) that the PQAT must meet specific standards and consequently CMS is not required to review and approve plan-specific tools. Under this proposal PQATs must include a set of clinically appropriate questions relevant to the C-SNP's focus condition(s); gather information on applicant's medical history, current signs/symptoms, and current medications; include the date and time of in-person assessments or receipt date of mail/electronic assessments (if available); and a signature line for the physician to confirm the individual's eligibility. This finalized change will go into effect in the Contract Year 2025.

CMS is finalizing its proposals at § 422.52(f)(1)(ii)(B) to require C-SNPs to conduct a post-enrollment confirmation of enrollee's information and eligibility via medical information (e.g. medical history, current signs/symptoms, diagnostic testing, and current medications) provided by their current PCP or specialist treating their chronic condition. At § 422.52(f)(1)(ii)(C), CMS is also finalizing its proposal to require the C-SNP to include the information gathered in the PQAT and from the verification process in enrollee records subject to the § 422.118 confidentiality requirements. This finalized change will go into effect in the Contract Year 2025.

CMS is also finalizing its proposal to require C-SNPs to track the total number of enrollees and the number and percent of enrollees whose post-enrollment verification matches the pre-enrollment assessment. These data and supporting documentation must be made available to CMS upon request. This finalized change will go into effect in the Contract Year 2025.

CMS is finalizing its proposal to codify their existing guidance for MA organizations offering C-SNPs at § 422.52(f)(1)(ii)(E) that C-SNP must continue enrollment if confirmation of the qualifying condition(s) is obtained before the end of the prior to the disenrollment date, as outlined at § 422.52(f)(1)(ii)(F).

Lastly, CMS is finalizing its proposal to codify at § 422.52(f)(1)(iii) that the C-SNP is required to have the individual's current physician (primary care physician or specialist treating the qualifying condition) administer the PQAT directly with the enrollee or provide confirmation (with or without the presence of the enrollee) that the information in the document supports a determination that the individual is eligible for the C-SNP.

Background/Rationale

CMS does not expect these finalized proposals to result in new or additional paperwork burden, as the policy to verify eligibility for C-SNPs has been in existence for some time. CMS intends for these finalized changes to provide transparency and stability for MA organizations offering C-SNPs and other interested parties about this aspect of the MA program. They also hope to clarify the SNP's roles and responsibilities and further assist MA organizations in meeting the requirements pertaining to verification of eligibility for C-SNPs.

CMS believes that by requiring a physician—either the applicant's primary care physician or a specialist treating the qualifying condition(s)—to provide the required verification of the applicant's condition, the accuracy and integrity of the verification process will be strengthened. By clarifying the verification process, CMS hopes that these procedures will allow the MA organization to efficiently serve special needs populations while maintaining the integrity of SNP offerings under the MA program. They specifically hope that pre-enrollment verification with the applicant's primary care physician or specialist treating the qualifying condition will allow C-SNP to process the enrollment promptly.

All burden impacts related to the SNP eligibility verification procedures have already been accounted for under OMB control number 0938–0753 (CMS-R267). These requirements have been previously implemented and are currently being followed by MA organizations. There is also no expected impact on the Medicare Trust Fund.

CMS received comments suggesting that CMS codify a sufficiently broad term to allow a variety of healthcare professionals with requisite qualifications to confirm the applicant's specific severe or disabling chronic condition(s). Examples include the following terms: "health care provider" or

"practitioner" to include those who work in clinic environments and any clinical staff in the physician's office, (e.g., registered nurses), which would align with existing verification protocols and will enable MA plans to offer and enroll beneficiaries with chronic conditions in plans best suited to meet their healthcare needs and preferences more efficiently.

CMS agreed with the feedback that the term "physician" may be overly restrictive or may not accurately reflect a beneficiary's overall care team. As such, CMS modified § 422.52(f)(1) to replace the term "physician" with language describing the three types of health care providers we believe are appropriate to furnish confirmation that an enrollee has a severe or disabling chronic condition: (1) a physician, as defined in section 1861(r)(1) of the Act; (2) a physician assistant, as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c); or (3) a nurse practitioner, as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii).

CMS received several comments pertaining to the PQAT. While commenters supported CMS' need to verify eligibility, several suggested the use of alternative data to support post-enrollment verification in lieu of the PQAT.

CMS responded that the applicant's current health care provider plays a critical role in verifying the beneficiary's chronic condition. Further, CMS believes that review by the applicant's current health care provider is an important step to maintain C-SNP program integrity and the involvement of a health care provider who has a current relationship with the applicant and is not an employee of the C-SNP (or of the MA organization that offers the C-SNP) reduces burden when compared to alternatives such as seeking an independent evaluation of the applicant from another health care provider.

Several commenters were concerned that the burden ultimately falls on the beneficiary to ensure that the provider responds to a plan's verification request in order to ensure they are able to enroll in their chosen plan.

CMS recognizes that in some instances the applicant's health care provider could potentially ask the applicant to schedule an office visit before the health care provider will verify that the applicant has a qualifying severe or disabling chronic condition for the C-SNP. However, CMS believes that this is unlikely based on our knowledge of how this policy has played out historically and by the fact that the applicant's current health care provider's office will likely have information pertaining to the relevant medical history to verify the chronic condition.

D. I-SNP Network Adequacy (section VIII.E page 744-752)

Finalized Changes

CMS is finalizing its proposal to adopt a new exception for facility-based institutional special needs plans (I-SNP) from the network evaluation requirements. Currently, § 422.116(f) allows an MA plan to request an exception to network adequacy criteria when both of the following occur: 1) certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file and 2) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria. CMS proposes to broaden the acceptable rationales for an exception from the requirements in § 422.116(b)-(e) for facility-based I-SNPs by allowing requests for an exception when only one of the two situations described above occurs. The text

will be reorganized accordingly with the original two requirements being moved to new paragraphs (f)(1)(i)(A) and (B) and the proposed rationales for an exception being added to new paragraphs (f)(1)(ii)(A) and (B).

CMS is finalizing its proposal to add new considerations for determining whether to grant an exception under § 422.116(f). First, CMS is finalizing the basis for an exception request that a facility-based I-SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I-SNPs receive care and can submit relevant evidence. The second finalized basis is if a facility-based I-SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits and can submit relevant evidence.

CMS is finalizing its proposal to add a new paragraph (f)(3) at § 422.116 to ensure that the exception for facility-based I-SNPs is used by and available only to facility-based I-SNPs. CMS is also finalizing its proposal to add, at § 422.504(a)(21), a new contract provision that MA organizations must not establish additional plans that are not facility-based I-SNPs to a contract that is within the scope of proposed § 422.116(f)(3).

CMS is finalizing all of the above proposals without modification. These changes will be effective beginning in Contract Year 2025.

Background/Rationale

The I-SNP industry has indicated through public comments and in prior correspondence to CMS that many facility-based I-SNPs have difficulty contracting with providers outside their facilities due to their model of care. This is rooted in the fact that providers know that I-SNP enrollees will not routinely seek care. Those in the business of offering facility-based ISNPs have concerns about whether CMS network standards are appropriate for the facility-based I-SNP coverage model, as it differs from other MA plan types. CMS has also received public comments regarding the challenges facility-based I-SNP plans have contracting.

CMS believes that the time and distance standards that apply to other plan types are not appropriate for I-SNP plans because enrollees in facility-based I-SNP plans do not generally travel to receive care. CMS hopes that these finalized changes appropriately balance the need to ensure access to covered benefits for enrollees in facility-based I-SNPs while recognizing the unique way this type of MA plan furnishes benefits and how enrollees generally receive services at the institution where the enrollee resides. CMS emphasizes that expanding this exception to other I-SNPs or MA plans that do not meet the requirements of this proposal would not serve the best interests of the Medicare program or beneficiaries.

Commenters overall were supportive of our efforts to broaden the bases of acceptable rationales for requesting an exception from the requirements in § 422.116 for facility-based I-SNPs.

Commenters also expressed support for CMS strengthening its general oversight of I-SNPs to ensure people are receiving the care they need. Specifically, commenters supported the proposal's expanded access to telehealth care to ease beneficiary access to care.

Commenters also believe this proposal is well-positioned to ensure individuals receive necessary supports across the continuum of their care needs without having to experience the disruption of

changing Medicare coverage types should there be a need for more extensive long-term care.

E. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38) (section VIII.F page 753-835)

1. Proposed changes to the special enrollment periods for dually eligible individuals and other LIS eligible individuals

Finalized Changes

CMS finalized its changes to § 423.38(c)(4)(i) to replace the quarterly dual SEP with a simpler new dual/LIS SEP. The dual/Low Income Subsidy (LIS) SEP would allow dually eligible and other LIS-enrolled individuals to enroll once per month into any standalone prescription drug plan.

CMS also finalized to create a new integrated care SEP at § 423.38(c)(35) for dually eligible individuals. This new integrated care SEP would allow enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans. Based on the comments received, CMS narrowed the scope so that the SEP is available only to facilitate aligned enrollment as defined at § 422.2.

In combination, these two SEPs will enable dually eligible beneficiaries to have a monthly election to:

- Leave an MAPD plan for Medicare FFS by enrolling in a PDP
- Switch between standalone PDPs
- Enroll in an integrated D-SNP such as a FIDE, HIDE, or AIP.

Background/Rationale

Many commenters generally supported the proposals to increase the percentage of dually eligible individuals who receive Medicare and Medicaid services from the same organization. They noted that together, they would reduce administrative burden, support efforts to coordinate care, create more efficient program management, make it easier to navigate integrated care, reduce misleading marketing, and strengthen alignment. Other commentors opposed the SEP and enrollment limitation proposals, noting unintended consequences including administrative burden and reduction of plan competition and beneficiary choice. CMS maintained that their proposals represent an incremental step towards increasing aligned enrollment for duals, balancing their long-erm vision with interest in limiting disruption in the short term.

Several commenters stated that partial-benefit dually eligible individuals experience similar health care needs as full-benefit dually eligible individuals and should have access to the same enrollment opportunities using the SEP, noting that partials also benefit from lower cost sharing, greater coordination of care and services, model of care requirements, and access to supplemental benefits

not available in Traditional Medicare. CMS acknowledges that the SEP proposals limit opportunities for partial benefit duals to enroll in MAPDs and CO D-SNPs. They point to their belief that current policies have resulted in the proliferation of CO D-SNPs and left duals susceptible to aggressive marketing tactics. Adopting a new SEP for partials or extending a new integrated care SEP into CO D-SNPs would not address these concerns, or further their goal of promoting aligned enrollment into integrated D-SNPs.

One commenter recommended limiting the use of the integrated care SEP only when it would result in aligned enrollment with the Medicaid MCO, highlighting a scenario where an enrollee could otherwise use the SEP to enroll in an unaligned HIDE SNP in states that do not require D-SNPs to comply with exclusively aligned enrollment. CMS agreed, and finalized a modification to their SEP proposal where the SEP is available only facilitate aligned enrollment, as that term is defined in § 422.2.

Numerous commenters stated the SEP proposals would increase movement in plans that could undermine care coordination and continuity of care. Some commenters recommended the integrated care SEP be limited to allow dually eligible individuals in Traditional Medicare or MA-PDs to enroll in integrated D-SNPs but not permit switching between integrated D-SNPs on a monthly basis. While CMS acknowledges these concerns, they maintain that the benefits of reduced agent and broker marketing, improved transparency for enrollment counselors and individuals, and increased access to integration of Medicare and Medicaid benefits and administration outweigh the downsides. Furthermore, they believe the likelihood of switching monthly between integrated care plans is low. CMS notes that they will continue to monitor dual/LIS SEP usage as it transitions to monthly once again and can revisit in future policy making if issues arise.

Some commenters expressed concern that the SEP proposals may increase burden on States and plans. CMS maintains the perspective that changing the SEPs to monthly would reduce burden on States as they work to align Medicaid MCO enrollment to D-SNP enrollment. Furthermore, only approximately 5 percent of the MA-PD plans that can currently enroll dually eligible individuals using the quarterly dual/LIS SEP would be available as options for full-benefit dually eligible individuals using the proposed new monthly integrated care SEP.

2. Enrollment limitations for non-integrated Medicare Advantage plans

Finalized Changes

CMS finalized changes with certain limited modifications at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and (2) to require the following:

- Beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization (abbreviated as "entity"), also contracts with a state as a Medicaid managed care organization (MCO) that enrolls dually eligible individuals in the same service area, the D-SNP offered by that entity must limit new enrollment to individuals enrolled in the D-SNP's affiliated Medicaid MCO. CMS now clarifies that this applies to MCOs that enroll full-benefit dually eligible individuals.
- With certain exceptions, only one D-SNP may be offered by the entity in the same service area as the aligned Medicaid MCO.
- Beginning in 2030, such D-SNPs must only enroll individuals enrolled in the affiliated Medicaid MCO. Thus, integrated D-SNPs would be required to disenroll individuals who are not enrolled in

both the D-SNP and Medicaid MCO offered under the same parent organization, except in instances of temporarily lost Medicaid coverage. CMS makes a small modification to clarify that these D-SNPs may only enroll (or continue coverage of people already enrolled) individuals also enrolled in (or in the process of enrolling in) the Medicaid MCO beginning in 2030.

CMS also proposes certain exceptions to its one D-SNP per service area policy:

- Allows MA organizations that share a parent organization and offer D-SNPs subject to these proposed new limits to crosswalk enrollees (within the same parent organization and same D-SNP type) when the MA organization chooses to non-renew or consolidate its current D-SNPs to comply with the new rules to only operate a single D-SNP.
- If a parent organization operates both HMO and PPO D-SNPs, they are allowed to continue doing so as long as they no longer accept new full-benefit dually eligible enrollees in the same service area as the D-SNP affected by the new regulations. I.e., the parent organization is "choosing" the HMO or PPO D-SNP that will align with its Medicaid MCO and enroll full-benefit duals. The other D-SNP may no longer enroll duals. CMS also finalizes a technical modification to further clarify this point.
- Allows an MA entity to offer more than one D-SNP for full-benefit dually eligible individuals in the same service area as the affiliated Medicaid MCO only when the SMAC requires it. For example, if the SMAC limits enrollment for certain groups into certain D-SNPs (e.g., by age). CMS clarifies that this also includes efforts to align enrollment in each D-SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s).

Background/Rationale

Many commenters offered support for the D-SNP enrollment limitation proposals. CMS appreciated these comments, agreeing that these proposals will increase the percentage of D-SNP enrollees who are in aligned arrangements, reduce the number of D-SNP options overall and mitigate choice overload, remove some incentives for agents and brokers to target dually eligible individuals, simplify provider billing and lower the risk of inappropriate billing, and promote integrated care and the benefits it affords.

A number of commenters suggested that the enrollment limitations could create barriers for dually eligible individuals in States where they are not required to be in or are explicitly carved out from Medicaid managed care. CMS appreciates the concern but continues to believe that these policies are an appropriate and practicable means to achieve its goals of further integrated care coverage. Creating exceptions or providing additional flexibility will reduce the effectiveness of the changes proposed. CMS also clarifies that Medicaid MCOs that solely enroll other Medicaid populations will not be impacted by this rule. As a consequence, they revised § 422.514(h)(1) to clarify that this provision applies only when a Medicaid MCO enrolls full-benefit dual eligible individuals as defined in § 423.772.

A few commenters suggested that CMS provide more information on how their proposals would impact States that have Medicaid managed care programs that only cover a subset of Medicaid services, such as long-term services and supports, including unique partially capitated situations like in New York. CMS thanked commentators for raising this issue, and believes that the exceptions to aligned enrollment it proposed would allow the MA organization to offer one D-SNP for full benefit duals affiliated with the Medicaid MCO and a second D-SNP for full benefit duals affiliated with the partially capitated PIHP if the state requires this arrangement in its SMAC. CMS chose to revise § 422.514(h)(3)(i) to clarify that they

will allow an MA organization to offer more than one D-SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to differentiate enrollment into D-SNPs either (i) by age group or (ii) to align enrollment in each DSNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s).

Several commenters highlighted the potential impact of proposals to limit the number of and align enrollment in D-SNPs in certain service areas on State Medicaid policy. few commenters acknowledged that States may not be aware of or planning ahead for how current State procurements may impact or be impacted by proposed new requirements for aligned enrollment applicable beginning 2027 and 2030, particularly when Medicaid procurement timelines do not align with MA service area expansion and bid filing timelines. The commenter further expressed concern that the proposed changes could result in unanticipated disruptions where States are making progress toward integration, including those States moving from the Financial Alignment Initiative to D-SNP models. CMS maintained that the benefits in reducing choice overload and market complexity along with providing an integrated experience outweigh the incremental constraints on state flexibility.

F. Comment Solicitation: Medicare Plan Finder and Information on Certain Integrated D-SNPs (section VIII.G page 836-841)

Finalized Changes
In the proposed rule, CMS noted that they are considering adding a limited number of specific Medicaid-covered benefits to MPF when those services are available to enrollees through the D-SNP or the affiliated Medicaid MCO. CMS solicited comments on the practicality of accomplishing this. In the final rule, CMS indicated that they are continuing to work on improving MPF functionality. Starting in contract year 2025, CMS plans to collect the Medicaid benefit data from the states using HPMS and work with the states to verify its accuracy.

Background/Rationale
Commenters expressed support for improving MPF functionality for dually eligible users, but also shared concerns regarding displaying accurate benefit data and the ability to update it off-cycle. Some commenters believed that it is necessary to distinguish between Medicare supplemental and Medicaid benefits while others did not. Commenters also provided recommendations for further improving MPF. CMS plans to take these comments into consideration as they discuss future updates.

Comments
CMS will continue to take all concerns, comments, and suggestions into account as they work to develop policies on these topics and may reach out to commenters for further discussion.

G. Comment Solicitation: State Enrollment Vendors and Enrollment in Integrated D-SNPs (section VIII.H page 842-848)

Finalized Changes

In the proposed rule, CMS noted that they are assessing ways to promote enrollment in integrated D-SNPs and outlined the multiple purposes state enrollment vendors serve within the FAI. CMS solicited comments and concerns regarding the feasibility of requiring integrated D-SNPs to contract with state enrollment brokers. CMS also solicited comments from interested parties, including states, D-SNPs, and Medicaid managed care plans, about their specific operational challenges related to potential changes to Medicaid cut-off dates to align them with the Medicare start date.

In the final rule, CMS clarified that they did not propose any new policy to impose a Federal requirement for D-SNPs to contract directly with state enrollment vendors rather they were seeking feedback on the idea. CMS thanked commenters for their input on these topics as it will help inform future rulemaking.

Background/Rationale
Several commenters expressed concerns with requiring integrated D-SNPs to contract with state enrollment vendors highlighting that requiring D-SNPs to contract directly with state enrollment vendors would add administrative burden for plans, vendors, and enrollees. Others expressed support for the idea. Several commenters believed that states have Medicaid managed care enrollment cut-off dates because of operational barriers while one commenter believed that cut-off dates allow for efficient planning and resource allocation, ensuring states can effectively manage and process a high volume of enrollments within a designated period. Some commenters expressed support for the idea of aligning Medicare and Medicaid enrollment effective dates.

H. Comment Clarification of Restrictions on New Enrollment into D-SNPs via State Medicaid Agency Contracts (SMACs) (§§ 422.52 and 422.60) (section VIII.I page 849-851)

Finalized Changes
CMS finalized without modification the proposed amendment at § 422.52(b)(2) to be explicit that, to be eligible to elect a D-SNP, an individual must also meet any additional eligibility requirements established in the SMAC. CMS also finalized without modification the proposed amendment to § 422.60(a)(1) and addition at § 422.60(a)(3) to be more explicit that MA organizations may restrict enrollment in alignment with § 422.52(b)(2).

Background/Rationale
Several commenters expressed support for the proposed revisions at §§ 422.52(b)(2) and 422.60(a)(1). One commenter requested that CMS be cognizant of state Medicaid procurement practices, timeframes, and underlying state regulations and noted that compliance with new Federal requirements may take time given reprocurement timeframes, contract amendment processes, and state regulatory policies that may need to be updated.

I. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 422.514) (section VIII.J page 852-903)

Finalized Changes

CMS finalized their proposal to lower the D-SNP look-alike threshold at § 422.514(d) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years, as proposed. CMS believes that this amendment will support their goal to encourage the enrollment of dually eligible individuals into integrated plans. In the final rule, CMS emphasized that nothing about the proposals would discourage states from contracting with D-SNPs that enroll partial-benefit dually eligible individuals. CMS also finalized the amendments to § 422.514(e) as proposed. CMS will continue to allow D-SNP look-alikes to transition enrollees into an MA plan or plans meeting certain criteria within the same parent organization through plan year 2026. CMS believes this will help provide continuity of care for individuals who are required to transition from D-SNP look-alikes under the initial years of implementing the lower thresholds. CMS also clarified that MA organizations cannot use the § 422.514(e) transition pathway concurrently with a crosswalk or crosswalk exception pathway at § 422.530.

CMS shared a list of the D-SNP look-alikes identified for plan years 2022 and 2023 and will post lists for subsequent years under "Information about D-SNP Look-Alikes" on the CMS website.

Background/Rationale

CMS received numerous comments supporting the proposal to lower the threshold used to identify D-SNP look-alikes and limit the D-SNP look-alike transition pathway to D-SNPs starting in plan year 2027. Many commenters emphasized the importance of dually eligible individuals having access to integrated care and that the D-SNP look-alikes interfere with those efforts. Some also recommended that CMS lower the D-SNP look-alike threshold further below the proposed threshold. CMS will continue to monitor non-SNP MA plans below the 60-percent threshold for potential gaming after implementation of the final rule and consider future rulemaking, as needed. Conversely, other commenters expressed general opposition to the CMS proposal to lower the D-SNP look-alike threshold, some noting that that certain states do not contract with D-SNPs that enroll partial-benefit dually eligible individuals, which could reduce plan choices and benefits available to these beneficiaries.

One commenter requested that CMS consider changing the D-SNP look-alike definition in future rulemaking, noting that the current definition is overly broad and captures MA plans that are not intentionally enrolling large percentages of dually eligible individuals. CMS responded saying that adding an additional criterion to the D-SNP look-alike definition of having a Part D basic premium set under the low-income premium subsidy amount as their only premium would not be helpful or necessary in identifying D-SNP lookalikes.

Many commenters discussed their concerns about transitions of D-SNP lookalike enrollees into other plans, noting that these transitions could cause potential disruptions in continuity of care among enrollees. CMS agreed that it is important to monitor for any gaps in coverage that may occur as enrollees are transitioned or crosswalked out of D-SNP look-alikes.

One commenter expressed concerns that an MA plan's Star Rating may be negatively impacted if an enrollee stays with the same parent organization but elects to enroll in a D-SNP, which better serves the enrollees' needs than a non-SNP MA plan. CMS does not currently have evidence to suggest allowing dually eligible individuals the opportunity to enroll into integrated D-SNPs in any month would negatively impact Star Ratings. Furthermore, CMS believes that the totality of the SEP proposals may actually benefit integrated D-SNPs, such as FIDE SNPs, on Star Ratings, including the Members Choosing to Leave the Plan measure.

J. For D-SNP PPOs, Limit Out-of-Network Cost Sharing (§ 422.100(o)) (section VIII.K page 903-913)

Finalized Changes

CMS finalized, as proposed, the amendment at § 422.100(o)(1) that, starting in 2026, for an MA organization offering a local PPO plan or regional PPO plan, cost sharing for out-of-network services under D-SNP PPOs will be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans, as described in § 422.100(f)(6). CMS also finalized, with minor technical edits, the proposed amendment at § 422.100(o)(2) to limit out-of-network cost sharing to the cost sharing limits for such services established at § 422.100(j)(1) when such services are delivered in network by cross-referencing § 422.100(j)(1).

Background/Rationale

Numerous commenters supported the proposal to impose limits on out-of-network cost sharing for Parts A and B benefits in the benefit packages offered by D-SNP PPOs. CMS received no comments on their burden estimates therefore believes that this rule does not create substantial information collection requirements. A few commenters asked CMS to require the new cost sharing limits for plan year 2025 rather than for the 2026 plan year, however CMS declined to accelerate the timetable for implementation.

Several commenters supported stricter limits, capping all D-SNP PPO out-of-network cost sharing to levels consistent with Traditional Medicare. However, some warned that imposing such limits could result in an increase in cost sharing levels for in-network services.

A few commenters expressed concern that the proposal would eliminate D-SNP PPOs which provide access to covered benefits outside of the plan's network while a few other commenters urged CMS to use its authority not to allow any D-SNP PPOs. CMS does not believe the requirements for increased cost sharing will force D-SNP PPOs to exit the markets.

VIII. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy

A. PACE Past Performance (§§ 460.18 and 460.19) (section IX.A page 913-936)

Finalized Changes

CMS finalized their proposal to amend the PACE regulation at § 460.18 (CMS evaluation of applications) to include an assessment of past performance as part of the evaluation process of applications submitted by PACE organizations looking to offer a PACE program or expand an approved program. The evaluation applies to expanding existing programs by adding a geographic service area and/or PACE

center site or sites. CMS finalized that this evaluation criterion, incorporated in section § 460.18(c), will allow CMS to deny applications from PACE organizations for reasons such as the organization's past performance. CMS also finalized that it has the authority to reject a PACE application if the organization's agreement was terminated by CMS or not renewed within the 38 months preceding the submission date of the application to CMS.

CMS also finalized that after receiving a complete PACE application, CMS has to: 1) approve the application; 2) deny the application; or 3) issue a request for additional information (RAI) in the event there are deficiencies. CMS must complete these actions within 90 days of submission of the initial application or a service area expansion (SAE) application that incorporates a proposed geographic expansion and a new center site. CMS must complete these actions within 45 days of submission of an SAE application that includes either a proposed geographic expansion or a new center site.

CMS finalized, as proposed, that the evaluation of an applicant organization's past performance, starting with the March 2025 quarterly application submission cycle, would include: 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; whether the organization failed to maintain fiscal soundness; whether the organization has filed for or is under State bankruptcy proceedings; and whether the organization has exceeded CMS's proposed 13-point threshold for compliance actions with respect to the PACE program agreement. CMS finalized their proposal, without modifications, to create a basis for denying a PACE application that an organization was under sanction within the twelve-month look-back period.

Background/Rationale
CMS received positive feedback from commenters regarding the evaluation of the past performance of PACE organizations in CMS's application review process and the 24- month grace period. CMS affirmed that they believe that an organization's past performance is an indicator of future performance and how a positive net worth is an important factor determining the future success of a PACE organization.

B. PACE Determining that a Substantially Incomplete Application is a Nonapplication (section IX.B page 937-942)

Finalized Changes
CMS finalized the proposal to strengthen the PACE regulations at §§ 460.12(a) and (b) and 460.20(b). These regulations relate to application requirements and attempt to define what constitutes a complete and valid application. CMS finalized the provisions in the proposed rule to continue the current practice of following the timeframes for PACE applications. This includes that CMS will continue to accept Part D applications from initial PACE applicants quarterly. CMS also finalized that they will treat an initial PACE application that does not incorporate responsive materials for one or more sections of its Part D application as substantially incomplete, and this aligns with current practice. For a Part D application associated with an initial PACE application that is deemed substantially incomplete, the PACE application would be considered incomplete, and CMS would not be required to review or reconsider the application. CMS finalized the proposed requirements at §§ 460.12 and 460.20 that a substantially incomplete PACE application without a State assurance document is a nonapplication.

CMS determined that these finalized measures would strengthen the PACE application requirement regulations and more specifically define what constitutes a complete and valid application.

Background/Rationale

CMS noted that a few commenters expressed disapproval of the State assurance form being a requirement for a PACE application submission. CMS responded that the State assurance document is a necessary part of the application and is important information.

C. Personnel Medical Clearance (§§ 460.64 and 460.71) (section IX.C page 943-954)

Finalized Changes

CMS finalized the proposed amendment to §§ 460.64 and 460.71 to require all PACE organizations to create and implement a medical clearance process. This process would have minimum conditions to meet the requirement of medical clearance and improve protections of the vulnerable populations served by PACE. CMS approved the proposal to separate the requirement to be medically cleared for communicable diseases from the requirement to be fully immunized. CMS finalized minimum requirements that should be included in the provisions of a PACE organization's risk assessment. CMS also finalized the requirement for a physical examination of direct care personnel with the risk assessment to be an alternative provided the risk assessment meets the minimum requirements set forth in the proposed rule.

CMS did not finalize provisions in the proposed rule at § 460.74(d) referencing the COVID-19 vaccination rule as part of our new paragraph § 460.64(a)(6). CMS also did not finalize a specific list of vaccination requirements and instead will keep language in provision § 460.64(a)(6) that "all immunizations must be up to date." CMS also did not finalize the proposed requirement that the physical examination or risk assessment be conducted annually. CMS finalized that the current requirement of PACE workers to be medically cleared will have to occur prior to them having direct interactions with participations.

CMS finalized the requirement for a physical examination of direct care personnel with the risk assessment.

Background/Rationale
CMS noted that several commenters expressed apprehension regarding the extensive nature of the mandated immunizations list and how it could affect PACE organizations' ability to hire and retain staff. CMS responded that they did not finalize specific lists of vaccination requirements. Other commenters expressed views that additional medical screening requirements proposed by CMS could be burdensome. CMS agreed and did not finalize requirements for an annual medical clearance.

D. Timeframes for Coordinating Necessary Care (§ 460.98(b)(4) and (c)) (section IX.D page 955-968)

Finalized Changes

CMS finalized, without modifications, the proposal at § 460.98(c) to create maximum timeframes for arranging and providing IDT-approved services for PACE participants through amending the service delivery requirements. CMS finalized that this would strengthen participant protections and accountability for PACE organizations.

CMS finalized to require PACE organizations to promptly arrange and schedule the dispensing of medications, ensuring fulfillment within 24 hours of the primary care provider's prescription.

CMS further finalized mandating that PACE organizations arrange or schedule the delivery of IDT-approved services, excluding medications, as identified in paragraph § 460.98(c)(2)(i). These services are to be provided quickly and must be initiated no later than 7 calendar days after initial approval by the IDT or member of the IDT. CMS also finalized the exclusion of routine or preventive services from the requirements in § 460.98(c)(2) when requirements in § 460.98(c)(3)(i) through (iii) are met without modification.

Background/Rationale
CMS received comments that largely expressed support for CMS establishing maximum timeframes for arranging and scheduling the dispensing of medications; however, a majority of commenters objected to CMS's proposal of a single timeframe for all medications, and they suggested creating separate time frames for emergency medications and non-emergency medications. The commenters suggested longer timeframes for non-emergency medications compared to emergency medications. CMS noted it was not persuaded by comments to lengthen the proposed time frame or create two distinct timeframes for emergency and non-emergency medications, and PACE organizations must always meet patient needs. CMS clarified that the timeframe requirements only relate to scheduling and arranging the dispensing of medications, not the provision of medications.

E. Care Coordination (§ 460.102) (section IX.E page 969-990)

Finalized Changes
CMS finalized, without modifications, the proposal to require IDT to be responsible for coordination and implementation of 24-hour care delivery that meets participant needs across all care settings. CMS also finalized the proposal related to specifying IDT coordination responsibilities across all care settings and the requirement for the interdisciplinary team to assess and act on recommendations from emergency or urgent care providers, employees, and contractors.

CMS finalized, with modifications, that the appropriate member(s) of the interdisciplinary team must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as quickly as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.

CMS finalized, with modifications, that 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 quickly as the participant's health condition requires, but no longer than 7 calendar days from the date the recommendation was made.

CMS also finalized, without modification, that if recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c).

Background/Rationale
CMS received many comments that expressed a preference for a longer timeframe than the proposed 24 hours from the time of the participant's discharge and recommended 72 hours. CMS compromised and finalized a timeframe of 48 hours.

CMS noted that many commenters recommended that CMS lengthen the maximum timeframe for the IDT to review and make determinations on all recommendations from other employees and contractors from 5 calendar days to 10. CMS compromised and finalized a timeframe of 47 calendar days. CMS stated that the 7-calendar day maximum time frame creates more flexibility for the IDT to coordinate with external providers and prioritizes participant wellbeing.

F. Plan of Care (§ 460.106) (section IX.F page 992-1016)

Finalized Changes
After considering the comments, CMS is finalizing the proposed changes to § 460.106 in part, with a modification to the language at § 460.106(b)(2) to clarify that the required timeline for the care plan reevaluation is 180 days from the date when the previous care plan was finalized. CMS has finalized changes regarding the reevaluation of care plans and participant involvement in the care planning process within PACE organizations. Despite concerns from some commenters about the burden of tracking care plans precisely and the timeline for unscheduled assessments, CMS has maintained the requirement for reevaluation at least every 180 days from the date of the previous care plan finalization. Additionally, CMS emphasized the importance of participant and/or caregiver participation in the care planning process, requiring documentation of attempts to engage them.

Background/Rationale
Many commenters appreciated CMS's clarification of the semi-annual requirement, but some expressed concerns about the change to a 180-day timeline, arguing that tracking the care plan precisely could be burdensome. CMS believes a clear standard reduces ambiguity and rejects the argument of burden, stating that PACE organizations are already tracking care plans semi-annually. The 180-day timeline restarts with each new care plan, ensuring consistency. Commenters also requested an extension of the 14-day timeframe for unscheduled assessments to 30 days, citing complexities and coordination needs, but CMS disagreed, emphasizing the importance of prompt attention to significant incidents and aligning PACE requirements with long-term care facilities to ensure equitable care standards. Concerns were raised about the level of detail in the proposed content requirements for plans of care, potential interference with participant wishes, and administrative burden. CMS clarified that the intent was not to override participant wishes but to ensure comprehensive care planning, emphasizing the importance of accurate documentation to reflect participant needs.

Additionally, commenters supported the exclusion of acute diseases from care plan requirements, and CMS agreed, stating that acute issues may not always be relevant. Vision was included in the required

content, but data collection on optometry appointments was deemed outside the rule's scope. Finally, commenters requested flexibility in documenting attempts to engage participants/caregivers or a grace period for their involvement, but CMS emphasized the importance of active participant involvement in care planning, rejecting the grace period suggestion to ensure participant goals are met.

G. Specific Rights to Which a Participant is Entitled (§ 460.112) (section IX.G page 1017-1030)

Finalized Changes
After reviewing the comments and in alignment with the rationale outlined in the proposed rule and previous responses, the finalized changes to § 460.112 are being implemented as originally proposed. Additionally, CMS finalized a requirement for PACE organizations to provide participants with clear, written definitions of these terms to enhance transparency. CMS also clarified that PACE organizations are required to staff and/or contract with palliative medicine specialists, ensuring expertise in pain and symptom management for participants requiring end-of-life care.

Background/Rationale
A majority of commenters urged the Centers for Medicare & Medicaid Services (CMS) to establish clear definitions for palliative care and end-of-life care, citing concerns about varying interpretations among PACE organizations. While CMS acknowledged the existing definition of palliative care in hospice regulations, it opted not to define these terms in the PACE regulations at this time, emphasizing the importance of transparency and participant understanding.

Regarding the implementation of palliative care, some commenters expressed concerns about the proposed requirement for written consent, fearing administrative burdens and potential misunderstandings about the continuation of curative treatments. CMS addressed these concerns by emphasizing the need for informed consent, particularly when palliative care entails discontinuation of curative treatment. The finalized rule maintains the requirement for written consent, aiming to protect participants from unintended treatment changes.

Additionally, comments highlighted the importance of informing participants about their rights regarding hospice care and ensuring adequate expertise within PACE organizations to provide end-of-life care. While CMS affirmed participants' rights to receive hospice care and be informed about their options, it did not mandate additional requirements regarding contractual relationships with hospices. Furthermore, CMS clarified that PACE organizations are required to staff and/or contract with palliative medicine specialists, ensuring expertise in pain and symptom management for participants requiring end-of-life care.

H. Grievance Process (§ 460.120) (section IX.H page 1031-1056)

Finalized Changes
The finalized changes to the regulation at § 460.120 include several key revisions. Firstly, complaints are now considered grievances regardless of whether remedial action is requested, as clarified in § 460.120(b). Additionally, caregivers are included in the grievance process under § 460.120(d). The timeframe for notifying individuals of grievance resolutions has been clarified in § 460.120(g)(2). The

proposed expedited grievance process has been discarded, with provisions redesignated to § 460.120(h). PACE organizations are now required to provide notification of grievance resolution either orally or in writing based on individual preference, as finalized in § 460.120(h)(1). Furthermore, § 460.120(h)(2)(ii) has been modified to require a summary of findings for each distinct issue requiring investigation. Corrective actions taken or to be taken by the PACE organization must now be included in grievance resolution notifications, as outlined in § 460.120(h)(2)(iii). Quality Improvement Organization (QIO) rights are now incorporated into grievance resolution letters for Medicare participants with quality of care grievances about Medicare covered services, finalized in § 460.120(h)(3). Finally, provisions from § 460.120(j) through § 460.120(m) have been redesignated to § 460.120(k) through § 460.120(l) without further modification.

Background/Rationale
The finalized rule for clarifying the grievance process at § 460.120 received support from most commenters. Some concerns were raised regarding the administrative burden and resource diversion from participant care due to formalizing the grievance process in regulation. However, CMS emphasized the importance of clarifying the process to meet the needs of PACE organizations and participants. Flexibilities were included in the proposed regulation to address certain conditions, such as providing oral or written resolution based on the participant's preference.

Regarding the definition of grievance at § 460.120(b), most commenters supported it but expressed concerns about aligning it too closely with Medicare Advantage (MA) regulations. CMS acknowledged the uniqueness of PACE and explained its rationale for basing the definition partially on MA regulations. The finalized rule includes complaints as grievances regardless of whether remedial action is requested, addressing concerns about administrative burden.

There were disagreements regarding the inclusion of caregivers in the grievance process at § 460.120(d). Some commenters raised concerns about defining "caregiver" and potential risks to participant care. However, CMS emphasized the involvement of caregivers in care planning and advocacy, leading to the final decision to include caregivers in the grievance process.

Questions about the timeframe for notifying individuals of grievance resolutions, processing expedited grievances, and the format of grievance resolution notifications were also addressed in the finalized rule. CMS clarified its expectations and reasons for the proposed requirements, ultimately finalizing them with slight modifications.

Additionally, the rule addressed the inclusion of Quality Improvement Organization (QIO) rights in grievance resolution letters at § 460.120(h)(3), clarifying that it applies to Medicare participants only. CMS emphasized the importance of participants understanding their rights and the role of PACE organizations in the QIO quality of care grievance process.

I. PACE Participant Notification Requirement for PACE Organizations with Performance Issues or Compliance Deficiencies (§ 460.198) (section IX.I page 1056-1059)

Finalized Changes

CMS has finalized changes requiring PACE organizations to disclose information regarding their performance and contract compliance to current and potential participants. These changes, prompted by comments from stakeholders, aim to enhance transparency within PACE programs. CMS clarified the scope and process of disclosure, specifying that it would be triggered primarily in cases of intermediate sanctions. PACE organizations will follow a similar disclosure process as Medicare Advantage and Part D programs, utilizing a provided letter template for communication. While comments sought clarification on the types of deficiencies triggering disclosure, CMS affirmed its commitment to transparency while finalizing the rule without modification. This finalized rule, adding § 460.198, underscores CMS's commitment to empowering PACE participants with essential information regarding program performance and compliance.

Background/Rationale
The finalized changes from CMS regarding the disclosure of information by PACE (organizations are rooted in the feedback received during the rulemaking process. Many commenters expressed support for the proposal, which aims to compel PACE organizations to disclose details about their performance and contract compliance to both current and potential participants.

Responding to requests for clarification, CMS outlined the scope, mechanism, format, and timing of the disclosure requirements. They specified that the requirement would be limited to instances where an intermediate sanction is imposed on a PACE organization. The process for disclosure would mirror that of MA and Part D programs, with CMS providing a letter template for PACE organizations to complete with requisite information, including the reasons for the intermediate sanction and participants' rights to a special election period if affected. PACE organizations will then be tasked with mailing the notice to participants and posting it on their website.

Commenters sought clarity on the types of deficiencies triggering disclosure requirements. CMS clarified that while disclosures would primarily apply to instances of intermediate sanctions, serious compliance or performance deficiencies necessitating immediate correction may also warrant disclosure. One comment regarding public reporting of PACE organization performance akin to Nursing Home Compare and updates to the PACE manual fell outside the proposal's scope and was not addressed.

J. PACE Participant Health Outcomes Data (§ 460.202) (section IX.J page 1060-1061)

Finalized Changes
The finalized changes entail modifying the PACE program agreement by removing the requirement for specificity regarding data collection, as mandated by § 460.32(a)(11). This amendment, proposed under § 460.202, is perceived not to increase the burden on PACE organizations, as they already furnish information to CMS and the SAA as per existing requirements. A few supportive comments were received regarding this proposal, and CMS is proceeding with the finalization of the amendment without modification.

Background/Rationale

CMS has periodically adjusted participant health outcomes data to ensure relevance and utility. However, the specified data collection requirements in the PACE program agreement often become outdated, as they are not routinely updated alongside changes in reporting requirements. In response, CMS proposed amending § 460.202(b) to remove the requirement for specificity regarding data collection in the program agreement, as the relevant data are routinely updated through the Paperwork Reduction Act process. This change aims to eliminate confusion and reduce administrative burden on PACE organizations. Support from commenters bolstered the proposal's rationale, leading to its finalization without modification.

K. Corrective Action (§ 460.194) (section IX.K page 1062-1066)

Finalized Changes

The finalized changes from CMS involve an amendment to § 460.194(b) of the Act, granting CMS and State administering agencies (SAAs) discretionary authority to monitor the effectiveness of corrective actions within PACE organizations. They emphasized consistent application of discretion to safeguard participant well-being and program integrity, without significantly reducing organizational responsibilities. Ultimately, CMS finalized the amendments to § 460.194(b) without modification, ensuring a balanced approach to oversight within the PACE framework.

Background/Rationale

Sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act mandate PACE organizations to collect and report data for program monitoring, prompting CMS to propose changes aimed at providing flexibility in oversight without increasing burden on PACE organizations or impacting the Medicare Trust Fund. Commenters generally supported the proposed change to § 460.194(b), acknowledging the need for discretion but seeking clarification on implementation and potential burden increases. CMS responded by emphasizing that the change would not compromise oversight quality but would align monitoring efforts with program needs and resource availability. While clarifying that specific criteria for monitoring discretion wouldn't be established, CMS assured that discretion would be consistently applied and focused on safeguarding participant well-being and program integrity. Despite requests for liberal use of discretion to reduce burden, CMS maintained that the change wouldn't significantly alleviate organizational responsibilities.

L. Service Determination Requests Pending Initial Plan of Care (§ 460.121) (section IX.L page 1067-1073)

Finalized Changes

The finalized changes from CMS pertain to modifications in the handling of service requests received before the finalization of the initial plan of care within PACE organizations. Despite some requests for clarification and adjustments to the regulation language, CMS proceeded with their proposal as initially outlined. They emphasized the significance of documenting pre-plan service requests to ensure participant concerns are adequately addressed during the care planning process. CMS rejected suggestions to require informing participants of the formal grievance process for declined requests, reiterating that such requests would be processed as service determination requests in accordance with existing regulations. Additionally, they declined to mandate data collection on declined requests, citing scope limitations. In summary, CMS finalized the regulation as originally proposed.

Background/Rationale

Most commenters supported CMS's proposal, emphasizing the importance of addressing participant requests during the initial care planning process. While some commenters sought clarification and adjustments to the regulation language, CMS maintained that documenting pre-plan service requests ensures participant concerns are adequately considered. They refuted concerns about additional burden, asserting that early documentation enhances participant engagement and understanding. CMS rejected requests to require informing participants of the formal grievance process for declined requests, affirming that such requests would be processed as service determination requests, aligning with existing regulations. They also declined to mandate data collection on declined requests, citing scope limitations.