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

[CMS-4201-F3 and CMS-4205-F]

Final Rule Summary

On April 4, 2024, the Centers for Medicare & Medicaid Services (CMS) placed on public display, along with a Fact Sheet, a final rule that would revise regulations affecting Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plans, and Programs of All-Inclusive Care for the Elderly (PACE). These changes address Star Ratings, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans (D-SNPs), utilization management, network adequacy, and other programmatic areas.

This final rule contains 47 sections that did not appear in the proposed version that was published in the Federal Register for Contract Year 2025 on November 15, 2023 (88 FR 78476). Rather, these provisions were proposed in the December 2022 proposed rule (87 FR 79452) but not finalized in the cycle for Contract Year 2024. These provisions are italicized in the table of contents below.

This final rule is scheduled for publication in the Federal Register on April 23, 2024. These regulations will be effective June 3, 2024.

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I. Executive Summary

A. Applicability Dates

This final rule codifies existing Part C and Part D sub-regulatory guidance and adds policies generally applicable to coverage beginning January 1, 2025 (contract year 2025). Differing from that general rule are the following applicability dates:

- Sixty days after publication of the final rule, revisions to—
    - The Risk Adjustment Data Validation (RADV) audit appeals process,
    - The appeals process for quality bonus payment determinations at §422.260,
    - Weighting of new Part C and D Star Ratings measures at §§422.166(e)(2) and 423.186(e)(2),
    - Part C and D Star Ratings non-substantive measure updates at §§422.164(d) and 423.184(d), and
    - The use and release of risk adjustment data provisions at §§422.310(f)(1)(vi), 422.310(f)(1)(vii), and 422.310(f)(3)(v).[1]
- Beginning October 1, 2024 for all contract year 2025 marketing and communications, updates to marketing and communication provisions regarding the disclaimer for Special Supplemental Benefits for the Chronically Ill (SSBCI) and agent/broker compensation (§§422.2267(e)(34), 422.2274, and 423.2274).
- Beginning September 30, 2025 for all contract year 2026 marketing and communications, provisions regarding the notice of availability of language assistance services and auxiliary aids and services (§§422.2267(e)(31)(ii) and 423.2267(e)(33)(ii)).[2]
- Beginning January 1, 2026, provisions requiring the mid-year notice of unused supplemental benefits, and codifying when prescription drug plan (PDP) sponsors can transfer their enrollees into a different PDP's plan benefit packages (PBPs) from year to year when those enrollees have made no other election, known as a "plan crosswalk" (§§422.111(l) and 423.530, respectively).

B. Summary of the Major Provisions

CMS received 3,463 timely pieces of correspondence commenting on the November 2023 proposed rule. This rule also implements certain sections of the Bipartisan Budget Act (BBA) of 2018 and the Consolidated Appropriations Act (CAA), 2023, and it finalizes numerous policies contained in the December 2022 proposed rule. Major provisions include the following:

Part D Medication Therapy Management (MTM) Program: Eligibility Criteria. Federal Medicare law (section 1860D-4(c)(2) of the Act) requires all Part D sponsors to have an MTM program designed to assure that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. Federal law further requires Part D sponsors to target those enrollees who have multiple chronic

[1] Unless noted otherwise, all statutory references are to the Social Security Act (or "the Act") and all regulatory section references are to Title 42 of the Code of Federal Regulations (CFR).

[2] Except that, at plan option for contract year 2025 marketing and communications, beginning September 30, 2024, the plan may use the model notice described in §422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to satisfy the requirements regarding the multi-language insert (MLI) in §§422.2267(e)(31)(i) and 423.2267(e)(33)(i).

diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. In this final rule, CMS establishes improved targeting criteria for the Part D MTM program that will help ensure more consistent, equitable, and expanded access to MTM services, including the following:

- Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases.
- The nine core chronic diseases currently identified in guidance, plus HIV/AIDS, are codified for a total of 10 core chronic diseases, with continued flexibility for sponsors to target additional chronic diseases.
- Sponsors must include all Part D maintenance drugs in their targeting criteria and may not limit the Part D maintenance drugs included in MTM targeting criteria to specific Part D maintenance drugs or drug classes.
- For the purpose of identifying Part D maintenance drugs, plans must rely on information in a widely accepted, commercially or publicly available drug information database.

Table A1 in the preamble (duplicated in section XI of the summary below) shows an estimated annual administrative cost of these provisions totaling $192.7 million.[3]

Improving Access to Behavioral Health Care Providers. CMS finalizes adding a new facility-specialty type, Outpatient Behavioral Health, to network adequacy reviews. The new facility-specialty type includes Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers, Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities, and other providers.[4] CMS' aim is to strengthen network adequacy requirements and improve beneficiary access to behavioral health services and providers by expanding network adequacy requirements for MA organizations (MAOs).

Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs). TPMOs are selling and reselling beneficiary contact information to skirt existing CMS rules that prohibit cold calling so they can aggressively market MA and Part D Plans. Beneficiaries are unaware that by placing a call or clicking on a generic-looking web-link they are unwittingly agreeing and providing consent for their personal contact information to be collected and sold to other entities for future marketing activities. As a result, CMS is finalizing requirements to prohibit personal beneficiary data collected by TPMOs for marketing or enrolling a beneficiary into an MA or Part D plan to be shared with other TPMOs, unless prior express written consent is given by the beneficiary. CMS is also finalizing a one-to-one consent structure where TPMOs must obtain prior express written consent through a clear and conspicuous disclosure for *each* TPMO that will be receiving the beneficiary's data. This will protect beneficiaries against unwanted calls, texts, email solicitations, and other contacts, while still ensuring that beneficiaries have control over their personal data and can connect with the TPMOs they would like to speak with.

[3] The financial impacts summarized in this section come from Table A1, when such an impact is expected and these estimates are provided. Additional details appear in sections X and XI.

[4] Due to the new statutory benefit category established by CAA, 2023, MFTs and MHCs were eligible to enroll in Medicare and start billing for services beginning January 1, 2024. "Other providers" may include nurse practitioners (NPs), physician assistants (PAs) and Clinical Nurse Specialists (CNSs) who furnish addiction medicine and behavioral health counseling or therapy services and meet other specific criteria.

Establish Guardrails for Agent and Broker Compensation. Federal law requires CMS to develop guidelines that ensure compensation to agents and brokers creates incentives to enroll individuals in MA plans that are intended to best meet their health care needs. Thus, for many years, CMS has set upper limits on the amount of compensation agents and brokers can receive for enrolling Medicare beneficiaries into MA and Part D prescription drug plans (PDPs). CMS says it has learned that many MA and PDP plans, as well as third-party entities with which they contract (such as Field Marketing Organizations (FMOs)), have structured payments to circumvent compensation caps, and that such payments appear to be increasing. The agency finalizes requirements that:

- Generally prohibit contract terms between MAOs and agents, brokers or other TPMOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan that best fits a beneficiary's health care needs;
- Set a single increased compensation rate for all plans to be updated annually;
- Revise the scope of items and services included within agent/broker compensation;
- Eliminate the regulatory framework that currently allows for separate payment to agents and brokers for administrative services; and
- Makes conforming edits to the Part D agent/broker compensation rules at §423.2274.

Special Supplemental Benefits for the Chronically Ill (SSBCI). To ensure that SSBCI services are appropriate, CMS finalizes that an MAO must do the following:

- Establish a bibliography of relevant acceptable evidence that an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee;
- Follow its written policies based on objective criteria for determining an enrollee's eligibility for SSBCI when making such eligibility determinations; and
- Document both denials and approvals of SSBCI eligibility.

CMS codifies its authority to do the following:

- Review and deny approval of an MAO's bid if the organization has not demonstrated, through relevant acceptable evidence, that its proposed SSBCI offerings have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee; and
- Review SSBCI offerings annually for compliance, considering the evidence available at the time.

CMS also finalizes new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility criteria, strengthening the SSBCI disclaimer that MAOs must use. For example, MAOs must list the relevant chronic condition(s) the enrollee must have to be eligible for the MAO's SSBCI, and that having that condition does not necessarily guarantee SSBCI for the enrollee because other coverage criteria may also apply.

Mid-Year Enrollee Notification of Available Supplemental Benefits. More MA plans are offering supplemental benefits, which are broader in scope and variety. However, plans have reported that enrollee utilization of these benefits is low, and it is not clear why. CMS finalizes

requiring MA plans to notify enrollees mid-year of the unused supplemental benefits available to them, to educate enrollees about their access to these benefits, encourage more utilization, and ensure MA plans are better stewards of the rebate dollars for these benefits. The provision has an administrative cost of $23.7 million.

Annual Health Equity Analysis of Utilization Management Policies and Procedures. CMS finalizes changes to the composition and responsibilities of the Utilization Management (UM) committee—that a member have expertise in health equity and that the UM committee conduct an annual health equity analysis of the use of prior authorization. The analysis must examine the impact of prior authorization on enrollees with social risk factors (SRFs) of (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE), or (2) having a disability. MAOs will be required to make the results of the analysis publicly available on their website in an easily accessible manner.

Amendments to Part C and Part D Reporting Requirements. CMS finalizes affirming its authority to collect detailed information from MAOs and Part D plan sponsors, in keeping with the administration's focus on improving transparency and data in MA and Part D. This lays the groundwork for new data collections to be established through the Paperwork Reduction Act (PRA) process, which will provide advance notice to interested parties and be subject to public comment. An example of increased data collection includes service-level data for all initial coverage decisions and plan-level appeals, such as decision rationales for items, services, or diagnosis codes to have better insights into utilization management and prior authorization practices.

Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services. Whether they are enrolled in Traditional Medicare or MA, beneficiaries have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. Quality Improvement Organizations (QIOs) currently act as the IRE and conduct these reviews. However, under current regulations, MA enrollees do not have the same access to QIO review of a fast-track appeal as Traditional Medicare beneficiaries. Therefore, in addition to the current right of MA enrollees to the fast-track appeal by an QIO of an MA plan's decision to terminate HHA, CORF or SNF services when the enrollee files a timely request, CMS finalizes aligning the approaches under MA and Traditional Medicare by (1) requiring the QIO, instead of the MA plan, to also review under the fast-track appeals process untimely requests filed by the enrollee for review of such decisions; and (2) fully eliminating the provision requiring the forfeiture of an enrollee's right to appeal through the fast-track appeals process a termination of services decision when they leave the facility. The revisions to this provision have an estimated annual administrative cost of $683,910.

Changes to an Approved Formulary—Substituting Biosimilar Biological Products. Under current regulations, Part D sponsors may immediately remove from their formularies a brand name drug and substitute its newly released generic equivalent. Part D sponsors meeting the requirements can provide notice of specific changes, including direct notice to affected beneficiaries, after they take place, without needing to provide a transition supply of the substituted drug, and at any time (including in advance of the plan year). However, Part D

sponsors must obtain explicit approval from CMS before making a midyear formulary change that removes a reference product and replaces it with a biosimilar other than an interchangeable biological product.[5] To increase access to biosimilars in Part D, CMS finalizes permitting Part D sponsors meeting all requirements to do the following:

- Immediately substitute an interchangeable biological product for its reference product, a new unbranded biological product for its corresponding brand name biological product, and a new authorized generic for its brand name equivalent; and
- Substitute upon 30 days' notice any biosimilar biological product for its reference product.

Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization. CMS finalizes (1) replacing the current quarterly special enrollment period (SEP) with a monthly SEP for LIS/DE individuals to elect a standalone PDP, (2) creating a new integrated care SEP to allow dual eligibles to elect an integrated D-SNP on a monthly basis, (3) limiting enrollment in certain D-SNPs to individuals also enrolled in an affiliated Medicaid managed care organization (MCO), and (4) limiting the number of D-SNP plan benefit packages an MAO, its parent organization, or entity that shares a parent organization with the MAO can offer in the same service area as an affiliated Medicaid MCO. CMS expects these policies to increase the percentage of dually eligible MA enrollees in plans also contracted to cover Medicaid benefits, thereby expanding access to integrated materials, unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal. It will also reduce the number of plans that can enroll dual eligibles outside the annual coordinated election period, thus reducing the number of plans deploying aggressive marketing tactics toward dual eligibles throughout the year. Over 10 years, CMS estimates a $1.3 billion savings to the Trust Fund for Part D plans and an additional $1 billion savings to the Trust Fund for Part C plans.

For D-SNP PPOs, Limit Out-of-Network Cost Sharing. This provision limits out-of-network cost sharing for D-SNP preferred provider organizations (PPOs) for specific services, which will reduce cost shifting to Medicaid, increase payments to safety net providers, expand dual eligibles' access to providers, and protect dual eligibles from unaffordable costs.

Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes. A D-SNP look-alike plan is an MA plan that is not a SNP but that has a high percentage (80 percent or more) of enrollees who are dual eligibles. It is not subject to the laws or regulations governing D-SNPs,

[5] For biologics, a reference product is essentially the "brand" version. More formally, a reference product is the single biological product, already licensed (approved) by the Food & Drug Administration (FDA) under section 351(a) of the Public Health Service Act (PHSA), against which a proposed biosimilar or interchangeable product is compared. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences in terms of safety or effectiveness from an existing FDA-licensed (approved) reference product. An interchangeable product is a biologic that meets the requirements for a biosimilar *and* is approved based on information that is sufficient to show that it can be expected to produce the same clinical result as the reference product in any given patient—and for a biologic that is administered more than once to an individual, there is not a greater safety risk or risk of reduced efficacy from alternating or switching between use of the interchangeable product and its reference product. An interchangeable product can be substituted for the reference product without the intervention of the prescribing health care provider. A biosimilar or interchangeable product is licensed (approved) by FDA under section 351(k) of the PHSA. For additional information on biologics, including biosimilars, see the FDA's "Purple Book."

and it is not required to coordinate Medicare and Medicaid benefits. It does not have a contract with a state Medicaid agency, which sets forth a D-SNP's responsibilities to better integrate care for dual eligibles and provide for accountability for their care. Under current regulations, CMS does not contract with and will not renew the contract of a D-SNP look-alike. The agency finalizes lowering the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent beginning with plan year 2026. CMS expects cumulative annual costs to non-SNP MA plans and MA plan enrollees to be less than $1 million per year.

Standardize the MA Risk Adjustment Data Validation Appeals Process. CMS finalizes language to address gaps and operational constraints in existing RADV appeal regulations. Currently, if MAOs appeal both medical record review determinations and payment error calculations resulting from RADV audits, both issues must be appealed and move through the appeals process concurrently, which could result in inconsistent appeal adjudications at different levels of appeal, causing burden, confusing MAOs, and negatively impacting the appeals processes. To standardize and simplify the RADV appeals process for CMS and MAOs, the agency finalizes that MAOs must exhaust all three levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. This will ensure adjudication of medical record review determinations are final before a recalculation of the payment error is completed and subject to appeal.

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

Federal law requires an MAO that "has received an overpayment" to "report and return the overpayment," no later than "60 days after the date on which the overpayment was identified."[6] In 2014, CMS finalized implementing regulations. A group of MAOs challenged that rule's inclusion of instances where an MAO "should have determined through the exercise of reasonable diligence … that [it] has received an overpayment" in the regulation's definition of "identified".[7] The District Court for the District of Columbia sided with the MAOs, holding that this regulatory provision was impermissible under the statute.[8]

While the District Court's ruling invalidated the definition of "identified" in §422.326(c), CMS notes that MAOs remain obligated under the statute to report and return all overpayments that they have identified. In the December 2022 proposed rule, CMS proposed to remove the existing definition of "identified" in the Parts C and D overpayment regulations at §§422.326 and 423.360 (as well as the corresponding Parts A and B regulation) (87 FR 79559). Under the Parts C and D overpayment proposal, an MAO or Part D sponsor would have identified an overpayment when it had actual knowledge of the existence of the overpayment or acted in "reckless disregard" or "deliberate ignorance" of the overpayment. CMS received inquiries regarding this proposal and wants to be clear that it remains under consideration and that CMS intends to issue a final rule to revise the definition of "identified" in the overpayment rules as soon as is reasonably possible.

[6] Section 1128J(d) of the Act.
[7] §422.326(c).
[8] UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. UnitedHealthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140).

D. Information on Cyber Resiliency

In light of recent cybersecurity events impacting health care operations nationally, CMS expects all payers to review and implement HHS's voluntary Cybersecurity Performance Goals (CPGs), which are part of HHS' broader cybersecurity strategy and designed to help healthcare organizations strengthen cyber preparedness, improve cyber resiliency, and ultimately protect patient health information and safety. HHS welcomes input on the approach via email at hhscyber@hhs.gov.

II. Strengthening Current MA and Part D Policies Regarding "Past Performance"

Under current regulations, CMS may deny an application submitted by MAOs and Part D sponsors that fail to comply with the requirements of a previous MA or Part D contract, which is referred to as "past performance." The agency proposed several technical regulatory changes to clarify the basis for application denials due to past performance and to ensure that the factors adequately account for financial difficulties that should prevent an organization from receiving a new or expanded MA or Part D contract.

For example, one factor regarding past performance is the record of imposition of intermediate sanctions, which represents significant non-compliance with MA or Part D contract requirements. To clarify the basis for application denials due to intermediate sanctions, CMS proposed to change "Was subject to the imposition of an intermediate sanction" to "Was under an intermediate sanction" (§§422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A)). MAOs and Part D sponsors may have a sanction imposed in one 12-month past performance review period and effective for all or part of the subsequent 12-month review period. Since an intermediate sanction may be active during multiple consecutive review periods, the proposed language would clarify that an organization's application may be denied as long as the organization is under sanction, not just during the 12-month review period when the sanction was imposed.

An additional factor regarding past performance of MAOs and Part D sponsors is involvement in bankruptcy proceedings. The agency previously codified state bankruptcy as a basis for an application denial for the past performance of an MAO or Part D sponsor, and more recently proposed adding federal bankruptcy as a basis for denial (§422.502(b)(1)(i)(C) and §423.503(b)(1)(i)(C)) and making other technical changes.

All commenters were supportive, and CMS finalizes its proposals without modification.

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

A. Effect of Change of Ownership Without Novation Agreement (§§422.550 and 423.551)[9]

Under existing practice and contracting regulations in §§422.550 and 423.551, when an MAO or Part D sponsor changes ownership, advance notice must be provided to CMS and a written

[9] The policies in this section were proposed during the cycle for Contract Year 2024.

novation agreement[10] is required for a transfer of ownership to a new entity. Failure to do so means the existing contract is invalid, and the new owner must enter into a new contract with CMS after submission of an MA or Part D application, if needed.

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

The agency also proposed other related regulatory changes:

- Outlining CMS' enforcement process, including applicable sanctions before terminating a contract that has a change in ownership without a novation agreement;
- Ensuring through either the novation agreement or the application process that MAOs and Part D sponsors are eligible to contract with CMS;
- Imposing enrollment and marketing sanctions on the affected contract, which will remain in place until CMS approves the change of ownership (including execution of an approved novation agreement) or the contract is terminated; and
- Providing an opportunity for organizations to demonstrate that the legal entity assuming ownership by way of a change of ownership without a novation agreement meets the requirements set forth in regulations, which may be completed in the following ways—
    - If the new owner does *not* participate in the same service area as the affected contract, at the next available opportunity, it must apply for and be conditionally approved for participation in the MA or Part D program and, within 30 days of the conditional approval (if not sooner), submit the documentation required under §§422.550(c) or 423.551(d) for review and approval by CMS.[11]
    - If the new owner currently participates in the MA or Part D program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions, submit the documentation required under §§422.550(c) or 423.551(d) for review and approval by CMS.
    - If the new owner is *not* operating an MA or Part D contract in the same service area and fails to apply for an MA or Part D contract in the same service area at the next opportunity to apply, the existing contract will be subject to termination.
    - If the new owner is operating in the same service area and fails to submit the required documentation within 30 days of imposition of intermediate sanctions, the existing contract will be subject to termination.

Imposition of intermediate sanctions triggers the past performance rules described in Section II. Imposition of intermediate sanctions is also a factor considered under CMS' evaluation and

[10] A novation agreement is an agreement among the current owner of the MAO, the prospective new owner, and CMS that meets certain conditions (§422.550(c)).
[11] Organizations may submit both the application and the documentation for the change of ownership concurrently.

determination of an organization's information from a current or prior contract during the MA and Part D application process.

Final Action. CMS finalizes its proposals, with minor grammatical and organizational revisions.

Selected Comments/Responses. A commenter suggested not terminating a contract when a change of ownership has occurred without notification to CMS, but rather that CMS apply a substantial penalty or fine to the new legal entity. The agency points out that its existing policy is consistent with the statute and that a substantial penalty or fine on the new owner would not protect enrollees already in MA or Part D plans that cannot adequately serve them. Moreover, entities can cure deficiencies within 30 days of the imposition of immediate sanctions and will have the opportunity to avoid termination.

Another commenter suggested that the proposed approach should not apply to ownership that occurs under the same parent organization. CMS responds that existing policy requires the agency to review any change in ownership from one legal entity to another, regardless of the relationship to the parent organization, to confirm the new legal entity meets the regulatory requirements for operating in that service area.

B. Part D Global and Targeted Reopenings (§§423.308 and 423.346)[12]

The Secretary has statutory authority to inspect and audit any books and records of a Part D sponsor or MAO regarding costs provided to the Secretary. CMS notes that authority would not be meaningful if, upon finding mistakes pursuant to such audits, the Secretary was not able to reopen final determinations made on payment. Thus, regulations from 2005 established reopening provisions, at CMS discretion and which could occur within the following timeframes after the final payment determination was issued:

- Within 12 months for any reason,
- Within 4 years for good cause, or
- At any time when there is fraud or similar fault.

CMS operationalized different kinds of reopenings:

- Global reopenings—that is, program-wide reopenings, and
- Targeted reopenings—that is, reopenings targeted to the contracts of a specific sponsor(s).

CMS proposed to codify the definitions of "global reopening" and "targeted reopening." It also proposed to modify the timeframe for performing a reopening for good cause from within 4 years to within 6 years. This would align with the 6-year overpayment look-back period for Part D sponsors at §423.360(f) and would help ensure that payment issues, including overpayments, can be rectified.

[12] The policies in this section were proposed during the cycle for Contract Year 2024.

In the preamble, the agency provides greater detail on the current process for Part D reconciliations and reopenings,[13] its related sub-regulatory guidance on global and targeted reopenings, the 6-year overpayment look-back period for Part D sponsors at §423.360(f), and examples of challenges posed by the current regulatory structure due to differing lookback periods, etc. Many of its examples pertained to results of revisions of prescription drug event (PDE) data and/or direct and indirect remuneration (DIR) data.

In terms of standards for performing reopenings, CMS says it will use its discretion to conduct a targeted reopening (or an additional global reopening for a program-wide issue) only under limited circumstances—to correct or rectify a CMS file or CMS-created PDE edit-type issue, revise a payment determination that was based on PDE and/or DIR data that was submitted due to fraudulent activity of the sponsor or the sponsor's contractor, or pursuant to a successful appeal under §423.350. CMS proposed:

- In order to be included in a reopening, a contract must have been in effect (that is, receiving monthly prospective payments and submitting PDE data for service dates in that year) for the contract year being reopened.
- If CMS has sent a nonrenewed or terminated contract the "Notice of final settlement" by the time CMS completes the reopening, CMS will exclude that contract from that reopening.
- For targeted reopenings, CMS will identify which contracts or contract types are to be included and notify sponsors of the specific inclusion criteria via the proposed reopening notification and/or the proposed reopening completion announcement.[14]

CMS also proposed codifying its existing policy regarding reopening notifications and reopening completion announcements in new §423.346(e) and (f). CMS will notify the sponsor of its intention to perform a reopening only when it is necessary for the sponsor to submit PDE data and/or DIR data prior to the reopening, along with a description of the contract(s) that will be included in the reopening.[15] Otherwise, CMS would notify the sponsor only after the reopening is complete.

The agency also proposed to codify when it has completed a reopening, consistent with existing policy and past practice, which would include the following:

- A description of the data used in the reopening;
- A statement of the contract(s) included in the reopening;
- The date by which reports describing the reopening results will be available to the sponsor; and
- The date by which a sponsor must submit an appeal, pursuant to §423.350, if the sponsor disagrees with the reopening results.

[13] This includes following the reopening of a Part D payment reconciliation (that is, the initial payment determination) as a result of revisions of prescription drug event (PDE) data and/or direct and indirect remuneration (DIR) data due to plan corrections, CMS system error corrections, post reconciliation claims activity, and audit and other post reconciliation oversight activity.

[14] To date, most targeted reopenings have been performed because of a CMS-identified issue that most sponsors were not aware of prior to CMS completing the targeted reopening.

[15] In this case, CMS will include in the notification the deadline for submitting the PDE data and/or DIR data, which must provide at least 90 calendar days after the date of the notice.

Final Action. CMS finalizes its proposed changes without modifications. Prior to the new reopening timeframe going into effect, CMS says it will provide operational guidance, as has been done for past regularly scheduled global reopenings.

C. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors that are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)[16]

Under current law, contracts between CMS and the legal entity that offers one or more MA or Part D plans must contain terms and conditions the Secretary finds necessary and appropriate, in addition to the specific requirements, standards, and terms of payment established in statute. For these contracts, federal regulations address a number of situations, such as when they are consolidated, nonrenewed, or otherwise terminated by the plan and/or CMS. In these circumstances, retroactive payment adjustments for a year that would have been made are held until after the reconciliations for the final payment year are calculated. After such time, all retroactive adjustments for the consolidated, nonrenewed, or otherwise terminated contract are totaled and either a net payment amount is made or charged to the MAO or Part D sponsor.

This final settlement process—that is, the process to determine the final net payments and provide notice to the MAO or Part D sponsor of these amounts, adjudicate disputes, and receive or remit payment—begins at least 18 months following the end of the last contract year in which the contract was in effect. Before determining the final settlement amount, CMS first calculates adjustment based on (1) MA risk adjustment reconciliation (§422.310(g)), (2) Part D annual reconciliation (§§423.336 and 423.343), (3) Coverage Gap Discount Program annual reconciliation (§423.2320), and (4) medical loss ratio (MLR) report submission and remittance calculation (§§422.2460, 422.2470. 423.2460 and 423.2470), as applicable. With each, the MAO or Part D sponsor may raise concerns about the calculation; if no errors have been identified after the completion of each reconciliation, the MAO and Part D sponsor is presumed to accept the amount and it is not reconsidered during the final settlement process. The final settlement amount is then calculated by summing the applicable reconciliation amounts from these 4 processes and any retroactive payment adjustments that accumulated after a contract has consolidated, nonrenewed, or otherwise terminated.

The final settlement adjustment period ends on the date that CMS issues to the MAOs and Part D sponsors the notice of final settlement, which does the following:

- Explains whether the MAO or Part D sponsor will receive or owe a final settlement amount,
- Provides the information needed to conduct that financial transaction,
- Gives the information CMS used to calculate the final settlement amount, including the payment adjustments reported on all monthly membership reports created from the date the contract ended until the month the final settlement amount was calculated, and
- Explains the process and timeline for requesting a review concerning the accuracy of the final settlement amount calculation.

[16] The policies in this section were proposed during the cycle for Contract Year 2024.

Once this notice has been issued, contracts that have been consolidated, nonrenewed, or otherwise terminated will also be excluded from reopenings, including program-wide reopenings, or reconciliations for prior payment years when the contract was in effect.

CMS proposed to codify longstanding, existing guidance for the final settlement process summarized above. In addition, CMS proposed the following:

- MAOs and Part D sponsors would be able to request an appeal of the final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement.
    - No response would be necessary or required—for example, if an MAO or Part D sponsor agrees with the final settlement amount. However, the agency strongly encourages MAOs and Part D sponsors to communicate their acceptance to CMS to facilitate prompt payment.
    - If an appeal request is not submitted within the 15-day deadline, CMS will not consider subsequent requests for appeal.
    - The MAO or Part D sponsor would have to specify the calculations they disagree with, the reasons for their disagreement, and evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect.
    - MAOs and Part D sponsors would not be able to submit new reconciliation data or data submitted to CMS after the final settlement notice was issued.
    - Once CMS has reconsidered the calculation of the final settlement amount in light of the evidence provided, CMS will provide written notice of the reconsideration decision.
    - If the MAO or Part D sponsor does not agree with CMS' reconsideration decision, it will be able to request an informal hearing from a CMS hearing officer, within 15 calendar days of the date of CMS' reconsideration decision.
- In addition to the current appeals process, two additional levels of appeal would be newly available (with much greater detail provided in the rule):
    - An informal hearing conducted by the CMS Office of Hearings to review CMS' initial determination, following a request for appeal of the reconsideration of CMS' initial determination; and
    - A review by the CMS Administrator of the hearing officer's determination, if there is an appeal of the hearing officer's determination.

CMS believes these additional levels of appeal would afford MAOs and Part D sponsors sufficient opportunities to present objections to the calculation of the final settlement amount (and not any prior payments or reconciliation amounts) but would only be used in exceptional circumstances given the narrow, mathematical nature of the final settlement process. If such calculation errors do occur, CMS generally expects they would be quickly corrected to the mutual satisfaction of both parties without a need for further review.

If the final settlement amount is not appealed:

- If an MAO or Part D sponsor owes a final settlement amount, the full payment must be remitted to CMS within 120 calendar days of receiving the notice of final settlement.
- If an MAO or Part D sponsor is owed a final settlement amount, CMS will remit payment within 60 calendar days of the date of issuance of the notice of final settlement.

Final Action. CMS received no comments on these provisions and finalizes its proposed changes without modifications.

D. Civil Money Penalty Methodology (§§422.760 and 423.760)[17]

CMS may impose Civil Money Penalties (CMPs) of up to $25,000, as adjusted annually under 45 CFR part 102, for each affected enrollee or per determination. The agency does not always apply the maximum penalty amount because the penalty amounts under the current CMP calculation methodology[18] are generally sufficient to encourage compliance with CMS rules. CMS believes current regulations unnecessarily complicate its calculations of CMPs, limiting the agency's ability to protect beneficiaries when it determines that an organization's noncompliance warrants a higher CMP amount than normally applied under the CMP methodology.

CMS finalizes its proposal, without modification, making revisions to the regulatory text for the determination of the amount of a CMP that may be imposed for violations, to clarify that it may impose amounts in excess of the minimum CMP based on the severity of the violation. The agency will set standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis. However, the regulation text re-emphasizes that CMS may issue penalties up to the maximum amount when it determines that an organization's noncompliance warrants a penalty higher than would be applied under the minimum penalty amounts.

CMS will continue to follow its existing CMP methodology and will only impose up to the maximum CMP amount in instances where it determines that the noncompliance warrants such a penalty. The update will also be incorporated in forthcoming revised CMP calculation methodology guidance.

E. Part D Medication Therapy Management (MTM) Program (§423.153(d))[19]

1. MTM Eligibility Criteria

All Part D sponsors must have an MTM program designed to assure, for targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. MTM programs must target Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs set by the Secretary. They must also target all at-risk beneficiaries (ARBs) in their Part D drug management program (DMP) for MTM. CMS notes that the high-cost threshold as well as restrictive plan criteria have significantly reduced the MTM program size over time, and Part D enrollees with more complex drug regimens who would benefit most from MTM services are often not eligible.

[17] The policies in this section were proposed during the cycle for Contract Year 2024.
[18] The first public CMP calculation methodology for MA organizations and Part D sponsors was published in 2016, affecting referrals received beginning in 2017, updated multiple times since then (most recently in 2019).
[19] The policies in this section were proposed during the cycle for Contract Year 2024.

CMS proposed changes to the current MTM targeting criteria, including:

- Requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current nine core chronic diseases[20] in regulation, and adding HIV/AIDS for a total of 10 core chronic diseases;
- Lowering the maximum number of covered Part D drugs a sponsor may require from eight to five drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and
- Revising the methodology for calculating the cost threshold ($5,330 in 2024) to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020).

Final Action. CMS finalizes its proposal with modifications (in response to comments) resulting in a smaller program size increase, less burden and lower costs than initially estimated in the December 2022 proposed rule. Specifically, CMS is not finalizing its proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs; the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs will continue to be eight (§423.153(d)(2)(i)(B)).

In addition, while the current annual cost threshold is $5,330[21] and the proposed level would have been around $1,000 (based on the average annual cost of five generic drugs), CMS finalizes a modified MTM cost threshold based on the average annual cost of eight generic drugs, beginning January 1, 2025. Based on analysis of 2023 PDE data, the MTM cost threshold will be $1,623 for 2025. For future years, the MTM cost threshold will be published in the annual Part D Bidding Instructions memo.

The resulting program size will be about 35 percent smaller than originally estimated in the December 2022 proposed rule. The changes will also be effective in 2025, rather than 2024 as initially proposed.

Selected Comments/Responses. For a variety of reasons, several commenters agreed that the proposed changes to the MTM eligibility criteria have the potential to significantly improve the effectiveness of the MTM program and achieve equity for underserved Medicare patients. However, many opposed the proposed eligibility criteria changes over significant concerns about the costs and resource burden associated with implementing such a large-scale expansion of the MTM program. Some opined that the proposed changes would increase Part D premiums and cost sharing for all enrollees, with one estimating that the proposed changes would more than double MTM administrative costs. Another suggested the changes would result in a loss of rebate dollars that would otherwise be used to improve affordability or provide supplemental benefits that support enrollee well-being.

Others raised concerns about a decline in MTM program quality that could result from a significant increase in program size, diluting plans' ability to target MTM interventions to those

[20] (1) Alzheimer's disease; (2) bone disease-arthritis; (3) chronic congestive heart failure (CHF); (4) diabetes; (5) dyslipidemia; (6) end-stage renal disease (ESRD); (7) HIV/AIDS; (8) hypertension; (9) mental health; and (10) respiratory disease.

[21] The 2024 amount is based on $3,000 for 2011 increased by the annual percentage in §423.104(d)(5)(iv).

beneficiaries who would most benefit from them. Concerns were raised that MTM providers may "water down" their approach due to the increased volume resulting in lower-value programs that satisfy the MTM requirements but are much less likely to improve health outcomes due to shorter consultations or fewer interventions. Another commenter stated that the pool of MTM vendors has decreased while costs have increased due to the loss of competition, hindering the ability of plan sponsors to administer quality MTM programs. Commenters estimated needing to double or triple their staffing to accommodate MTM enrollment increases of up to 60 percent in one year. A commenter said many plan sponsors that use local community pharmacists to furnish MTM services would not be able to meet the higher demand in time, or that there would be pressure to use call centers, possibly employing customer service representatives without clinical training, potentially leading to lower quality of care or member experience.

CMS says it understands commenters' concerns and therefore is finalizing the proposed changes with modifications that ensure a smaller increase in program size and promote the administration of high-value MTM programs. The agency points out that sponsors may also leverage effective MTM programs to improve several measures in the Medicare Part D Star Ratings[22] and display page such as medication adherence, polypharmacy, and gaps in therapy. CMS says it is optimistic that the increase in demand for MTM services will incentivize plan sponsors to strengthen their hiring efforts and that its scaled back MTM expansion may alleviate a portion of the staffing concerns raised.

A few commenters suggested that CMS should engage the industry to determine alternative options for better targeting or increased CMR participation rather than finalize the proposed modifications. One commenter stated that many MTM enrollees choose not to participate, and to be more consistent with the Administration's health equity goals, CMS should engage those already eligible, who have the greatest need. CMS says it has engaged numerous interested parties through this rulemaking while also having engaged in its own extensive data analysis on the issue, as discussed in the December 2022 proposed rule. The agency believes the modified policy finalized here balances eligibility and program size while allowing CMS to address specific problems identified in the Part D MTM program, including marked variability and inequitable beneficiary access to MTM services. However, CMS states its commitment to addressing the main drivers of the inequities in MTM program eligibility discussed in the December 2022 proposed rule and will continue to request input from interested parties on improving aspects of the MTM program in the future.

Some commenters requested clarification on whether all diseases included under the 10 core chronic disease categories must be targeted, or whether plans will have the flexibility to choose specific diseases within the core chronic diseases. CMS states that plan sponsors must target all

[22] Many commenters stated that the proposed eligibility criteria changes would result in a substantive update to the Part D Star Rating MTM Program Comprehensive Medication Review (CMR) Completion Rate measure (MTM Star Rating Measure) due to the program size expansion and impacts to resources. See sections VII.B and VII.D on the proposal to modify the MTM Program Completion Rate for CMR measure and the discussion of the weight of newly modified measures, respectively. The MTM Program Completion Rate for CMR measure is being updated in this rule to align with the revised targeting criteria finalized here (§423.153(d)).

10 core chronic diseases, including all conditions within each core chronic disease.[23] As discussed in the proposed rule, CMS' analysis found that a significant proportion of the Part D population that had three or more core chronic diseases and using eight or more drugs were not eligible to be targeted for MTM, and variation in plan-specific targeting criteria (for example, plans targeting fewer than all of the core chronic diseases) was a key driver of gaps in eligibility for MTM. Reducing the variability in targeting criteria across plans will significantly reduce situations where enrollees meet the requirement in § 423.153(d)(2)(i) of having three chronic diseases but are not targeted for MTM enrollment because their plan does not target their chronic diseases.

In response to CMS' request for information and feedback on including additional diseases, such as cancer, in the list of core chronic diseases, a couple of commenters supported including cancer. One commenter felt it would align well with some pharmacies' specialty pharmacy offerings and clinical services. Others opposed, indicating that complex cancer treatment needs timely, ongoing monitoring by specialists with expertise across Part B and Part D medications, which may not be best managed by Part D MTM programs through annual CMRs or by pharmacists without specialized training. Others noted that specialty pharmacies, which dispense the majority of oral cancer medications (including specialty pharmacies within oncology clinics), already provide monitoring or counseling for their oncology patients. For reasons cited, CMS does not believe it would be appropriate to add cancer to the core chronic diseases in §423.153(d)(2)(iii); however, some cancer patients may still be eligible for MTM based on meeting the eligibility criteria.

As previously mentioned, many commenters opposed the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. Commenters were concerned that MTM would not be as useful for beneficiaries with less complex drug regimens and suggested that beneficiaries should qualify for MTM enrollment based on higher pill burdens and more complicated medication regimens. Thus, CMS is not finalizing this particular policy. Plan sponsors will maintain the flexibility to set a lower threshold (between two and eight Part D drugs) for targeting. This will maintain the MTM program focus on beneficiaries with the most complex drug regimens and will result in a more moderate expansion of the MTM program size.

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

MTM programs must offer each MTM enrollee an annual CMR, including an interactive, person-to-person consultation performed by a pharmacist or other qualified provider, including when the beneficiary is in a long-term care (LTC) setting. Acknowledging the difficulty of conducting CMRs for individuals unable to participate in the CMR because of cognitive impairments, CMS authorized CMR providers to perform the CMR with an enrollee's prescriber, caregiver, or other authorized individual if the enrollee is unable to accept the offer to participate.

[23] However, in response to a comment requesting greater specificity, CMS says it does not have guidance for plan sponsors to define or code core chronic diseases such as "other chronic lung disorders" or "chronic/disabling mental health conditions" but that sponsors should retain documentation supporting their eligibility criteria determinations.

CMS proposed to codify this exception by specifying that in order for the CMR to be performed with an individual other than the beneficiary, the beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment. Cognitive status could be determined using interviews with the beneficiary or their authorized representative, caregiver, or prescriber. Part D sponsors would not be allowed to rely on administrative information like claims data or diagnosis codes alone to determine whether a beneficiary is cognitively impaired and unable to accept the offer to participate in their own CMR.

CMS finalizes its proposal without modification.

3. Requirement for In-Person or Synchronous Telehealth Consultation

Annual CMRs must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. The consultation must be conducted in real-time, either face-to-face or via an alternative real-time method, such as the telephone.

CMS proposed to amend its regulation to require that the CMR be performed either in person or via synchronous telehealth; the goal of the change is to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth. Plans would retain the ability to determine whether the CMR can be performed in person or using the telephone, video conferencing, or another real-time method.

CMS finalizes its proposal without modification.

F. Part D Subcontractors May Terminate Only at the End of a Month (§423.505)[24]

Part D sponsors often rely on first tier, downstream, and related entities (FDRs, as these 3 entities are separately defined at §423.501) that perform critical functions on the sponsor's behalf. These critical functions include administering formularies, processing beneficiaries' plan enrollments, contracting with pharmacies, processing Part D claims at the point of sale, and operating enrollee appeals and grievance processes. CMS is concerned about the limited situations when an FDR suddenly terminates its contract with the Part D sponsor or stops paying claims to prevent or minimize operating losses.

An example is provided of a PDP contract terminated in the middle of March 2021 due, in part, to the PBM terminating its contract mid-month for nonpayment. This disrupted care for almost 40,000 beneficiaries and forced CMS to incur additional expense to ensure that all beneficiaries had continuous coverage for the month of March. When an FDR performing critical functions on a sponsor's behalf terminates a contract mid-month, CMS has already paid the sponsor for the services that the FDR was supposed to render for the entirety of that month.

If CMS finds it necessary to terminate a sponsor's contract, such terminations may occur at any time; if at a time other than the end of a contract year, CMS reassigns affected beneficiaries to other Part D plans in the same service area. When these reassignments occur mid-month, CMS

[24] The policies in this section were proposed during the cycle for Contract Year 2024.

makes a full prospective payment for that month to the plan into which enrollees are reassigned, so that CMS pays twice for the same month. While CMS has authority under §423.509(b)(2)(ii) to recover the prorated share of the capitation payments made to Part D sponsors covering the period of the month following the contract termination, as a practical matter, a contract terminated due to financial difficulties usually does not have the funds available to repay CMS.

To protect beneficiaries and the Part D program from the consequences of mid-month terminations of certain FDR contracts, a requirement was proposed that Part D sponsors' contracts with FDRs that perform certain key Part D functions require a minimum of 60 days' prior notice of termination, with an effective date that coincides with the end of a calendar month. (CMS notes mid-month terminations have been very rare to date and thus expects no significant additional expense for sponsors.) The functions for which this requirement would apply are the following:

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

Final Action. CMS finalizes its proposal without modification.

Selected Comments/Responses. One commenter requested clarification on whether the rule would be applicable to terminations initiated by Part D sponsors or limited to terminations initiated by FDRs. CMS responds that the rule would only apply to terminations initiated by FDRs. Part D sponsors would remain free to terminate their FDRs mid-month or on less than 60 days' notice if their contracts with FDRs permit such terminations, but those sponsors would remain accountable for ensuring that their enrollees continue to receive uninterrupted Part D benefits in compliance with the statute, regulation, and contracts with CMS.

G. Application of 2-Year Ban on Reentering the Part D Program Following Non-renewal (§§423.507 and 423.508)[25]

Under current regulations, Part D sponsors that non-renew or mutually terminate their contracts with CMS are ineligible to enter into a new Part D contract for two years, absent special circumstances. However, CMS sees no reason to prohibit sponsors that non-renew their plans in one region from offering plans in a *new* region before the 2-year exclusion period elapses.

CMS proposed that the prohibition on PDP sponsors that non-renew or mutually terminate a contract applies at the PDP region level. That is, for those sponsors, the two-year exclusion would only prohibit them from entering into a new or expanded PDP contract *in the PDP region(s) they exited* and would not prevent them from entering into a new or expanded contract in another region(s). This 2-year exclusion would apply whenever a PDP sponsor terminates all

[25] The policies in this section were proposed during the cycle for Contract Year 2024.

of its plan benefit packages (PBPs) in a PDP region, commonly known as a "service area reduction," even if they continue to serve other PDP regions under the contract.

EGWP PBPs would be exempted from the two-year ban.

CMS finalizes the provision as proposed with minor grammatical and formatting changes.

H. Crosswalk Requirements for Prescription Drug Plans (§423.530)[26]

Under the statute, individuals who have elected a plan are considered to make the same election until they change it or the plan is discontinued in the area in which they reside. Thus, enrollees are to remain in a renewing PBP for the following year if they do not make another election (or opt to discontinue Part D coverage) and the PBP's plan ID number is to remain the same.

Plan crosswalk is the term for the process where PDP sponsors transfer their enrollees into a different one of their PBPs when enrollees make no other election. About 20 percent of beneficiaries enrolled in Part D plans that non-renew without a subsequent crosswalk fail to select new coverage. In these cases, the beneficiaries not only lose Part D coverage, but are also subject to the Part D late enrollment penalty. The subregulatory guidance for crosswalks was developed in order to:

- Prevent beneficiary disruptions when a PDP sponsor discontinues PBP(s),
- Allow the consolidation of PDP contracts of subsidiaries of the same parent organization,
- Facilitate statutorily required "evergreen" enrollments by not requiring additional enrollment transactions when a PBP renews in a new plan year, and
- Prevent plans from "dumping" beneficiaries who are high cost or whom the organization otherwise no longer wishes to cover.

CMS proposed to codify, with some modifications, the current subregulatory plan crosswalk process, defining terms and the circumstances in which plan crosswalk may (or must) occur and providing protections against excessive premium increases. Specifically, the new §423.530 lays out numerous policies, including the following:

- Define a plan crosswalk as the movement of enrollees from one PDP PBP to another PDP PBP.
- Allow enrollees in EGWPs to be transferred between PBPs in accordance with their usual process rather than the provisions of §423.530, which apply only to Part D individual market PDPs.
- *Prohibit* certain crosswalks:
    - Between PBPs in different PDP contracts unless the PDP contracts are held by the same Part D sponsor or by sponsors that are subsidiaries of the same parent organization;
    - That split enrollment of one PBP into multiple PBPs; and
    - From PBPs offering basic coverage to PBPs offering enhanced alternative coverage, because enhanced alternative coverage is accompanied by a

[26] The policies in this section were proposed during the cycle for Contract Year 2024.

supplemental premium that could have a particularly detrimental effect on LIS-eligible individuals.

- Codify current policy for the 2 types of *mandatory* crosswalks: to require enrollees in PDP PBPs that are renewing to be transferred into the same PBP—specifically to either enhanced alternative or basic coverage—for the following contract year.
- Codify current policy (with some exceptions) for the 2 types of plan *crosswalk exceptions*—that is, where a Part D sponsor of a PDP *may* perform a crosswalk:
    - *Consolidated renewals*, where a Part D sponsor discontinues a PBP offering enhanced alternative coverage[27] but continues to offer Part D individual market coverage under the same PDP contract, into which enrollees would be crosswalked; and
    - *Contract consolidations*, where a Part D sponsor(s) under a single parent organization operates multiple PDPs that they wish to consolidate, with enrollees crosswalked into the contract's surviving PBPs.

Under both consolidated renewal crosswalks and contract consolidation crosswalks, enrollment from a non-renewing PBP cannot be "split" into multiple PBPs; all enrollees from non-renewing enhanced alternative PBPs are transferred into another PBP offering either enhanced alternative or basic coverage.

Plan crosswalks in consolidated renewal scenarios will be permitted (but not required) if PDP sponsors request a crosswalk from a non-renewing PBP to another PBP under the same contract that meets certain requirements, including:

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

CMS proposed 4 major changes from current policy regarding consolidated renewal scenarios:

- Allow, but not require, plan crosswalks in consolidated renewal scenarios, in which PDP sponsors could request a crosswalk of enrollment from a nonrenewing PBP to another PBP under the same contract, provided it meets the other requirements of §423.530;
- Require enrollees from non-renewing PBPs offering enhanced alternative coverage to be cross-walked into the PBP that will result in the lowest premium increase;
- Prohibit plan crosswalks if it would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in §423.286(c), compared to the current year premium for the non-renewing PBP; and

[27] Under current regulations, organizations may not non-renew a PBP offering basic prescription drug coverage unless they are non-renewing all individual market PBPs in a PDP region, because a basic prescription drug plan offering is a requirement in order for a sponsor to offer enhanced alternative coverage within the same service area.

- Prohibit sponsors that fail to request and receive a plan crosswalk exception from offering a new enhanced alternative PBP in the same service area for the contract year after they non-renew an enhanced alternative PBP.

While CMS recognizes that premiums are not the only aspect of a PBP's structure that affect costs to beneficiaries, premiums for a PBP are the same for every enrollee and are therefore the most straightforward factor to use to protect enrollees from unexpected cost increases.

Final Action. CMS is finalizing its proposal without modification regarding crosswalk requirements for PDPs at §423.530.

Selected Comments/Responses. Several commenters asked CMS to consider plan characteristics other than total premiums when determining which plan beneficiaries could be cross-walked into—for example, changes to cost sharing and formulary drugs. CMS says it does not have a methodology to determine whether a particular approved formulary will be "better" for a group of beneficiaries. Similarly, while each plan has an estimated OOPC value for a group of beneficiaries, the actual costs incurred by beneficiaries are highly variable based on characteristics such as LIS status, health status, medications used, and pharmacies chosen. Premiums, on the other hand, are uniform for all beneficiaries in the PBP. CMS believes attempting to use other information to determine which plans beneficiaries may be cross-walked into is too complicated to be practical at this time.

I. Call Center Teletypewriter (TTY) Services (§§422.111 and 423.128)[28]

CMS proposed a technical change to regulations that require MAOs and Part D sponsors to connect 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes. The revised regulation would instead require that contact be established with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services. The proposed change was intended to remove any ambiguity that might result from the term "TTY operator"; its intent was to ensure a beneficiary could establish contact with a customer service representative within 7 minutes.

The comments submitted were all in support. CMS finalizes its proposal without modification.

J. Clarify Language Related to Submission of a Valid Application (§§422.502 and 423.503)[29]

CMS proposed to codify its authority to decline to consider a substantially incomplete application for a new or expanded Part C or D contract, and to codify criteria for determining that an application is substantially incomplete. CMS will not consider an application submitted after its strict deadlines, and some MAOs have submitted placeholder applications (those lacking too much information to constitute a valid submission) before those deadlines. CMS has treated placeholder applications as invalid.

[28] The policies in this section were proposed during the cycle for Contract Year 2024.
[29] The policies in this section were proposed during the cycle for Contract Year 2024.

CMS proposed to revise its regulations to specifically state that it does not evaluate or issue a notice of determination when an entity submits a substantially incomplete application. A notice of determination is issued for an approval of an applications, an intent to deny an application, or for a denial of an application. This proposed modification would treat substantially incomplete applications as if they were not submitted by the application deadline and therefore the submitting entity is not entitled to review of its submitted material or an opportunity to cure deficiencies. The agency proposed to codify its definition of *substantially incomplete application* as an application that, as of the deadline for submission of applications, is missing content or responsive materials for one or more sections of the application form required by CMS. The preamble includes examples for missing sections that would render an application substantially incomplete—for a Part D application, an MA application, and a SNP application.

CMS also proposed to clarify that a determination that an application is substantially incomplete is not a contract determination, and that a determination that an organization submitted a substantially incomplete application is not subject to appeal.

CMS finalizes its proposal without substantive modification. (The final regulation text includes minor stylistic changes.)

K. Expanding Network Adequacy Requirements for Outpatient Behavioral Health

In its June 2020 final rule (85 FR 33796), CMS codified a list of 27 provider specialty types and 13 facility specialty types subject to CMS network adequacy standards for MA. In its April 2023 final rule (88 FR 22120), the agency added two new specialty types to the provider-specialty types list at §422.116(b)(1), clinical psychology and clinical social work, to be subject to the specific time and distance and minimum provider number requirements. For coverage beginning January 1, 2024, four behavioral health specialty types are now part of network adequacy requirements: psychiatry, clinical psychology, clinical social work, and inpatient psychiatric facility services.

MAOs are required to maintain and consistently monitor their provider networks to ensure they are sufficient to provide adequate access to covered services that meet the needs of enrollees (§422.112(a)). The Health Plan Management System (HPMS) provides MAOs with access to the "Evaluate my Network" functionality, to test their provider networks against the evaluation standards in §422.116 outside of a formal network review and using different scenarios, including at the PBP level. CMS encourages MAOs to utilize the "Evaluate my Network" tool to monitor their PBP-level active provider networks and keep abreast of any network issues that could hinder access to care for enrollees. Any compliance issues or significant changes in their provider network should be reported to their CMS Account Manager.

In a continued effort to address access to behavioral health services within MA networks, CMS proposed to:

- Add to the list of provider specialties at §422.116(b) a combined behavioral health specialty type, *Outpatient Behavioral Health*, which includes—

    - Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs),[30]
    - Opioid Treatment Programs (OTPs),[31]
    - Community Mental Health Centers, and
    - Physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), addiction medicine physicians, and outpatient mental health and substance use treatment facilities that regularly furnish or will regularly furnish behavioral health counseling or therapy services (including psychotherapy or prescriptions for SUD).
- Add corresponding time and distance standards for Outpatient Behavioral Health in §422.116(d)(2), as shown in the table below.
- Add Outpatient Behavioral Health to the list of specialty types in §422.116(d)(5) that will receive a 10 percentage point credit toward the percentage of beneficiaries residing within published time and distance standards if the MAO's contracted network includes one or more telehealth providers of that specialty type that provide additional telehealth benefits (as defined in §422.135) for covered services.

Provider/ Facility type	Large Metro		Metro		Micro		Rural		CEAC	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100

Note: CEAC is Counties with Extreme Access Considerations. County type designations are defined in §422.116(c). Time is in minutes. Distance is in miles.

Final Action. CMS finalizes its proposal but, in response to comments, adds more specificity about what it means for PAs, NPs and CNSs to "regularly furnish or will regularly furnish" behavioral health counseling or therapy services. As finalized, to be considered as regularly furnishing behavioral health services, a PA, NP or CNS must have furnished specific psychotherapy or medication prescription services to at least 20 patients within a 12-month period. CMS will identify the specific services in the Health Service Delivery (HSD) Reference File described in current §422.166(a)(4)(i) using Healthcare Common Procedure Coding System (HCPCS) codes, narrative descriptions, or something sufficiently similar to specify the necessary type of services on an annual basis. To determine that a PA, NP or CNS meets this standard, an MAO must (1) annually independently verify the provider has furnished such services within a recent 12-month period; (2) if there is insufficient evidence of past practice, have a reasonable and supportable basis for concluding the provider will meet the standard in the next 12 months; and (3) submit evidence and documentation to CMS upon request of the MAO's determination that the provider meets the standard.

[30] Services furnished by MFTs and MHCs were added as new Part B benefit categories effective January 1, 2024, by the Consolidated Appropriations Act (CAA), 2023 (P.L. 117-328). MAOs are required to cover virtually all Part B covered services, including these new services. As a practical matter, MAOs need to ensure access to these services that can only be provided by these types of providers and therefore must contract with these types of providers in order to furnish basic benefits as required by section 1852 of the Act.

[31] In 2020, OTP providers had the largest number of claims for SUD services, according to CMS' Medicare fee-for-service claims data.

Selected Comments/Responses. While numerous commenters were supportive of the proposal to improve behavioral health network adequacy standards in MA plans, several others expressed concerns about consolidating several specialty and facility types into a new single category for purposes of evaluating network adequacy in MA. Specifically, commenters expressed concern that combining mental health (MH) and substance use disorder (SUD) specialties into one category may diminish the distinct access needs for these individual specialty types and that the combined standard as proposed was too broad.

Among many reasons provided in response, CMS says it is taking this approach to provide additional time to collect the specific claims and utilization data for MFTs and MHCs, and may engage in future rulemaking to establish specific time and distance standards for these specialties separately. CMS' review of certain Traditional Medicare claims data from 2017–2020 (Place of Service codes, Type of Bill codes, CCN codes, and Revenue Center codes) also indicates that facility types treat individuals with both mental health disorders and substance use disorders. While the individual providers may specialize in either mental health or substance use disorder treatment, many of the facility providers will offer a variety of services and provider types to meet the range of enrollees' behavioral health needs. In the absence of more robust utilization and claims data, CMS states that the Outpatient Behavioral Health specialty type should be effective for use in its MA plan network adequacy standards for now.

Many commenters requested that CMS revise the proposed Outpatient Behavioral Health time and distance standards to align with those already established for Qualified Health Plans (QHPs), emphasizing that aligning these standards and shortening the MA standards to reflect the benchmarks set for QHPs would potentially benefit enrollees. CMS says that while it is interested in aligning policies across programs, the data used for MA network adequacy time and distance requirements is based on Medicare beneficiaries' unique health care utilization patterns, geographic locations, providers and facilities. Thus, at this time, it believes the requirements proposed and now finalized are appropriate for providing access and meeting the health care needs of the specific beneficiary population.

Multiple commenters expressed concerns that MA provider network adequacy standards could be met utilizing NPs, PAs and CNSs within the new Outpatient Behavioral Health facility-specialty type. They expressed concern about the absence of clear and transparent criteria for incorporating these provider types and that they might lack the necessary skills, training or expertise to effectively address the mental health and substance use disorder needs of enrollees.

As mentioned above, CMS reiterates that for purposes of network adequacy evaluation, providers—including NPs, PAs, and CNSs—must regularly furnish or will regularly furnish behavioral health counseling or therapy services in order to be included in the new facility specialty Outpatient Behavioral Health. CMS acknowledges the concerns regarding the use of NPs, PAs and CNSs to satisfy the Outpatient Behavioral Health network adequacy standards without verifying their qualifications to address and actual practice of addressing behavioral health or SUD needs. As a result, CMS makes the aforementioned modification to establish that satisfying the Outpatient Behavioral Health network adequacy standards requires the NP, PA or

CNS to have furnished certain psychotherapy or SUD prescribing services to at least 20 patients[32] within the previous 12 months.

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

Current statute and regulations require Part D sponsors to have a drug management program (DMP) for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs), currently defined by CMS as opioids and benzodiazepines. CMS identifies potential at-risk beneficiaries (PARBs) who meet the clinical guidelines (§423.153(f)(16)), also known as the minimum Overutilization Monitoring System (OMS) criteria. The agency reports such beneficiaries to their Part D plans, which are required to conduct case management for PARBs. Such case management must inform the beneficiary's prescriber(s) of their potential risk for misuse or abuse and request information from the relevant prescriber(s) to evaluate the beneficiary's risk and whether they meet the regulatory definition of exempted beneficiary. If the sponsor determines the enrollee is an at-risk beneficiary (ARB), after notifying the beneficiary in writing, the sponsor may limit their access to opioids or benzodiazepines to a selected prescriber, network pharmacy(ies), or through a beneficiary-specific point-of-sale claim edit, in accordance with requirements at §423.153(f)(3).[33]

1. Definition of Exempted Beneficiary (§423.100)

At §423.100, CMS defines an exempted beneficiary as an enrollee being treated for active cancer-related pain or who has sickle-cell disease, resides in a long-term care facility, has elected to receive hospice care, or is receiving palliative or end-of-life care. These criteria, finalized in 2018, were based on feedback and available information, including the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (2016 CDC Guideline) issued in March 2016. There is now a 2022 CDC Guideline, with updated evidence-based recommendations.

To align with the 2022 CDC Guideline, CMS proposed to amend the regulatory definition of "exempted beneficiary" by replacing "active cancer-related pain" with "cancer-related pain." This change would more broadly refer to enrollees being treated for cancer-related pain, including beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

CMS finalizes its proposal, without modification, to amend the regulatory definition of "exemption beneficiary" replacing the reference to "active cancer-related pain" with "cancer-related pain".

[32] The 20-patient threshold is consistent with the minimum denominator requirement of several quality measures, including many at the clinician-level in the Merit-based incentive payment system (MIPS) in Traditional Medicare.
[33] CMS regulations at §423.100 define exempted beneficiary, at-risk beneficiary, potential at-risk beneficiary, and frequently abused drug.

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

The statute requires that a sponsor send an initial and second notice to an ARB prior to imposing a limit on FADs based on the OMS criteria, adopted in regulation in 2018. Specifically:

- The initial notice must inform the beneficiary that they have been identified as a PARB and must include required information (§423.153(f)(5)(ii)).
- Within 30 days of the initial notice, the second notice must be sent, informing the beneficiary that they have been identified as an ARB and of the limitations on the beneficiary's coverage of FADs (§423.153(f)(6)(ii)).
- After sending an initial notice, if a sponsor determines that a PARB is not an ARB, a second notice would not be sent. Although not required by statute, current regulations require the "alternate second notice" be sent to inform the beneficiary that they are not an ARB and that no limitation on their coverage of FADs will be implemented under the DMP.

CMS requires sponsors to send either the second or alternate second notice on a date *not less than* 30 days from the date of the initial notice and not later than the earlier of the date the sponsor makes the determination or 60 days after the date of the initial notice. In some cases, sponsors identify exemptions very quickly after issuing the initial notice, prior to 30 days elapsing.

Based on program experience during the first several years of DMPs, CMS proposed that for a beneficiary who is determined to be exempt from the DMP after receiving an initial notice, the sponsor must provide the alternate second notice within 3 days of determining the beneficiary is exempt, even if this occurs less than 30 days from the date of the initial notice.[34] In other words, CMS proposed to remove the requirement that sponsors wait at least 30 days from the date of the initial notice to send the alternate second notice to *exempted beneficiaries*.[35] However, in other situations, CMS believes the existing 30-day requirement before a sponsor may send an alternate second notice is important to maintain because it allows the beneficiary and other prescribers enough time to provide the sponsor with information that may influence the sponsor's determination.

Because sponsors may not always be able to issue printed notices on the exact day they make a determination—for example, because they made the determination on a day when there is no USPS mail service—CMS proposed to add at §423.153(f)(8)(i)(A) a window for sponsors of up to 3 days to allow for printing and mailing the second notice or alternate second notice.

CMS finalizes its proposal without modification.

[34] As a temporary solution, CMS released DMP guidance in April 2023 that in such a situation where less than 30 days have passed since the initial notice, the sponsor should send a Part D Drug Management Program Retraction Notice for Exempted Beneficiaries, rescinding the initial notice. After the effective date of this provision (for coverage beginning January 1, 2025), the retraction notice will no longer be used.

[35] The agency reminds Part D sponsors that, during their review and case management, they are expected to use all available information to identify whether a PARB is exempt *before* sending an initial notice.

3. Request for Feedback on OMS Criteria

Regulations at §423.153(f)(16) provide detailed definitions of PARBs and ARBs, based on clinical guidelines developed with stakeholder consultation and on expert opinion backed by analysis of Medicare data. The agency reviews these definitions, their evolution, and the evidence behind them. In this section, no regulatory changes were proposed, but CMS provided its own detailed analyses and sought feedback on its machine learning model and how guidelines might be developed for implementing the model into the existing DMP and OMS processes.

While overall opioid-related overdose prevalence rates among Part D enrollees declined from 2017 through 2021 at about 6.5 percent per annum, they increased by 1.0 percent between 2020 and 2021. About 1.6 percent of all Part D enrollees had a provider-diagnosed OUD in 2021, and the OUD prevalence rate has grown by 3.2 percent per annum since contract year 2017. A past overdose is the risk factor most predictive for another overdose or suicide-related event. A recently published article that evaluated the use of machine learning algorithms for predicting opioid overdose risk among Medicare beneficiaries taking at least one opioid prescription concluded that the machine learning algorithms appear to perform well for risk prediction and stratification of opioid overdose especially in identifying low-risk groups having minimal risk of overdose.

The agency recounts how, in the proposed rule, it offered no changes to the clinical guidelines or OMS criteria but provided detailed information on its own recent data analysis and welcomed feedback for future changes. Its data analysis of nearly 7 million Medicare beneficiaries was intended to determine the top risk factors for Part D enrollees at high risk for one of two outcomes: (1) having a new opioid poisoning (overdose) or (2) developing newly diagnosed OUD. Since Part D enrollees with a known opioid-related overdose are already identified in OMS, CMS focused on individuals at high risk for a new opioid-related overdose or OUD.

After an explanation of the data (from October 1, 2021 through March 31, 2022), variables, and analytic approach, CMS described the factors found to contribute most to a new OUD or opioid-related overdose diagnosis—for example, the number of short-acting prescription opioid fills. With that, the model was tested to predict new opioid-related overdose events and OUD diagnoses during the period from April 1 to September 30, 2022. Between 9 percent and 15 percent of the beneficiaries with a predicted new opioid-related overdose/OUD actually experienced a new overdose or OUD diagnosis during the evaluation period, among many other findings.

From its analysis, CMS concludes that there was very little overlap between the population identified through its modeling and beneficiaries already identified through the OMS, confirming that machine learning models can analyze large datasets and identify complex patterns not easily discernible by current non-statistical approaches. This makes them a powerful tool for identifying new opioid-related overdose or OUD risk and capturing an additional population of potential at-risk beneficiaries who have not been identified through the current OMS criteria.

As CMS plans its next steps, it solicited feedback on a number of related topics, including potentially using such a model to enhance the minimum or supplemental OMS criteria (either in addition to the current criteria or as a replacement).

Selected Comments/Responses. Commenters supported CMS' machine learning model approach or further testing. Several encouraged CMS to provide a demographic breakdown or the fairness analysis used to evaluate the model and to use clearly defined risk factors that foster case management, ensure correctness of the risk factors used, or focus on distinguishing factors to identify at-risk beneficiaries and to minimize misapplication of the criteria for beneficiaries with low risk of overdose or OUD. CMS thanks the commenters for their support of its machine learning model approach and will consider the feedback as it proceeds with further testing to improve the model and risk factors.

M. Codification of Complaints Resolution Timelines and Other Requirements Related to the Complaints Tracking Module (CTM)

The CTM in the HPMS is the central repository for complaints received by CMS from various sources, including the Medicare Ombudsman, CMS contractors, 1-800-MEDICARE, and CMS websites. Complaints from beneficiaries, providers and their representatives regarding their MAOs, Cost plans, PACE organizations, and Part D sponsors—hereafter in this section referred to as "plans"—are recorded in the CTM and assigned to the organization determined by CMS to be responsible for resolving the complaint.[36] CMS reviews relevant subregulatory guidance related to the CTM.

In §§417.472(l) and 460.119, CMS proposed to codify existing guidance regarding the timeliness of complaint resolution by plans in the CTM to include Cost plans and PACE organizations, not just MAOs and Part D sponsors as in current regulations (§§422.504(a)(15) and 423.505(b)(22)). In new §§422.125 and 423.129. The agency also proposed to codify in detail the existing priority levels for complaints[37] based on how quickly a beneficiary needs to access care or services, along with a new requirement for plans to make first contact with individuals filing non-immediate need complaints within 3 days.[38]

[36] Requirements for resolution of complaints received in the CTM do not override regulatory requirements related to the handling of appeals and grievances. CTM requirements supplement the appeals and grievance requirements by specifying how plans must handle complaints received by CMS in the CTM and passed along to the plan. A beneficiary who filed a complaint directly with CMS may later contact CMS to find out the status of the complaint, and the plan's use of the system would allow CMS to answer the beneficiaries inquires more quickly. Plans must handle any CTM complaint that is also an appeal or grievance in such a way that complies with the notice, timeliness, procedural, and other requirements of the regulations governing appeals and grievances.

[37] See, for example, CMS HPMS "CTM Plan Standard Operational Procedures (SOP)," May 10, 2019. In addition, chapter 7, section 70.1 of the Prescription Drug Benefit Manual, "Medication Therapy Management and Quality Improvement Program," requires Part D sponsors to resolve any "immediate need" complaints within 2 days of receipt into the CTM and any "urgent" complaints within 7 days of receipt into the CTM. It also sets forth CMS' expectation that Part D sponsors promptly review CTM complaints and notify the enrollee of the plan's action as expeditiously as the case requires based on the enrollee's health status.

[38] This 3-day time frame for contact would not apply to immediate need complaints, which must be *resolved* within *2* days.

Specifically, in new §§422.125 and 423.129, CMS proposed to codify the following, which are substantially similar to current guidance for MA and Part D-related complaints:

- Definitions of "immediate need" and "urgent" complaints—
    - "Immediate need complaint" would mean a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need, including when the beneficiary currently has enough of the drug or supply to last for 2 or fewer days.
    - "Urgent complaint" would mean a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do *not* have an immediate need, including when the beneficiary currently has enough of the drug or supply to last for 3 to 14 days.
- Timeframes for resolving Part D and non-Part D complaints in the CTM—
    - A 2 calendar day deadline for immediate need complaints,
    - A 7 calendar day deadline for urgent complaints, and
    - For all others, within 30 days of receipt.

CMS does not anticipate that plans will have difficulty meeting these timeframes, since the vast majority (94 percent and higher) were resolved within these timelines in 2022.

Final Action. CMS finalizes its proposal with 4 significant modifications:

(1) Changing the requirement to *make* contact to a requirement to *attempt* contact;
(2) Adding language that permits the extension of time to resolve non-immediate need and non-urgent complaints that also qualify as non-expedited grievances in a manner consistent with the extension permitted for grievances under §§422.564, 422.630, and 423.564;
(3) Adding language that requires organizations to adhere to the shortest timeframe required by the regulation for CTM complaints and grievances when a CTM complaint also qualifies as a grievance; and
(4) Requiring that organizations contact individuals filing complaints within 7 calendar days (rather than 3 calendar days).

Select Comments/Responses. Comments were generally supportive, with many commenters representing plans requesting more flexibility, while some representing beneficiaries and providers requested more stringent requirements and improved transparency.

In response to specific comments and concerns, CMS made the changes described above. For example, one commenter requested clarification of whether CMS expects all complaints to be treated as appeals or grievances and, if not, whether complaints that are appeals or grievances would be held to the CTM timeframes in addition to the appeals and grievance timeframes. In response, CMS clarifies that CTM complaints should only be treated as appeals or grievances when they otherwise meet the regulatory definition of appeals or grievances. MA and Part D appeals and grievances must be resolved "as expeditiously as the case requires," which would require resolution of the appeal or grievance within the finalized timeframe for immediate need and urgent complaints. While existing regulations permit the 30-day timeframe resolution of grievances to be extended by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the

interest of the enrollee, the stricter timing requirements for CTM complaints finalized here will control where a CTM complaint has been filed.

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

Because existing regulations explicitly permit extension for MA and Part D appeals and grievances, CMS did not think it appropriate to penalize an organization for extending the resolution of a *non-immediate* need and *non-urgent* CTM complaint that meets the definition of an MA or Part D appeal or grievance. Therefore, the agency adds a new paragraph (4) to §§422.125(b) and 423.129(b) to allow organizations to extend the timeline to respond to a CTM complaint if the complaint is also a grievance and if it meets the requirements for an extension of time. This extension will not be available for any complaint that meets the definition of an immediate need complaint or urgent complaint or that requires expedited treatment under §§422.564(f), 422.630(d), or 423.564(f) because such a delay would present an unacceptable risk of harm to the beneficiary.

PACE organizations are not permitted to extend the 30-day timeframe for resolution grievances under the revisions to §460.120 finalized in this rule or for non-expedited appeals under §460.122(c)(6), and service determinations must be resolved within eight days even with the permitted five-day extension under §460.121(i), so it is not necessary to allow an extension of the 30-day timeline for non-immediate need and non-urgent complaints that also qualify as PACE grievances, service determination requests, or appeals.

CMS acknowledges the potential conflict between various timelines. The agency says it did not intend to allow organizations to take longer to resolve an expedited MA or Part D grievance or PACE service determination request or expedited appeal than is currently required merely because it was received as a CTM complaint. Therefore, a new paragraph (5) is added to §§422.125(b) and 423.129(b) to make clear, as described above, 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.

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

In section III.Q. of the proposed rule for Contract Year 2024, CMS proposed a number of changes to its regulations which permit Part D sponsors to get approval to make changes to a formulary previously approved by CMS, including extending the scope of immediate formulary substitutions and requiring Part D sponsors to provide notice of those changes. CMS received comments on its proposals but did not finalize them. In response to those comments, in the proposed rule for Contract Year 2025, the agency proposed what it described as a limited number of changes to the proposed regulatory text relating to section III.Q. of the Contract Year 2024 proposed rule.

The significant proposed changes in the Contract Year 2025 proposed rule were (i) to define a new term, "biosimilar biological product," which would be distinct from the previously proposed term "interchangeable biological products" but would include interchangeable biological products; (ii) to permit substitution of biosimilar biological products (other than interchangeable biological products) for reference products as a maintenance change, with 30 days advance notice to enrollees; and (iii) to permit Part D sponsors to make a negative formulary change to the related drug within a certain period (30 days for immediate changes and 90 days for certain maintenance changes) following the addition of the corresponding drug—rather than at the same time they add the corresponding drug.

CMS finalizes its proposals, as updated by changes in the Contract Year 2025 proposed rule, with only minor and technical modifications described below. Under the final rule, CMS permits the following changes to drugs currently provided on a plan's formulary:

- Immediate substitutions of corresponding drugs for a brand name drug, a reference product, or a brand name biological product, such as new generic drugs for brand name drugs and interchangeable biological products for reference products;
- Immediate removal of drugs withdrawn from sale by their manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons;
- Maintenance changes, which include substitutions of generic drugs for brand name drugs that are not being made on an immediate substitution basis, substitutions of interchangeable biological products for their reference products, and removals based on long term shortage and market availability;
- Non-maintenance changes, which can only be made if CMS provides explicit approval and which do not apply to enrollees currently taking the applicable drug; and
- Enhancements to the formulary (for instance, Part D sponsors can add a drug to the formulary or lower its cost-sharing), which can be made at any time.

Notice requirements, which are described below, are finalized without modification.

1. Approval of Changes to Approved Formularies

CMS has implemented a multi-step process for review and approval of formularies, including formulary and tiered formulary structure, to ensure they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Anticipating that formularies may change due to new developments, it supports small scale, mid-year formulary changes that allow enrollees to

quickly benefit from the latest clinical research, new potentially lower-cost options, or possibly better health outcomes. Some commenters objected to any formulary changes during the plan year because enrollees selected Part D plans based on their expectations of which drugs were on the formulary. CMS does not believe formularies should be static for the plan year, and it notes section 1860D-4(b)(3)(E) of the Act contemplates formulary changes during the plan year.

CMS finalizes the proposed codification of its sub-regulatory process for reviewing and approving changes to approved formularies. It defines several types of formulary changes, adopts rules for agency approval of negative formulary changes, revises requirements for implementation of certain formulary changes that may be made immediately, and updates and streamlines notice requirements. Several key terms are added to §423.100 as follows:

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is subject to a negative formulary change that affects the Part D enrollee's access to the drug during the current plan year. This extends beyond removal or change in preferred or tiered cost-sharing status.

Negative formulary change means one of the following changes with respect to a covered Part D drug:

1. Removing a drug from a formulary.
2. Moving a drug to a higher cost-sharing tier.
3. Adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements.

Negative formulary changes do not include safety-based claim edits which are not submitted to CMS as part of the formulary; however, they do include adding PA, ST, or QL requirements to a drug for the first time, making existing applicable PA or ST requirements more restrictive, or making QL edits more restrictive by reducing allowances (e.g., reducing a daily dose from two tablets per day to one tablet per day) unless the reduction is a safety edit.

Currently, a negative formulary change is either a maintenance or non-maintenance change. Maintenance changes are generally expected to pose a minimal risk of disrupting drug therapy or are needed to address safety concerns or administrative needs.

Immediate negative formulary change means an immediate substitution or a market withdrawal. This is a new category intended to capture certain negative formulary changes that may be made immediately if they fall within certain parameters described below, which Part D sponsors may implement as maintenance changes.

Maintenance change means one of the following negative formulary changes with respect to a covered Part D drug:

1. Making any negative formulary change to a drug within 90 days of adding a corresponding drug to the same or lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements (other than immediate substitutions).
2. Making any negative formulary change to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that

reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.
3. Removing a non-Part D drug.
4. Adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning.
5. Removing a drug withdrawn from sale by the manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons if the Part D sponsor chooses not to treat it as an immediate negative formulary change.
6. Removing a drug based on long-term shortage and market availability.
7. Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization.
8. Adding PA to help determine Part B versus Part D coverage.

CMS clarifies that Part D sponsors may ask to apply more than one negative formulary change simultaneously to a drug. In the Contract Year 2024 proposal, the provisions for making negative formulary changes permitted the change to be made at the same time the corresponding drug is added, subject to other conditions. CMS was concerned that this requirement might cause sponsors to delay adding a corresponding drug or biosimilar biological product (other than an interchangeable biological product) until they operationalize the negative changes to the brand name drug or reference product currently on the formulary. Instead, for the negative changes described in paragraphs 1. and 2. above, it codifies its current operational limitation of a 90-day timeframe for a Part D sponsor to remove a brand name drug from the formulary when a generic drug is added.

Some commenters asked the agency to add more categories of maintenance changes, including applying PA to exclude non-Part D drugs or to reflect new indications or placing PA or ST on protected class drugs specified under section 1860D-4(b)(3)(G)(iv) of the Act to ensure they are used for protected indications. CMS indicates it did not propose to do so though it may consider the additions for future rulemaking.

Non-maintenance change means a negative formulary change that is not a maintenance change or an immediate negative formulary change. These are negative formulary changes that limit access to a specific drug without implementing a corresponding offset (such as adding an equivalent drug) or addressing safety or administrative needs.

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.

Other specified entities are State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists.

CMS also adds new terms and their definitions, and makes modifications to the existing definitions of terms, in §423.4.

Biological product means a product licensed under PHSA section 351.

Biosimilar biological product means a biological product licensed under PHSA section 351(k) that, in accordance with PHSA section 351(i)(2), is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and has no clinically meaningful differences between the biological product and the reference product, in terms of the safety, purity, and potency of the product.

Brand name biological product means a product licensed under PHSA section 351(a) or 351(k) and marketed under a brand name.

Interchangeable biological product means a product licensed under PHSA section 351(k) that the FDA has determined meets the standards described in PHSA section 351(k)(4), which in accordance with PHSA section 351(i)(3), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. In response to comment, CMS modifies the definition by adding a reference to the standards described in PHSA section 351(k)(4) to make the regulatory definition align more closely with the statutory language.

Reference product means a product as defined in PHSA section 351(i)(4). In the proposed rule, the term used was "reference biological product." In the final rule, CMS strikes "biological" from the term.

Unbranded biological product means a product licensed under a biologics license application (BLA) under PHSA section 351(a) or 351(k) and marketed without a brand name. It is licensed under the same BLA as the corresponding brand name biological product.

2. Approval and Implementation of Maintenance and Non-Maintenance Changes

Generally, a Part D sponsor may not make a negative formulary change to its CMS-approved formulary unless it submits a request to CMS. This requirement does not apply to immediate negative formulary changes described below.

Negative change requests for maintenance changes are deemed approved within 30 days of submission, unless CMS notifies the sponsor to the contrary. Non-maintenance changes may not be implemented by Part D sponsors until they receive notice of approval from CMS, and affected enrollees will be exempt from non-maintenance changes for the remainder of the contract year.

Sponsors may not make a negative formulary change that takes effect between the beginning of the annual coordinated election period and 60 days after the beginning of the contract year associated with that annual coordinated election period. However, this prohibition does not apply in the case of immediate negative formulary changes for immediate substitutions or market withdrawals.

A commenter observed that a product that is identical in all respects because it is approved or licensed under the same NDA or BLA (e.g., an authorized generic or unbranded biological

product) should not be considered a "negative" formulary change, immediate or otherwise. While the agency agrees that technically the commenter is correct, it nonetheless finalizes the proposal to treat all these substitutions as replacements, noting that an enrollee at the pharmacy would not know the difference between an authorized generic and a generic drug.

3. Immediate Negative Formulary Changes

The general requirement for a request to make a change to an approved formulary does not apply to immediate negative formulary changes, which are for immediate substitutions or market withdrawals. Immediate negative formulary changes for market withdrawal are allowed when a Part D drug is deemed unsafe by the FDA or withdrawn from sale by the manufacturer.

Immediate Substitutions. Under the final rule, a Part D sponsor may make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary where the sponsor could not have included that corresponding drug on its formulary when it submitted its initial formulary for CMS approval because such drug was not yet available on the market. The authority is subject to certain conditions:

- The corresponding drug must be placed on the same or lower cost sharing tier of the formulary.
- The corresponding drug must have the same or less restrictive formulary PA, ST, or QL requirements.
- The sponsor has provided advance general notice specified in §423.120(f)(2).

As originally proposed, immediate substitutions would have required the sponsor to simultaneously add a corresponding drug to its formulary on the same or lower cost-sharing tier and with the same or less restrictive formulary PA, ST, or QL requirements. In response to commentors who noted that the "at the same time" standard might discourage sponsors from adding new corresponding drugs, CMS permits negative formulary changes as immediate substitutions if made within 30 days of adding a corresponding drug to a formulary. Other commenters believe CMS should have retained the contemporaneous notice requirement in these circumstances. The agency notes that the main reason it does not require advance direct notice of specific changes in these cases is to support and encourage Part D sponsors to add corresponding drugs to their formularies as soon as possible.

A Part D sponsor that otherwise meets the requirements for immediate substitution that adds a corresponding drug, and chooses to retain (rather than remove) the drug currently on its formulary, may apply more than one negative formulary change to that drug (e.g., add an interchangeable biologic product to the formulary and both move the reference product currently on the formulary to a higher cost-sharing tier and add PA requirements).

Permissible immediate substitutions may apply to generic equivalents, authorized generics and for certain biological products. Authorized generics are defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act. They are marketed under their corresponding brand name drug's NDA and are the exact same drug product as their corresponding brand name drugs. For biological products, CMS includes the substitution of interchangeable biological products

and unbranded biological products when immediate substitution would not disrupt existing therapy. CMS states that both of these products are the same products as the brand name biological product. In response to comment, CMS clarifies that to make an immediate substitution, the generic drug being added to the formulary must be newly available.

In the final rule, CMS includes the substitution of biosimilar biological products (other than interchangeable biological products) for their reference products as maintenance changes. CMS reasons that FDA standards for approval should provide health care providers and patients confidence in the safety and effectiveness of all biosimilar biological products, just as they do for their reference products. It believes this policy strikes the right balance between promoting utilization of more biosimilar biological products and providing enrollees with sufficient advance notice of the changes. However, immediate substitutions of reference products for biosimilar biological products (other than interchangeable biological products) without 30 days advance notice is not permitted.

The substitution will work as follows:

- The removal or making of any negative changes to a reference product requires the addition of a biosimilar biological product (other than an interchangeable biological product) at the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements as the reference product.
- 30 days advance written notice is required before making any negative change to the reference product. The notice must include information on the change, cost-sharing and utilization management restrictions, appropriate alternatives at the same or lower cost-sharing tier as the reference product, and how to request a coverage determination or exception to a coverage rule. In the final rule, CMS makes a modification to the regulation text at §423.120(f)(4)(v) to clarify that an exception is a type of coverage determination.

Part D sponsors making any immediate negative formulary changes—that is market withdrawals or immediate substitutions, are not required to provide transition supplies of the affected biological products. Some commenters objected to this policy, asking that CMS impose a transition supply policy for immediate substitutions and maintenance changes. The agency responds that this policy has been in place for the substitution of generic drugs for brand name drugs for some time and has not been the subject of widespread complaints. Further, having disparate policies for different categories of substitutions would cause confusion and add administrative burden. It also believes the 30-day notice requirement for maintenance changes is effectively a type of transition policy.

CMS clarifies a number of points in response to comments. First, the following substitutions will not be allowed as immediate substitutions:

- A brand name drug for an authorized generic drug.
- A generic drug for an authorized generic drug.
- An authorized generic drug for a generic drug.
- An interchangeable biological product for another interchangeable biological product that may be interchangeable with the same reference product.

It also says the definitions of maintenance change and immediate substitution would not permit, as a maintenance change, substitutions among biosimilar biological products (including interchangeable biological products) that share the same reference product. CMS also notes that it could revisit these policies in the future.

Additionally, the notice requirement for a list of alternative drugs is clarified to be those alternative drugs on the plan's formulary.

4. Notice Requirements

CMS makes changes to its notice requirements for formulary changes, which it believes will both update and streamline current policies. Only maintenance and non-maintenance negative formulary changes will require 30 days' advance notice to CMS and other specified entities. Notice to CMS is satisfied when the sponsor submits a negative change request to the agency. Additionally, a written notice must be provided to affected enrollees at least 30 days before the date the change becomes effective. Alternatively, when an affected enrollee requests a refill of the Part D drug, the Part D sponsor could provide the affected enrollee with an approved month's supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change. However, for non-maintenance changes, Part D sponsors may not provide notice to other specified entities or affected enrollees, or otherwise update formularies or other materials, until CMS has approved the non-maintenance change.

Some commenters objected to the 30-day notice, seeking a longer period. The agency feels, based on its experience and a lack of widespread complaints, 30 days is adequate for this purpose. It also clarifies that "days" as used in regulations for the notice and approval of changes refers to "calendar days."

CMS requires online notice of negative formulary changes for other specified entities (i.e., State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists).

For other formulary changes, Part D sponsors must provide advance general notice to all current and prospective enrollees and other specified entities, in formulary and other relevant beneficiary communication materials, advising that the formulary may change subject to CMS requirements. The notice must include information on how to access the plan's online formulary and how to contact the plan as well as a statement that the written notice of any change, when provided, will describe the specific drugs involved. The advance written notice must also contain information on the steps that enrollees may take to request coverage determinations and exceptions. The advance general notice of immediate substitutions is provided to CMS during the bid submission process, and the advance general notice of market withdrawals is provided to CMS in the advance notice of immediate negative formulary changes that Part D sponsors provide to enrollees and other specified entities.

Affected enrollees must be notified in writing as soon as possible but in no case later than the end of the month following any month in which an immediate negative formulary change takes effect. The content for direct written notices is mostly the same as is currently required for

immediate generic drug substitutions, with the removal of the requirement that alternative drugs must be in the same therapeutic category or class. Some commenters objected to expanding the list of alternative drugs included in the notice beyond those in the same therapeutic category or class; they worried that plans may use this flexibility to switch enrollees to drugs with different forms or modes of therapeutic action. The agency indicates that the notice does not dictate what types of drugs may be substituted or the conditions for making those substitutions; those rules are established in clause (iv) of §423.120(b)(5) and specify the drugs that may be substituted. The notice requirement under clause (ii) of §423.120(b)(5) for a list of alternatives is intended to notify the enrollee and provider of multiple drug options, some of which they may not have considered.

One commenter indicated that CMS' proposals assume all enrollees receive and understand notices of mid-year formulary changes, whereas the reality is different, especially for enrollees with low health literacy, language barriers, or cognitive impairments. Additionally, enrollees from socioeconomically disadvantaged communities and those experiencing major health challenges such as rare diseases may not be capable of navigating the exceptions process. The agency responds that it has in place several requirements and resources to protect and assist these enrollees.

CMS had proposed a technical amendment to the section of the regulations[39] that requires the inclusion on sponsors' formularies of each covered Part D drug that is a selected drug under the Drug Price Negotiation Program for which a maximum fair price is in effect with respect to the plan yean. It does not finalize the proposed language in §423.120(b)(5) to identify a successor regulation at this time because the provision does not apply for the 2025 plan year.

O. Parallel Marketing and Enrollment Sanctions Following a Contract Termination

CMS reviews the statute and regulations regarding the situations under which CMS may terminate MA and PDP contracts or, for the same situations, impose intermediate sanctions and civil monetary penalties (CMPs). If CMS terminates a contract during the plan year but the termination is not effective until January 1 of the following year, the plan could potentially continue to market and enroll beneficiaries, unless CMS imposes separate marketing and enrollment sanctions. A terminating contract that continues to market to and enroll eligible beneficiaries would cause confusion and disruption for those who enroll between when the termination action is taken and the January 1 effective date.

CMS proposed to add paragraph (e) to §422.510 and paragraph (f) to §423.509 so that, effective contract year 2025, marketing and enrollment sanctions will automatically take effect after a termination is imposed—15 days after CMS issues a contract termination notice. This timeframe is consistent with the number of days CMS often designates as the effective date for sanctions after issuing a sanction notice. As proposed, if an MAO or Part D sponsor appeals the contract termination, the marketing and enrollment sanctions will not be stayed pending the appeal. Finally, the sanction would remain in effect until the effective date of the termination—or, if the

[39] Beginning with the 2026 plan year, section 1860D-4(b)(3)(I)(i) of the Act requires sponsors to include on their formularies each covered Part D drug that is a selected drug under the Drug Price Negotiation Program enacted as part of the Inflation Reduction Act for which a maximum fair price is in effect with respect to the plan year.

termination decision is overturned on appeal, until the final decision to overturn the termination is made by the hearing officer or CMS Administrator.

Several commenters expressed support for the proposal, which CMS finalizes without modification.

P. Update to the Multi-Language Insert Regulation

CMS cites research regarding how individuals with limited English proficiency (LEP) experience obstacles to accessing health care and how language barriers negatively affect the ability of patients with LEP to understand their diagnoses and medical instructions when they are delivered in English. This can impact, for example, their comfort with post-discharge care regimens. Although the use of qualified interpreters is effective in improving care for patients with LEP, some clinicians choose not to use them, fail to use them effectively, or rely instead on ad hoc interpreters such as family members or untrained bilingual staff. In addition to posing legal and ethical concerns, ad hoc interpreters are more likely to make mistakes than professional interpreters. Clinicians with basic or intermediate non-English spoken language skills often attempt to communicate with the patient without using an interpreter, increasing patient risk. These barriers contribute to disparities in health outcomes for individuals with LEP, which likely worsened during the COVID-19 pandemic.

The multi-language insert (MLI) required at §§422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.[40] Plans are also required to provide the MLI in any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area but is not already included on the MLI. The MLI states, "We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service."[41]

In short, Section 1557 of the Affordable Care Act (ACA) prohibits discrimination in federal health programs. Beginning May 2016, the HHS Office for Civil Rights (OCR) published rules based on section 1557 that required applicable "significant communications" to have a tagline for non-English speakers. CMS reviews some of this history but also notes that none of that rulemaking impacts the various notifications of interpreter services required of MAOs, Part D sponsors, or cost plans to provide these services under applicable law.

OCR's latest proposed rule on this issue, proposed August 2022 (87 FR 47853), has not been finalized but would result in misalignment with the MLI requirements for MA and Part D. The

[40] These are the 15 most common non-English languages in the United States.

[41] These requirements also apply to Cost plans per §417.428. Note, the issuance of the MLI is independent of the Medicare written translation requirements for any non-English language that meets the 5 percent threshold, as currently required under §§422.2267(a)(2) and 423.2267(a)(2), and the additional written translation requirements for fully integrated D-SNPs (FIDE SNPs) and highly integrated D-SNPs (HIDE SNPs) provided in §§422.2267(a)(4) and 423.3367(a)(4).

agency also notes conflicts between MLI requirements for MA and Part D plans versus Medicaid requirements (for example, at §438.10(d)(2)). Any applicable integrated plans (AIPs, §422.561) must then comply with these regulatory requirements for *both* Medicare and Medicaid, which can result in a very long multi-page list of statements noting the availability of translations services in many languages and distract from the main information conveyed in the material.

CMS proposed to update §§422.2267(e)(31) and 423.2267(e)(33) to require that notice of availability of language assistance services and auxiliary aids and services be provided in the 15 most common languages in a state, to better align with Medicaid translation requirements at §438.10(d)(2) and more closely reflect the actual languages spoken in the service area. If the OCR final rule differs from the original August 2022 proposed rule, CMS will consider modifying its final rule accordingly.

Specifically, CMS proposed the following changes to §§422.2267(e)(31) and 423.2267(e)(33):

- Replace references to the MLI with references to a Notice of Availability, which would be a model communication material rather than a standardized communication material; CMS would no longer specify the exact text that must be used in the required notice.
- Require MAOs and Part D sponsors to provide enrollees a notice of availability of language assistance services and auxiliary aids[42] and services that, at a minimum, says that MAOs and Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge.
- The Notice of Availability must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant state and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.
- If there are additional languages in a particular service area that meet the 5 percent service area threshold,[43] the Notice of Availability must also be translated into those languages, similar to the current MLI requirement.

Final Action. CMS finalizes its proposal on the Notice of Availability with the following modifications, some of which are discussed in greater detail in the comment/response section:

- Delaying the applicability date to marketing beginning for contract year 2026—September 30, 2025—with the option to begin in contract year 2025.
- The Notice of Availability must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant state *or states* associated with the plan's service area.

Selected Comments/Responses. Many commenters supported CMS' proposal. The Medicaid and CHIP Payment and Access Commission (MACPAC) noted that the change aligns with work they have underway, more closely aligns Medicare requirements with existing Medicaid standards, reduces administrative burden on health plans, and may reduce health disparities for beneficiaries whose primary language is not English. A commenter stated that integrated

[42] For a definition of auxiliary aids, CMS points to 45 CFR 92.102(b)(1).
[43] Annually, CMS provides the non-English languages meeting the 5 percent threshold for each plan in the HPMS Material Language Lookup functionality in the Marketing Review Module. Most recently (based on September 25, 2023 HPMS memo), CMS provided these languages for each Contract Year 2024 plan.

Medicare and Medicaid plans have been experiencing this conflict between Medicaid requirements and Medicare MLI requirements for many years. CMS said it appreciates the "widespread support" for its proposal.

A few commenters opposed the proposal, saying that it would place an undue administrative burden on plans, including national subcontractors that work with multiple plans across multiple states. CMS shares the concerns about plans that have a service area covering multiple states and that requiring such plans to include the Notice of Availability in at least the top 15 non-English languages in each state in the plan's service area, potentially resulting in many more than 15 languages, may cause enrollee confusion and undue administrative and financial burden to the plan. As a result, it is updating the regulation to require the Notice of Availability to be provided in at least the top 15 languages most commonly spoken by individuals with LEP within the state *or states* associated with the plan benefit package service area, consistent with the section 1557 proposed rule. Thus, plans may aggregate the populations with LEP across all states in the service area for determining the 15 languages for the Notice of Availability.

As an example, if a plan's service area consists of Connecticut, New Jersey and New York, the plan may aggregate the populations with LEP across those 3 states to determine the 15 languages for its Notice of Availability. If the service area does not include an entire state, the plans should still use the top 15 languages for the entire state.

Several commenters requested that the agency work with OCR and Medicaid to ensure consistency between its proposal, the OCR section 1557 final rule, and Medicaid regulations. CMS says it is striving to achieve this goal by better aligning Medicare regulations at 42 CFR §§422.2267(a)(2) and 423.2267(a)(2) with OCR regulations at 45 CFR §92.11 and Medicaid regulations at 42 CFR §438.10(d)(2). CMS has worked closely with OCR, the CMS Center for Consumer Information and Insurance Oversight (CCIIO), and other offices throughout the drafting of this rule to ensure alignment of regulations and mitigate burden on plans.

Several commenters opposed the use of a model notice instead of standardized language for the Notice of Availability, with one commenter expressing concern that a model notice may result in more errors. Others supported the flexibility. To mitigate errors in messaging, CMS says it specified that the Notice of Availability must include, at minimum, a statement that the MAO provides language assistance services and appropriate auxiliary aids and services free of charge. In addition, for the purpose of compliance with section 1557 of the ACA, OCR will be providing model language translated into the 15 languages most commonly spoken by individuals with LEP in every state and nationally that plans can use as a template to comply with the proposed CMS notice requirements. Also, allowing the use of a model Notice of Availability provides flexibility for D-SNPs in states that may require the use of a specific tagline or Notice language so that they do not have to include additional language in materials. Allowing this flexibility along with the OCR model language outweighs the risk of errors in messaging, according to CMS.

In response to concerns about the timing of implementing this provision, CMS modified the language in this final rule to allow plans to continue using the MLI until the beginning of contract year 2026 marketing on September 30, 2025. Plans will have the choice to use the

Notice of Availability to satisfy the MLI requirement for marketing for contract year 2025 (September 30, 2024).

Q. Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§422.310)

Federal law requires CMS to risk-adjust payments to MAOs based on data MAOs must submit on the services provided to enrollees and other information the Secretary deems necessary. The implementing regulation (§422.310) requires MAOs to submit MA encounter data, which are comprehensive data equivalent to Medicare FFS data. The agency describes other statutes and regulations, and their evolution, pertaining to the release of MA encounter data (or "risk adjustment data," as referred to in regulation).

Current regulations permit the release of MA encounter data to other HHS agencies, other federal executive branch agencies, states, and external entities, but only in specified circumstances—for example, only after risk adjustment reconciliation for the applicable payment year has been completed. Currently, states' ability to obtain MA encounter data for program analysis and evaluations or program administration for dual eligibles in an MA plan is limited to support of a Medicare-Medicaid demonstration. Current regulation text does not otherwise permit CMS to make MA encounter data available to states for Medicaid program administration or to conduct evaluations and other analyses for the Medicaid program.

1. Expanding Access to MA Encounter Data for State Medicaid Agencies

CMS proposed to add "and Medicaid program" to the current MA encounter data use purposes codified at § 422.310(f)(1)(vi) and (vii), explaining that these additions would enable CMS to use the data and release it (in accordance with §422.310(f)(2) and (3)) for the purposes of evaluation and analysis and program administration for Medicare, Medicaid, or Medicare and Medicaid combined purposes. The release to states of MA encounter data for data use purposes that support the Medicare and Medicaid programs would, among other things, support the responsibility to improve the quality of health care and long-term services for dually eligible individuals.

CMS notes that its usual data sharing procedures will apply to the release of MA encounter data in accordance with §422.310(f)(2) and address access to and storage of CMS data to ensure that beneficiary identifiable information is protected. The agency employs data sharing agreements, such as a Data Use Agreement and Information Exchange Agreement, that limit external entities to CMS-approved data uses and disclosure. For example, states requesting data for care coordination and program integrity initiatives may disclose the data to its contractors, vendors, or other business associates; in accordance with CMS data sharing agreements, these state contractors, vendors, or other business associates must also follow the terms and conditions for use of the CMS data, including limiting use of the CMS-provided data only for approved purposes. Under this rule, states receiving MA encounter data for care coordination may disclose MA encounter data to Medicaid managed care plans to coordinate services for enrolled dual eligibles.

Comments submitted on the August 2014 final rule (79 FR 50328) cited concerns that access to MA encounter data could permit a competitor to gain an advantage by trending cost and utilization patterns over a number of years. Given that §422.310(f)(2)(iv) provides for aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data and that any release of MA encounter data to states would comply with applicable statutes, regulations and processes, CMS believes that concern around potential competitive advantage is mitigated if the risk exists at all. CMS intends to only approve requests for MA encounter data that have clear written data use justifications and identify any downstream disclosure—such as to state contractors, vendors, or other business associates—for each requested purpose.

2. Permitting State Medicaid Agencies to Receive MA Encounter Data Prior to Reconciliation

Current regulations provide that MA encounter data will not become available for release until the risk adjustment reconciliation for the applicable payment year has been completed or under certain emergency preparedness or extraordinary circumstances (§422.310(f)(3)). Current regulations also specify deadlines for determining which risk adjustment data submissions to consider for calculating risk scores and the reconciliation process for adjusting payments based on additional data submitted after the end of the MA risk adjustment data collection year, and other related policies (§422.310(g)). The current timing limitation on release of MA encounter data is tied to the established deadline for the payment year, resulting in a data lag of at least 13 months after the end of the MA risk adjustment data year (that is, the year during which the services were furnished) before CMS may release the MA risk adjustment data.

CMS believes that for purposes of care coordination, there will be increased utility of MA encounter data for Medicaid programs if the data is released before final reconciliation. Thus, it proposed adding a new §422.310(f)(3)(v) to allow for MA encounter data to be released to states for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a state Medicaid agency before reconciliation is necessary and appropriate to support authorized activities and uses authorized under paragraph (f)(1)(vii), as described above.

CMS proposed these amendments to §422.310(f) would be applicable on the effective date of the final rule. While the majority of the proposals in this rule would apply beginning January 1, 2025, the agency does not believe that delaying the applicability of these proposed amendments beyond the effective date of the final rule is necessary because they address CMS' authority to use and share MA encounter data and do not impose any additional obligations on MAOs.

Final Action. CMS finalizes its proposal without modification.

Selected Comments/Responses. The vast majority of commenters supported the proposal to expand the allowable MA encounter data uses and timing for states. CMS provided answers to implementation questions, including about how states may obtain technical assistance.

One commenter suggested that CMS include other data collected from or submitted by MAOs, such as data obtained from chart reviews, lab results, EMR records, and other clinical

documents. CMS says that current regulation at §422.310(f) specifies the purposes and procedures according to which it may use and release the MA risk adjustment data, which is defined in §422.310(a) and includes encounter data and other data submitted by MAOs for risk adjustment purposes (such as chart review records, which are reports of diagnoses, and may be sourced from chart reviews, lab results, EMR record or other clinical documents).

However, aside from the chart review records, any clinical documentation that CMS may have access to will not be released. The regulation at §422.310(f) excludes the use and release of the data for validation of risk adjustment data (§422.310(e)); this means that the medical records or other clinical documents that MAOs submit to validate their risk adjustment submissions are not released under § 422.310(f). CMS did not propose any changes to expand data sharing to include medical records or other clinical documents; therefore, CMS is not finalizing any regulatory changes related to sharing such information.

R. Standardize MA Risk Adjustment Data Validation (RADV) Appeals Process

CMS conducts RADV audits of MAOs' submitted diagnosis data from a selection of MAOs for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. Contract-level RADV audits are CMS' main corrective action for overpayments made to MAOs when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. CMS can collect improper payments identified during CMS and Department of Health and Human Services Office of Inspector General (HHS-OIG) audits, including the extrapolated amounts calculated by the OIG. The RADV audit appeals process, as outlined in §422.311, is applicable to both CMS and HHS-OIG audits and is therefore referred to as the "MA RADV audit appeals process."[44]

CMS proposed to revise certain timing issues for when RADV medical record review determination (MRRD) and payment error calculation (PEC) appeals can be requested and adjudicated—specifically, that MAOs must exhaust all levels of appeal for medical record review determinations before the payment error calculation appeals process can begin. Several other conforming amendments were proposed.

1. Current MA RADV Appeals Process

The process for MAOs to appeal RADV audit findings is outlined in §422.311(c)(6) through (8). Once the review of the medical records submitted by MAOs to support audited HCCs is completed and overpayment amounts calculated, HHS issues an audit report to each audited MAO contract, which must include a number of elements per §422.311(b)(1).

MAOs have 60 days from the date of issuance of a RADV audit report to file a written request for appeal and must follow the regulatory procedures and requirements. MAOs may appeal RADV medical record review determinations, the MA RADV payment error calculation, or both, and must specify the findings they are appealing. Under existing RADV audit appeals regulations at §422.311(c)(6) through (8), the MA RADV administrative audit appeals process

[44] For additional information regarding CMS' contract level RADV audits, see the RADV final rule, CMS-4185-F2, published on February 1, 2023 (88 FR 6643).

consists of three sequential levels—reconsideration, hearing, and CMS Administrator review—which is described in the rule's preamble for background information but is not revised by this regulation.

2. Proposed Policies, Finalized without Modification

Because RADV payment error calculations are based on the outcomes of medical record review determinations, CMS proposed to amend §422.311(c)(5)(iii) by providing that MAOs that 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.[45] The medical record review appeal process would be complete when (1) the medical record review determination appeals process has been exhausted through the three levels of appeal, or (2) when the MAO does not timely request a medical record review determination appeal for the hearing officer or CMS Administrator review stage. This would alleviate operational concerns for CMS and burden on MAOs by preventing unnecessary appeals of payment error calculations that will be moot if revisions must be made based on medical record review determination appeal decisions.

At §422.311(c)(5)(iii)(B), CMS proposed that an MAO whose *medical record review determination appeal* has been completed has 60 days from the issuance of a revised RADV audit report to file a written request for *payment error calculation appeal*, specifying where the MAO disagrees and the reasons.

The agency proposed a number of related changes, including the following:

- An MAO's request for medical record review determination reconsideration must specify any and all audited HCCs from an audit report that the MAO wishes to dispute, so that the MAO can submit only a single request per audited contract.
- The *reconsideration official*'s decision is final unless it is reversed or modified by a final decision of the hearing officer.
    - The reconsideration official's written decision will not lead to the issuance of a revised audit report until the decision is considered final.
    - If the reconsideration official's decision is considered final, the Secretary will recalculate the MAO's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MAO.
- If the *hearing officer*'s decision is considered final, the Secretary will recalculate the MAO's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports for the specific MA contract audit.[46]
- Regarding the *CMS Administrator*:

[45] An MAO may also choose to only appeal the payment error calculation, and therefore no preceding medical record review determination appeal would occur. MAOs choosing to only file a payment error calculation appeal will forgo their medical record review determination appeal, because medical record review appeals decisions need to be final prior to adjudicating a payment error calculation appeal.

[46] Issuing a revised audit report is a standard process and applies the final adjudicator's medical record review determination findings. This process is consistent with other longstanding CMS appeals programs, such as the Provider Reimbursement Review Board (PRRB).

- If the Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MAO or CMS' timely request for review (whichever is later), the hearing officer's decision becomes final.
- CMS and the MAO 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.
- Once the Administrator's decision is considered final, the Secretary will recalculate the MAO's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MAO.

Final Action. CMS finalizes its proposal without modification.

Selected Comments/Responses. Commenters generally expressed support for the proposed policies regarding the timing of MRRD and PEC appeals, stating that the proposals will provide needed clarity in the RADV audit appeals process and that by disallowing MRRD appeals and PEC appeals from being adjudicated concurrently, it will avoid administrative complications. CMS agrees.

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

A. Part C and Part D Midyear Benefit Changes (§§422.254, 423.265)[47]

CMS provides extensive background on its regulations relating to midyear benefits changes (previously referred to as midyear benefit enhancements (MYBEs)) for MA and Part D plans.

CMS finalizes its proposal included in the December 2022 proposed rule[48] to add into regulatory text its longstanding prohibition of MYBEs for MA and Part D plans, which it refers to as midyear benefit changes (MYBCs), rather than midyear benefit enhancements. Specifically, CMS finalizes:

- Prohibiting MAOs from making midyear changes to non-drug benefits, premiums, and cost sharing, except for modifications in benefits required by law.
- Prohibiting Part D sponsors from making midyear changes to the benefits described in its CMS-approved plan benefit package for the contract year (i.e., from making midyear changes to the benefit design or waiving or reducing premiums, bid-level cost sharing (for example, cost sharing associated with an entire tier of drugs), or cost sharing for some or all of the enrollees of the plan), except for modifications in benefits required by law.

These midyear changes with respect to each contract year, will not be allowed to be made beginning once plans are permitted to start marketing their prospective contract year offerings on October 1 prior to the applicable contract year and until the end of the applicable contract year.

[47] The policies in this section were proposed during the cycle for Contract Year 2024.

[48] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly, Health Information Technology Standards and Implementation Specifications (87 FR 79452) (referred to as the "December 2022 proposed rule").

Employer Group Waiver Plans (EGWPs) are not subject to this prohibition on MYBCs. However, if an MAO offers an MA plan that enrolls both individual beneficiaries and employer or union group health plan members, the employer or union sponsor may only make mid-year changes with respect to non-MA benefits (i.e., benefits that are not included in the MA basic benefit or MA supplemental benefit part of the plan).

The changes will not prohibit MA plans from covering required changes or additions to basic benefits when those changes or additions to basic benefits are the result of a change in the law, rulemaking or an NCD; those changes must be made by MA plans. MAOs also will not be prohibited from making changes to their own rules on prior authorization or referral, for example, or from making changes to their provider network as long as those changes are consistent with regulatory requirements and with the approved plan benefit package.

Part D plans will not be prohibited from making midyear formulary changes that result in cost sharing changes for individual drugs (e.g., when a drug moves from one already approved tier of the formulary to another already approved tier), but would be prohibited from such changes for an entire tier of drugs. CMS further clarifies that the prohibition will not prohibit Part D plans from adding coverage of new FDA-approved products. However, CMS makes a distinction for the Part D program between changes in "bid-level" cost sharing (e.g., the cost sharing associated with an entire tier of drugs) and changes in the cost sharing for an individual drug (e.g., when a drug moves from one already approved tier of the formulary to another already approved tier). Plan sponsors must provide notice for removal of a drug from a formulary and any change in the preferred or tiered cost-sharing status of the drug. Changes in bid-level cost sharing not only violates bid requirements but also runs afoul of the uniform benefit requirements, because plans would not be providing the same coverage to all eligible beneficiaries within their service area.

In the December 2022 proposed rule and in response to comments received in this final rule, CMS explains that it is concerned that allowing MYBCs undermines the integrity of the bidding process (because MAOs may alter their benefit packages after the bidding process is complete) and permits the misrepresentation an MAO's actual costs and the noncompetitive revision of their benefit packages later in the year. Allowing MYBCs would also violate the uniformity requirements, which require MAOs offer their plan to all beneficiaries in a service area "at a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2)." The agency found similar reasoning in the context of Part D. It found that it was not appropriate to allow either MA organizations or Part D sponsors to waive premiums or offer midyear benefit enhancements, as they would be de facto adjustments to benefit packages for which bids were submitted earlier in the year.

CMS finalizes these proposals with minor modifications to clarify the text.

B.[49] Failure to Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts (§§423.293 and 423.294)[50]

Proposal. In the December 2022 Proposed Rule, CMS proposed requirements for Part D sponsors to refund incorrect collections of premiums and cost sharing and recover underpayments of premiums and cost sharing. In addition, the agency proposed to establish a lookback period and timeframe to complete overpayment and underpayment notices and proposed a de minimis threshold for refunds and recoveries.

CMS explained that the incorrect collection of cost sharing and premiums by a Part D sponsor could have the effect of making the benefit non-uniform. While the MA regulations address the issue of incorrect collection of premiums and cost sharing, the Part D regulations fail to do so. Therefore, in the December 2022 Proposed Rule, CMS proposed to align the policies for Part D with the established policies for MA plans on this issue. It proposed to add a new §423.294 where requirements regarding incorrect collections of premiums and cost sharing amounts would be codified for Part D plan sponsors. It would also add new requirements in that same section for failure to collect premiums and cost sharing amounts.

First, CMS proposed to state that a Part D sponsor violates the uniform benefit provisions if it fails to collect or incorrectly collects applicable cost sharing or premiums (i) in accordance with the timing of premium payments, (ii) at the time a drug is dispensed, or (iii) by billing the enrollee or another appropriate party after the fact. Part D sponsors would be required to make a reasonable effort to collect monthly beneficiary premiums under the established timing rules and ensure collection of cost sharing at the time a drug is dispensed.

Next, Part D sponsors would have to make reasonable efforts to identify all amounts incorrectly collected and to pay any other amounts due during the 3-year timeframe for coordination of benefits (i.e., a 3-year period that starts on the date the monthly premium is due or the date on which the prescription was filled). The terms "amounts incorrectly collected" and "other amounts due" are to be defined as follows:

- *Amounts incorrectly collected* would—
    - Mean amounts that exceed the monthly Part D enrollee premium limits or exceed permissible cost-sharing or copayment amounts, whether paid by or on behalf of the enrollee;
    - Include amounts collected with respect to an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled; and
    - Exclude de minimis amounts, as calculated per prescription drug event (PDE) transaction or per monthly premium billing.
        - *De minimis amounts* would mean an amount per PDE transaction for claims adjustments and per month for premium adjustments that does not exceed the de minimis amount determined established by CMS for purposes of the ability for Part D prescription drug plans to waive a de

[49] In the final rule, CMS labeled this as "AA." HPA is using standard lettering, which causes the labeling in the remainder of this section to also differ from that used by CMS.
[50] The policies in this section were proposed during the cycle for Contract Year 2024.

minimis premium amount for LIS enrollees (see §423.34(c)(2)), which is $2 for 2022.

- *Other amounts due* would mean amounts due to affected enrollees or others on their behalf (other than de minimis amounts) for covered Part D drugs that were—
    - Accessed at an out-of-network pharmacy; or
    - Initially denied but, upon appeal, found to be covered Part D drugs the enrollee was entitled to have provided by the Part D plan.

Additionally, Part D sponsors would have to issue a refund for an identified enrollee overpayment within 45 days of the sponsor's receipt of complete information. Refunds would have to be done on a lump sum basis for (i) amounts incorrectly collected as cost-sharing, (ii) other amounts due (as defined above), and (iii) all amounts due if the Part D plan is going out of business or terminating its Part D contract for a prescription drug plan(s). For amounts incorrectly collected (as defined above) in the form of premiums, or included premiums as well as other charges, the Part D sponsor could provide the refund by adjusting future premiums or by a combination of premium adjustment and lump-sum payments. If an enrollee has died or cannot be located after reasonable effort, the Part D sponsor must make the refund in accordance with state law. If the Part D sponsor fails to issue the refund within the 45-day period, CMS will reduce the premium the sponsor may charge the enrollee by the amounts incorrectly collected or otherwise due. CMS may also issue a compliance notice and be subject to intermediate sanctions (e.g., suspension of marketing or enrollment).

With respect to collection of cost-sharing and premium amounts due to plans, the Part D sponsor would have to make a reasonable effort to attempt to collect cost sharing from a beneficiary or to bill cost sharing or premiums to another appropriate party for all amounts other than de minimis amounts. Recovery notices would have to be processed and issued in accordance within the 45-day period beginning on the date of the sponsor's receipt of complete information. A Part D sponsor must make a reasonable effort to attempt to collect these amounts during the 3-year lookback period for coordination of benefits under §423.466(b). CMS does not propose to change the requirements of its regulations at §423.293(a)(4) (relating to retroactive collection of premiums) that permit an enrollee to pay the MAO by lump sum, by equal monthly installments spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the MAO.

Final Action. CMS finalizes its proposals.

Selected Comments/Responses. A commenter noted the fundamental difference between the collection of Part D cost sharing (which is collected by pharmacies) and premiums (which are collected by plans) and that it was inappropriate to include cost sharing together with premiums under the proposal since plans are not responsible for collecting cost sharing. CMS responds that it has interpreted the uniform benefit requirement[51] as prohibiting Part D sponsors from varying cost sharing and premiums within its service area, and that existing regulations place significant responsibility for the correct collection of cost sharing on plan sponsors.

[51] §423.104(b)(2) requires part D plan sponsors to offer "a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area."

In response to a request for clarification regarding whether recoupment of underpayments will apply to dually eligible beneficiaries, CMS clarifies that plan sponsors are currently required under regulations and guidance to recover underpayments and refund overpayments, regardless of amount. The policy would apply to dually eligible beneficiaries, but the abbreviated lookback period and application of the de minimis amount policy might decrease the recovery attempts with respect to that population.

C. Definition of "Basic Benefits" (§422.2)

Per statute,[52] each MA organization is required to provide enrollees basic benefits—that is, benefits under the original Medicare FFS program option. Section 1852(a)(1)(B)(i) of the Act defines the term "benefits under the original Medicare FFS program option". The 21st Century Cures Act amended that section to, effective January 1, 2021, exclude from that term (and therefore exclude from the basic benefits coverage requirement) coverage for organ acquisitions for kidney transplants, including costs for living donors. In implementing that exclusion in the "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021," final rule (84 FR 15680), CMS inadvertently omitted a revision to the "basic benefits" definition at §422.2 that would add that exclusion of coverage.

CMS finalizes its proposed technical change to §422.2 to align the definition of basic benefits with the statute by changing the phrase "all Medicare-covered benefits" to "Part A and Part B benefits" and to, beginning in 2021, exclude from such definition (in addition to the current exclusion for hospice services) organ acquisitions for kidney transplants, which includes costs for living donors covered under section 1881(d) of the Act.

D. Standards for Determining Whether a Special Supplemental Benefit for the Chronically Ill Has a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (§422.102(f)(3)(iii) and (iv) and (f)(4))

Background. The Balanced Budget Act (BBA) of 2018 provided for new authorities concerning supplemental benefits that may be offered by MA plans to chronically ill enrollees (referred to by CMS as Special Supplemental Benefits for the Chronically Ill or "SSBCI"). In the Medicare Program Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (the June 2020 final rule), CMS interpreted this authority as allowing MA plans to offer SSBCI that are not uniform across the entire population of chronically ill enrollees in the plans and to tailor and cover them for an enrollee's specific condition and needs.

Per statute, an item or service offered as an SSBCI must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.[53] SSBCI can be in the form of (i) reduced cost sharing for Medicare-covered benefits; (ii) reduced cost

[52] Section 1852(a)(1)(A) of the Act.
[53] Section 1852(a)(3)(D)(ii)(I); codified as part of the SSBCI definition at §422.102(f)(1)(ii).

sharing for primarily health-related supplemental benefits; (iii) additional primarily health-related supplemental benefits; and (iv) non-primarily health-related supplemental benefits.[54]

To offer to an enrollee an item or service as an SSBCI, an MA plan must make the following determinations:

- Determine[55] that the enrollee is a chronically ill enrollee,[56] which is an individual who:
    - Has one or more comorbid and medically complex chronic conditions that is life-threatening or significantly limits the overall health or function of the enrollee;
    - Has a high risk of hospitalization or other adverse health outcomes; and
    - Requires intensive care coordination.
- Determine that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the enrollee.

An MA plan has the discretion to determine what is a "reasonable expectation" for the second determination so that the plan may tailor its SSBCI offerings and the eligibility standards for those offerings to the specific chronically ill population. The burden is currently on CMS to provide evidence if it determines that an MA plan may *not* offer a specific item or service as an SSBCI because it does not have a reasonable expectation as described in the second determination prong above. In addition, MA plans are required by statute[57] to offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. Supplemental benefits, including SSBCI, are funded using MA plan rebate dollars.

CMS describes how the number of MA plans offering SSBCI has significantly increased and that the agency believes it is important therefore to update its processes for reviewing and approving SSBCI to manage the growth and development of new SSBCI offerings, as well as to maintain good stewardship of Medicare dollars (including the required MA rebates used to pay for these benefits).

Final Action. CMS finalizes, with modifications described below, several policies that together require that an MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee, shifting the burden of proving the second determination prong described above to MA organizations instead of CMS having the burden to disprove it.

First, CMS finalizes with modification, effective for coverage beginning on and after January 1, 2025, its proposal that by the date of submission of the bid, the MA organization would need to establish a bibliography of a comprehensive list of relevant acceptable evidence (i.e., a list of scholarly publications or other works) concerning the impact that the item or service has on the health or overall function of its recipient, which would be made available to CMS upon request

[54] April 24, 2019, Health Plan Management System memorandum.
[55] According to §422.102(f)(3)(i) and (ii), an MA plan must have written policies for making this determination and have documentation of each determination, which must be made available to CMS upon request.
[56] The definition of "chronically ill enrollee" is under section 1852(a)(3)(D)(iii) of the Act.
[57] Section 1854(b)(1)(C) of the Act.

(and not as a matter of course in submitting bids). For each citation, there will need to be a working hyperlink to or a document containing the entire source cited. CMS will be able to use the bibliography without limitation during bid review to assess whether SSBCI offerings comply with regulatory requirements or during the coverage year as part of its oversight activities.

- The term "relevant acceptable evidence" will include large, randomized controlled trials or prospective cohort studies published in a peer-reviewed journal and specifically designed to determine whether the item or service impacts the health or overall function of a population. If such publications are not available, the bibliography is to include case studies, federal policies or reports, and internal analyses or other investigation of the impact that the item or service has on the health or overall function of an individual.
- The bibliography must include "a comprehensive list" of relevant acceptable evidence (as opposed to "all relevant evidence", as proposed) published during the 10 years preceding the June prior to the coverage year during which the SSBCI will be offered. The final rule adds that this list must include any available negative evidence and literature.
- This proposal will apply only to SSBCI offered as non-primarily health-related supplemental benefits or SSBCI offered as additional primarily health-related supplemental benefits, and will not apply to SSBCI offered as reduced cost sharing, to those offered as primarily health-related supplemental benefits, or to supplemental benefits offered under the CMI Value-Based Insurance Design (VBID) Model, unless CMI specifically incorporates the policy.

In addition, CMS finalizes its proposal to require that an MA plan apply its written policies, which must be based on objective criteria, that it establishes for determining whether an enrollee is eligible to receive an SSBCI. Currently, the regulation requires that an MA organization have written policies based on objective criteria and document the criteria, but does not explicitly say that the MA plans must apply those policies.

CMS finalizes the requirement that an MA plan must document, and submit to CMS upon request, each SSBCI eligibility determination, whether eligible or ineligible, to receive a specific SSBCI. This is a modification made by the agency, in response to comments, from its proposal for the plan to document only instances the plan determines that a chronically ill enrollee is ineligible to receive an SSBCI.[58] This will give the agency more complete information to fully understand how plans are using their resources with respect to SSBCI.

CMS had solicited feedback on whether to exempt SSBCI from the general rule that allows MA plans to change certain plan rules for SSBCI during the coverage year if notice is provided. Comments generally expressed the need to preserve benefits and reduce confusion around plan requirements. In response, the agency is prohibiting plans from making changes to eligibility requirements for SSBCI during a coverage year by finalizing a new paragraph (f)(4)(v) as part of the changes being made to §422.102(f). The new paragraph will require that an MA plan offering SSBCI maintain without modification for the full coverage year evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, and the specific objective criteria used by the plan as part of SSBCI eligibility determinations. CMS is not at this time

[58] Currently, plans must document SSBCI eligibility approvals, but not denials.

finalizing any prohibition on a plan from making during the coverage year changes to the utilization management policies related to SSBCI.

In addition, CMS is finalizing its proposals to (i) codify its authority to decline to approve an MA organization's bid if it determines that the organization has not demonstrated through relevant acceptable evidence that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee; and (ii) codify that CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, based on the evidence available at the time.

Selected Comments/Responses. Some commenters opposed the SSBCI evidentiary standard that plans must provide "all relevant acceptable evidence" as being too burdensome and as potentially stifling innovation for SSBCI benefits. Acknowledging the concerns, CMS is modifying the proposal (as described above) to include "a comprehensive list" of relevant acceptable evidence (rather than "all relevant acceptable evidence", as proposed) published within the 10 years before the June preceding the coverage year during which the SSBCI will be offered. However, the agency states that plans must demonstrate genuine efforts to be thorough and inclusive of evidence and must provide any available negative evidence and literature. CMS also clarifies that, although ideally evidence would include the specific chronic condition used by the MA plan in its SSBCI eligibility criteria and how the item or service would address that condition, the agency is not requiring that at this time. That is, relevant acceptable evidence does not need to relate to a specific chronic condition and does not necessarily have to be related to Medicare eligible populations. Acceptable studies and evidence may focus on other groups, including communities that share a trait other than Medicare eligibility.

E. Mid-Year Notice of Unused Supplemental Benefits (§§422.111(l) and 422.2267(e)(42))

Background. MA organizations may offer mandatory supplemental benefits, optional supplemental benefits, and SSBCI. MA plans are required by statute[59] to offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. MA organizations may choose how to provide these MA rebates. For example, instead of offering supplemental benefits through covering additional items and services, MA organizations may use rebate dollars to further reduce Part B and Part D premiums, reduce cost sharing for basic benefits, or reduce maximum out-of-pocket amounts.

CMS notes that while supplemental benefit offerings have significantly increased, utilization of these benefits remains low. The agency is concerned that underutilization of supplemental benefits could remove any potential value they offer and that MA plans may use supplemental benefits as marketing tools while not encouraging enrollees to use the benefits.

The agency believes that outreach in the form of communications specific to the utilization of supplemental benefits may further ensure covered benefits are accessed. CMS also believes that MA plans could use MA rebates (i.e., Trust Fund dollars) as a way to fill coverage gaps in Traditional Medicare by offering additional health benefits or SSBCI that address social

[59] Section 1854(b)(1)(C) of the Act.

determinants of health needs, and that targeted outreach to encourage utilization of supplemental benefits could further more equitable utilization of the benefits.

Final Action. CMS finalizes its proposal to establish standards to ensure MAOs provide adequate notice to enrollees on supplemental benefits coverage, but with a modification to clarify that supplemental benefits in the form of cost-sharing reductions are excluded from the notice. Beginning January 1, 2026, MAOs will be required to provide a model notification to enrollees of supplemental benefits they have not yet accessed; specifically, MAOs will need to mail a mid-year notice annually (during the period beginning on June 30 and ending on July 31 of the plan year) to each enrollee with information on each supplemental benefit available during the plan year that the enrollee has not begun to use.

- For each covered mandatory supplemental benefit and optional supplemental benefit for which the enrollee is eligible but has not yet accessed, the MAOs will be required to include in the mailing information on that benefit that appears in the Evidence of Coverage (EOC).
- For SSBCI for which the enrollee is determined eligible but which the enrollee has not yet accessed, the mailing would need to include an explanation of the SSBCI covered (including eligibility criteria, limitations, and scope of covered items and services), provide point-of-contact information for information on beginning the SSBCI eligibility determination process and other questions about the availability of SSBCI under the plan, and include the information that would be required in the SSBCI disclaimer proposed under section VI.B of the rule.
- In addition, each notice will need to (i) include the scope of the supplemental benefit, applicable cost sharing, instructions on how to access the benefit, and applicable information on the use of network providers, (ii) list the benefits consistent with the format of the EOC and (iii) provide a toll-free customer service number and, as required, a corresponding TTY number for additional help.

Selected Comments/Responses. Several commenters suggested more frequent notifications (such as monthly or quarterly), but the agency believes the mid-year annual notice is sufficient and less burdensome. Many other comments expressed concern about burden and complexity of the annual July 31 deadline and cost of providing personalized information to each enrollee.

In response to comments, CMS clarifies that all unused supplemental benefits offered by the MAO must appear in the mid-year notice regardless of whether they are mandatory, optional, or SSBCI. The only exception, which CMS clarifies in the finalized regulation text, is that a cost-sharing reduction supplemental benefit does not need to be included in the notice.

The agency further clarifies in its response to comments that it intends to use the findings from this outreach requirement along with improved collection of supplemental benefit utilization data to inform whether additional future rulemaking is needed. It believes that addressing potential underutilization of benefits, which are funded through MA rebates, is an appropriate function of the agency in ensuring appropriate use of Medicare funding.

Some commenters raised concern about providers' ability to provide utilization information for the Mid-Year Notice in a timely manner because of limited resources. CMS responds that information that is up to date as of June 30 of the plan year will satisfy the requirement for accuracy as far as information in the Mid-Year Notice.

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

CMS describes feedback from various interested parties that utilization management practices in MA, especially prior authorization, can create a barrier for patients in accessing medically necessary care. The agency also notes research has indicated that prior authorization may disproportionately impact those who have been historically underserved and marginalized. Further, CMS points to the policy changes made in the April 2023 final rule[60] to ensure the proper use of utilization management in ways that ensure timely and appropriate access to care for enrollees in MA plans. As part of the April 2023 final rule, at §422.137, CMS required all MAOs that use utilization management policies and procedures to establish a Utilization Management (UM) Committee to review and approve all such policies and procedures at least annually to ensure consistency with statutory and regulatory requirements and national and local coverage decisions.

Final Action. CMS finalizes the following policies, as proposed, except with two modifications (as noted below), to (i) clarify that the data used for the health equity analysis and reporting excludes data on drugs and (ii) remove the unnecessary language "but is not limited to" from the sentence that provides the non-exhaustive list of examples of health equity expertise. Specifically, the agency finalizes that beginning January 1, 2025:

- The UM Committee must include at least one member with expertise in health equity, including educational degrees or credentials with an emphasis on health equity, experience conducting studies identifying disparities, experience leading organization-wide policies to achieve health equity, or experience leading advocacy efforts to achieve health equity. The proposed and finalized regulation text provides a non-exhaustive list of examples to illustrate what constitutes expertise in health equity (without defining it) to leave flexibility for MAOs.
- The UM Committee must conduct an annual health equity analysis of the use of prior authorization, which the member with health equity expertise would be required to approve before it is posted on the plan's publicly available website. The analysis would be on the plan level and would compare metrics (specified below) for the use of prior authorization (during the prior contract year) for enrollees with one or more social risk factors (SRFs) to those without such risk factors. The analysis for a plan year would be required to be posted on the plan's publicly available website in a prominent manner and in a machine-readable format with the data digitally searchable and downloadable, beginning July 1, 2025, and annually thereafter. The finalized text adds a clarification that the data used for the analysis and report excludes data on drugs.

[60] "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" final rule, which appeared in the Federal Register on April 12, 2023 (88 FR 22120).

- The social risk factors are:
  - Receipt of low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or
  - Having a disability.[61]
- The specific metrics to be compared for the use of prior authorization are the following 8 metrics:
  - The percentage of each of the following, each aggregated for all items and services:
    - Standard prior authorization requests that were approved;
    - Standard prior authorization requests that were denied;
    - Standard prior authorization requests that were approved after appeal;
    - Prior authorization requests for which the timeframe for review was extended, and the request was approved;
    - Expedited prior authorization requests that were approved; and
    - Expedited prior authorization requests that were denied;
  - The average and median time that elapsed between the submission of a request and determination by the MA plan for standard prior authorizations, aggregated for all items and services; and
  - The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorization, aggregated for all items and services.

Selected Comments/Responses. Some commenters expressed concern that prior authorization denial rates are not necessarily correlated with social risk factors and that therefore the proposed form of data could inadvertently be misleading to enrollees. Another commenter requested plans be required to explain their rates of denials of services that meet coverage rules. Others expressed concern about presenting public data in a manner and format that is useful and useable, including by requiring MA plans to include an executive summary with each report. CMS appreciates the concerns raised, but believes the analysis is a first step for understanding the use of prior authorization and its effects. Since the required data is to be aggregated for all items and services at the plan level, CMS does not believe the analysis will be overwhelming for public understanding. The agency also notes the similarities between the performance metrics adopted in this final rule and the metrics adopted in the 2024 Interoperability Final Rule[62] for

[61] Disability status would be 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. These two SRFs mirror the SRFs that will be used to measure the Health Equity Index reward for the 2027 Star Ratings.

[62] Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program" (CMS-0057-F) final rule (89 FR 8758).

reporting under §422.122(c). The reports are with respect to different populations but will be complementary by providing information on the same metrics. To further align the performance metrics to address concerns about burden, CMS is finalizing additional language to exclude drugs from the scope of reporting and health equity analysis metrics, making the specific metrics for the two reports the same (but reported for different populations).

CMS had requested feedback on whether it should add a requirement for MA plans to submit directly to CMS a link to their health equity analysis. Many commenters supported the addition, and some suggested plans submit a link only to CMS and not post the report publicly. The agency decides not to include the additional requirement at this time and instead finalizes as proposed the requirement that the MAO publish the results of the health equity analysis on the plan's website. CMS further clarifies it is not requiring a comparison of metrics across plans, but is seeking through this policy to identify whether the use of prior authorization causes disparities among enrollees with the SRFs within MA plans.

Several comments requested further explanation on how CMS intends to use the information gathered through the health equity analyses. Some suggested that the data be taken into consideration for determinations for 2027 Star Rating Health Equity Index rewards. The agency responds that at this time the intent is to use the analysis for information purposes and will take the data into account when considering future policymaking.

V. Enrollment and Appeals

A. Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§422.74)[63]

Individuals who lose special needs status are provided a period of deemed continued eligibility if they are reasonably expected to regain special needs status within, at most, the succeeding 6-month period. The period of deemed eligibility must be at least 30 days but may not exceed 6 months. The regulations require the disenrollment of individuals who lose special needs status and whose period of deemed continued eligibility expires. MA SNPs must send notice of involuntary disenrollment under these circumstances both before and after the effective date of the disenrollment.

CMS is finalizing its proposal included in the December 2022 Proposed Rule to codify its long-standing notice requirements for loss of special needs status. MA SNPs must provide the enrollee a minimum of 30 days advance notice of disenrollment, regardless of the date of the loss of special needs status. Additionally, the SNP must provide the advance notice to the enrollee within 10 calendar days of the plan learning of the loss of special needs status, and give the enrollee an opportunity to prove that they are still eligible to remain in the plan. Advance notices must provide certain information, including the disenrollment effective date; a description of the eligibility for a special enrollment period; and, if applicable, information on the period of deemed continued eligibility, the duration of the period of deemed continued eligibility, and the

[63] The policies in this section were proposed during the cycle for Contract Year 2024.

consequences of not regaining special needs status within the period of deemed continued eligibility.

MA SNPs will be required to send a final involuntary disenrollment notice to the enrollee within 3 business days of the disenrollment effective date. The disenrollment effective date will be either the last day of the period of deemed continued eligibility, if applicable, or a minimum of 30 days after providing the advance notice of disenrollment. This final notice must include information on the enrollee's right to file a grievance. The notice will be sent to the enrollee before the MA SNP submits the disenrollment to CMS.

Because MA SNPs have largely been complying with these notice requirements established in guidance, CMS does not believe that their codification will impose any burdens on MAOs or individuals enrolled in SNPs.

B. Involuntary Disenrollment for Individuals Enrolled in a MA Medical Savings Account (MSA) Plan (§422.74)[64]

Section 1851(a)(2)(B) of the Act allows an MAO to offer an MA medical savings account (MSA) option, which is a combination of a high-deductible MA plan (as defined in section 1859(b)(3) of the Act) with a contribution into a Medical Savings Account (MSA). Certain restrictions apply to this option, including prohibitions on enrollment in an MA MSA plan by individuals covered under other health programs such as the Federal Employee Health Benefits Program (FEHB) plan. The current regulations do not specify whether the eligibility criteria that preclude an individual with certain health care coverage from electing an MA MSA plan apply to individuals who gain or become eligible for other coverage while enrolled in an MSA plan.

CMS finalizes, without modification, its proposal included in the December 2022 Proposed Rule to add a requirement that an MA MSA enrollee must be disenrolled, prospectively, due to the loss of eligibility.

Specifically, if an MA MSA enrollee does not provide assurances that they (1) will reside in the United States for at least 183 days during the year the election is effective; (2) is eligible for or begins receiving health benefits through Medicaid, FEHBP, DoD, or the VA; or (3) obtains other health coverage that covers all or part of the annual Medicare MSA deductible, that enrollee will have to be involuntarily disenrolled by the MSA plan effective the first day of the calendar month after the month in which notice by the MAO is issued that the individual no longer meets the MA MSA's eligibility criteria. MA MSA plans will be required to provide, before the disenrollment transaction is submitted to CMS, written notice of the disenrollment with an explanation of why the MAO is planning to disenroll the individual.

Individuals involuntarily disenrolled under this policy will be defaulted to enrollment in the Medicare fee-for-service program, which will pay claims incurred by the former MA MSA enrollees. The individuals will also have the option to elect to join another MA plan during a valid enrollment period.

[64] The policies in this section were proposed during the cycle for Contract Year 2024.

C. Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§422.60 and 423.32)[65]

Current regulations codify the process under which an MA plan or PDP may terminate enrollees' coverage for failure to pay monthly premiums (optional disenrollment), as well as requirements for mandatory disenrollment for individuals who fail to pay the Part D Income Related Monthly Adjustment Amount (Part D-IRMAA). CMS regulations include provisions for MAOs and PDP sponsors to reinstate for good cause an individual who is disenrolled for failure to pay plan premiums. Individuals are disenrolled when they enroll in a different plan. However, an individual's enrollment can also be reinstated if their enrollment in another plan is subsequently canceled within timeframes established by CMS. Subregulatory guidance also includes notification requirements for enrollment reinstatement based on cancellation of enrollment in a different plan.

CMS finalizes its policy included in the December 2022 Proposed Rule to require MA and PDP plans to notify individuals when their enrollment is reinstated due to their cancellation of enrollment in a different plan, codifying longstanding guidance and practice. This scenario is for when a beneficiary is automatically disenrolled from their plan because of enrollment in a new plan but then cancels the request to enroll in the new plan within established timeframes. The organization from which the individual was disenrolled must send the member notification of the enrollment reinstatement within 10 days of receipt of Daily Transaction Reply Report (DTRR) confirmation of the individual's reinstatement. This notice is to confirm the individual's enrollment in the previous plan with no break in coverage, any needed plan-specific information, and plan contact information.

D. Part D Plan Failure to Submit Disenrollment Timely (§423.36)[66]

The statute grants the Secretary the authority to establish a process for the enrollment, disenrollment, termination, and change of enrollment of individuals in PDPs, which must be similar to MA rules. As currently codified, the Part D regulations do not quite align with CMS subregulatory guidance or MA regulations regarding the repayment of Part D capitation payments when the PDP fails to submit a disenrollment transaction to CMS in a timely fashion.

To align the Part D regulation with the requirements for MAOs, CMS finalizes its proposal in the December 2022 Proposed Rule, to codify its longstanding guidance by creating a new §423.36(f). If the Part D sponsor fails to submit a disenrollment notice to CMS timely, resulting in the Part D sponsor receiving additional capitation payments from CMS, the Part D sponsor must reimburse CMS for payments received after the month in which payment should have ended.

[65] The policies in this section were proposed during the cycle for Contract Year 2024.
[66] The policies in this section were proposed during the cycle for Contract Year 2024.

E. Codify Existing Policy "Incomplete Disenrollment Requests" (§§422.66 and 423.36)[67]

An individual who elects an MA plan and then chooses to terminate that election can do so by submitting a request to the MAO, with this voluntary disenrollment process codified at §422.66(b). Neither this provision nor the comparable Part D provision (§423.36) addresses what plans should do if they receive incomplete disenrollment requests, although such guidance appears in the Medicare Managed Care Manual (MMCM) and the Medicare Prescription Drug Benefit Manual (PDBM).

CMS finalizes without modification its proposal included in the December 2022 Proposed Rule to codify its longstanding policies as follows:

- A disenrollment request is considered to be incomplete if the required but missing information is not received by the MA plan or Part D sponsor within the specified timeframes:
    - For incomplete disenrollment requests received during the annual election period (AEP), information to complete the request must be received by December 7, or within 21 calendar days of the plan sponsor's request for additional information, whichever is later.
    - For all other election periods, required information must be received by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.
- If the disenrollment request is incomplete, the plan would be required to document its efforts to obtain information to complete the election, including notifying the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request.
- If any additional information needed to make the disenrollment request complete is not received within the required timeframes, the disenrollment request would be denied.

F. Reinstatement of Enrollment for Good Cause (§§417.460, 422.74 and 423.44)[68]

As mentioned above, MA and Part D plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums on a timely basis, and must disenroll individuals with higher incomes who fail to pay the additional monthly premium, the Part D IRMAA, for their Part D coverage. Under current regulations, an MA or Part D plan that chooses to disenroll beneficiaries for failure to pay premiums must be able to demonstrate it made a reasonable effort to collect the unpaid amounts by notifying the beneficiary of the delinquency, providing the beneficiary no less than 2 months (grace period) to resolve the delinquency, and advising the beneficiary of the termination if the amounts owed are not paid by the end of the grace period. CMS involuntarily disenrolls individuals from their Part D coverage for failure to pay Part D IRMAA following an initial grace period of 3 months.

For an HMO or competitive medical plan (cost plan), current regulations permit disenrolling a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. While there is no grace period parallel to that required by the MA and Part D regulations, the requirements for cost plans are otherwise similar. The cost plan must

[67] The policies in this section were proposed during the cycle for Contract Year 2024.
[68] The policies in this section were proposed during the cycle for Contract Year 2024.

demonstrate it made reasonable efforts to collect the unpaid amount and send the enrollee written notice of the disenrollment prior to transmitting the disenrollment to CMS.

Under current regulations, MA and Part D coverage (as well as cost plan coverage) can be reinstated if non-payment of premiums was for good cause—that is, in certain circumstances where the non-payment of premiums was due to a circumstance that the individual could not reasonably foresee and could not control, such as an extended period of hospitalization. The entity can effectuate reinstatements when good cause criteria are met.

CMS finalizes its proposal included in the December 2022 Proposed Rule to codify current subregulatory guidance in the MMCM and PDBM that reinstatement for good cause would occur only when the individual requests reinstatement within 60 calendar days of the disenrollment effective date and that an individual may make only one reinstatement request for good cause in this 60-day period.

G. Required Notices for Involuntary Disenrollment for Disruptive Behavior (§§417.460, 422.74 and 423.44)[69]

MAOs, Part D sponsors, and cost plans can disenroll individuals for disruptive, unruly, abusive, or uncooperative behavior. Current regulations outline definitions and processes for disenrolling an enrollee for disruptive behavior. For example, CMS approval is required before the disenrollment may be submitted, and entities must make serious efforts to resolve the problem considering any extenuating circumstances, such as beneficiaries' mental or cognitive conditions.

CMS finalizes its proposal included in the December 2022 Proposed Rule to codify current policy for MA, Part D, and cost plan notices during the disenrollment for disruptive behavior process. The two required notices are:

1. An advance notice, informing the plan member that continued disruptive behavior could lead to involuntary disenrollment; and
2. A notice of the plan's intent to request CMS permission to disenroll the member, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior.

These notices will inform the individual of the right to use the plan's grievance procedures. The plan will be required to submit dated copies of these required notices to CMS, along with the other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

H. Codification of the Part D Optional Disenrollment for Fraud and Abuse Policy (§423.44)[70]

MAOs may disenroll individuals for fraud or abuse on the enrollment form—for example, knowingly providing false information—or for misuse of their enrollment card. Even though the Secretary is required to use similar rules for both MA and Part D, Part D does not have a comparable regulatory requirement (although it is addressed in the PDBM).

[69] The policies in this section were proposed during the cycle for Contract Year 2024.
[70] The policies in this section were proposed during the cycle for Contract Year 2024.

CMS finalizes its proposal included in the December 2022 Proposed Rule to codify the policy for optional disenrollment from a PDP based on individuals providing fraudulent information on their election form or permitting abuse of their enrollment card. A PDP that opts to disenroll an individual who commits fraud or permits abuse of their enrollment card will be required to provide the individual a written notice that meets the notice requirements in §423.44(c). PDPs will also be required to report to CMS any disenrollment based on fraud or abuse by the individual.

I. SPAP or Other Payer Exception for Disenrollment for Failure to Pay (§423.44)[71]

State Pharmaceutical Assistance Programs (SPAPs) and other third-party payer assistance programs have the option to cover Part D premiums for individuals. The statute directs the Secretary to establish coordination rules between SPAPs and Part D plan sponsors for paying premiums, which were implemented in regulations at §432.464(a).

CMS finalizes its proposal included in the December 2022 Proposed Rules to codify policy currently in the PDBM that excepts PDP members from being disenrolled for failure to pay plan premiums if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium and the sponsor has not yet coordinated with the SPAP or other payer. Sponsors will not be able to initiate the disenrollment process or disenroll members who qualify for this exception.

J. Possible End Dates for the SEP for Government Entity-Declared Disaster or Other Emergency (§§422.62 and 423.38)[72]

Special Enrollment Periods (SEPs) are available for Medicare-eligible individuals to elect an MA plan or PDP or to change their plan election when they meet an exceptional condition determined by the Secretary. In 2020, a number of SEPs previously implemented through subregulatory guidance were codified in regulation, including one for Government Entity-Declared Disaster or Other Emergency. This SEP begins the earlier of (i) the date the disaster/emergency declaration is made, (ii) the incident start date, or (iii) the start date identified in the declaration. It ends 2 full calendar months following the later of the end date identified in the declaration or the date the end of the incident is announced.

CMS finalizes it proposal included in the December 2022 Proposed Rule for two changes to the end date for this SEP:

- For state or local emergencies/disasters, the end date for the SEP may also be based on an emergency/disaster order automatically expiring pursuant to a state or local law.
    - If the announced incident period end date is different than the expiration date specified in state or local law, the announced incident end date controls the SEP end date.

[71] The policies in this section were proposed during the cycle for Contract Year 2024.
[72] The policies in this section were proposed during the cycle for Contract Year 2024.

- The SEP ends based on the end of the emergency/disaster period, regardless of whether that period ends based on an announcement by the applicable authority or expires based on applicable state or local law.

- If no end date for the period of disaster/emergency is otherwise identified within 1 year of the start of the SEP, an automatic incident end date will fall 1 year after the SEP start date. Thus, if no end date is otherwise identified, the SEP will be 14 full calendar months in length.

K. Updating MA and Part D SEPs for Changes in Residence and Codifying Procedures for Developing Addresses for Members Whose Mail is Returned as Undeliverable (§§422.62, 422.74, 423.38 and 423.44)[73]

Medicare beneficiaries are eligible to elect an MA plan only if it serves the geographic area in which the individual resides. Regulations exist for a continuation-of-enrollment option under which an MAO offering an MA local plan may offer its enrollees the option to continue enrollment when they move out of the service area and into a continuation area,[74] so long as the organization provides or arranges for coverage of all Medicare-covered benefits. Individuals who are no longer eligible to elect an MA plan because they moved are eligible for a SEP.

Under current subregulatory guidance in the MMCM and the PDBM, these SEPs are available not only to individuals who move out of the service area, but also to those who move within the service area but have new plan options available to them. These SEPs are also available to those not currently enrolled in a Medicare health or drug plan who move and have new plan options available to them.

CMS finalizes its proposal included in the December 2022 Proposed Rule to codify these longstanding subregulatory options into regulation, as well as subregulatory requirements when returned mail indicates a possible change of address.

L. Codify the Term "Whole Calendar Months" (§§422.74 and 423.44)[75]

In the MMCM and MPDB, CMS defines the grace period for nonpayment of plan premiums in MA and Part D as at least 2 "whole calendar months," not fractions of months.

CMS finalizes its proposal included in the December 2022 Proposed Rule to codify this in MA and Part D regulations, with the grace period to begin on the later of (1) the first day of the month for which the premium is unpaid or (2) the first day of the month following the date on which premium payment is requested.

[73] The policies in this section were proposed during the cycle for Contract Year 2024.
[74] Section 42 CFR §422.54(a) defines a continuation area as an additional area (outside the service area) within which the MAO offering a local plan will furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.
[75] The policies in this section were proposed during the cycle for Contract Year 2024.

M. Researching and Acting on a Change of Address (§§422.74 and 423.44)[76]

MA organizations and Part D plan sponsors are generally required to issue a disenrollment notice within 10 days of the plan learning of an enrollee's permanent move out of the plan service area. For MA enrollees who are disenrolled because they are absent from the service area for more than 6 months, the disenrollment notice must be provided within the first 10 calendar days of the sixth month. Individuals enrolled in MA plans that offer a visitor/traveler benefit are permitted an absence from the service area for up to 12 months but are disenrolled if their absence from the service area exceeds 12 months (or the length of the visitor/traveler program if less than 12 months).

CMS finalizes its proposal included in the December 2022 Proposed Rule to codify these requirements consistently for MA and Part D. In addition, plans will be required to document their research efforts regarding an enrollee's relocation and the basis for involuntary disenrollment action based on the residency requirements.

N. Part D Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members (§§423.32 and 423.36)[77]

EGHP sponsors are provided an exception to process election forms for their Medicare-entitled group members in MA regulations but not in Part D regulations. To align the Part D regulation with the requirements that MAOs follow in existing Part C regulations and codify existing Part D subregulatory guidance, CMS finalizes its proposal included in the December 2022 Proposed Rule to permit a Part D plan sponsor with a contract with an employer or union group to arrange for the employer or union to process enrollment and disenrollment elections for their members who wish to enroll in or disenroll from a Part D EGHP, based on details in the PDBM.

O. Drug Management Program (DMP) Appeal Procedures (§423.562)[78]

A 2016 law permitted Part D plan sponsors to establish drug management programs (DMPs) for at-risk beneficiaries, to reduce opioid overutilization in the Part D program. In the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, DMPs are required for plan years beginning on or after January 1, 2022. CMS finalizes its proposal included in the December 2022 Proposed Rule to make the technical change in regulation to make DMPs mandatory for Part D plan sponsors.

P. Revise Initial Coverage Election Period Timeframe to Coordinate with A/B Enrollment (§422.62)

Background. Eligible individuals may choose to enroll in Part A and Part B during their first opportunity, which is their initial enrollment period (IEP), during the general enrollment period (GEP), or during an existing special enrollment period (SEP). These individuals also have an opportunity to enroll in an MA plan at the time of, or after, they have both Part A and B, until the

[76] The policies in this section were proposed during the cycle for Contract Year 2024.
[77] The policies in this section were proposed during the cycle for Contract Year 2024.
[78] The policies in this section were proposed during the cycle for Contract Year 2024.

last day of their IEP. The Secretary is required under section 1851(e)(1) of the Act to establish an initial coverage election period (ICEP) during which an individual who first becomes entitled to benefits under Part A and enrolled under Part B may elect an MA plan. Per statute, if an individual elects coverage under an MA plan during that period, that coverage will become effective as of the first day on which the individual may receive that coverage. Currently, the ICEP of an individual begins three months immediately before the individual is first entitled to part A and enrolled in Part B and ends on the later of (1) the last day of the month preceding entitlement to Part A and enrollment in Part B, or (2) the last day of the individual's Part B initial enrollment period (IEP).

Not all individuals enroll in both Part A and Part B during their IEP. For example, those who are working past age 65 may not have both Part A and Part B for the first time until after their IEP (i.e., they may enroll for Part B during a GEP or SEP occurring after their IEP). The Consolidated Appropriations Act (CAA), 2021 provided that for individuals who enroll during the GEP in a month beginning on or after January 1, 2023, their entitlement begins with the first day of the month following the month in which they enroll. For example, an individual who enrolled in Part A during their IEP, but enrolls in Part B later in a GEP during April would first have both Part A and Part B effective May 1. In this case, the individual's ICEP for electing to enroll in an MA plan would occur prior to the Medicare effective date and not provide the individual with time to consider their options for MA plans after their Part A and Part B coverage goes into effect. In the example, the ICEP would be from February 1 through April 30. If the ICEP is not used to enroll in an MA plan, the individual would need to wait until the next enrollment period that is available to them.

Final Action. CMS finalizes without modification its proposal to extend the end date for the ICEP, specifically providing that an individual will have two months after the month in which they are first entitled to Part A and enrolled in Part B to use their ICEP. In the example above, the individual's ICEP would therefore still begin February 1, but extend through June 30 (instead of April 30).

Selected Comments/Responses. All commenters supported the proposal to extend the ICEP for individuals who are first entitled to Part A and enrolled in Part B, but who did not enroll in parts A and B during their IEP. Some of the commenters suggested alternative end dates for the ICEP, such as three full months after the month of first being entitled to Part A and enrolled in part B. However, CMS responds that the proposed timeframe aligns with other timeframes, such as (i) the SEP timeframe for individuals to enroll in an MA or MA-PD plan when their Medicare entitlement determination is made for a retroactive effective date and the individual does not have an opportunity to elect a plan during their ICEP and (ii) the timeframe for an individual to enroll in such a plan when they enroll in Medicare using an exceptional condition SEP. The agency believes that the finalized timeframe, which results in 5 months for the individual to determine if they want Traditional Medicare or an MA plan, is sufficient and notes there are other opportunities to change plans, such as the MA OEP, annual coordinated election period, or an SEP for which the individual is eligible.

Q. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services (§422.626)

If an MA enrollee's skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated by an MA plan, the enrollee has a right to a fast-track appeal by an Independent Review Entity (IRE).[79] Currently, Quality Improvement Organizations (QIOs) serve as the IRE for these reviews. The provider of the relevant service is required to provide the enrollee, before the service is terminated, with a standardized written notice (called the Notice of Medicare Non-Coverage (NOMNC)) informing the enrollee of the MA organization's decision to terminate the provider's services for the enrollee and of the enrollee's right to a fast-track appeal. If an MA enrollee misses the deadline (stated in the NOMNC) to appeal or ends services from the provider before the termination date, the enrollee loses their right to the fast-track appeal. In the case of an untimely appeal (i.e., the enrollee misses the appeal deadline) the enrollee still has a right to appeal to their MA plan under §422.566(b)(3), but not the IRE. However, in the same circumstances (i.e., an untimely appeal or ending services before the termination date), beneficiaries in Traditional Medicare maintain their right to appeal in a parallel fast-track appeal process in effect under Traditional Medicare.[80]

Final Action. To align the MA program process with that under Traditional Medicare, CMS finalizes without modification its proposal to (1) require the IRE (i.e., the QIO), instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) allow enrollees the right to appeal the decision to terminate services after leaving a SNF or otherwise ending covered care before the planned termination date.

Selected Comments/Responses. In response to comments asking for clarification on the deadline to request an untimely appeal, CMS clarifies there is no deadline, which is consistent with the parallel provision for Traditional Medicare. A few comments were related to the denial of care by plans, including a comment requesting CMS ensure that enrollees receive care that is equal to that provided through Traditional Medicare and other comments expressing concern with plans' use of utilization management. While noting these issues are outside of the scope of the proposal, CMS does note that some of the recommendations regarding prior authorization and patient care have been addressed in recent regulations the agency has issued.[81]

R. Amendments to Part C and Part D Reporting Requirements (§§422.516 and 423.514)

Background. CMS describes its statutory and regulatory authorities to require MA organizations and Part D plans sponsors to provide it with "such information…as the Secretary may find

[79] The regulations for these reviews are at §§422.624 and 422.626.
[80] §§405.1200 and 405.1202.
[81] The Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (88 FR 22120) finalized regulatory changes clarifying when MA organizations may utilize prior authorization processes, the effect and duration of prior authorization approvals, and the circumstances under which MA organizations may utilize internal or proprietary coverage criteria.

necessary and appropriate".[82] CMS uses this authority to collect retrospective information from MA organizations and Part D sponsors according to the Parts C and D Reporting Requirements it issues each year.[83] The agency describes how the authority allows it to collect data in aggregate at the contract level (such as grievances, enrollment/disenrollment, rewards and incentives, and payments to providers) and granular data, as well as how the authority supports more timely data with greater frequency or closer in real-time than it has historically collected.

Final Action. To clarify that the regulations do not limit data collection to statistical or aggregated data, CMS proposed to amend §§422.516 and 423.514. The agency finalizes its proposal with a modification. Specifically, at §422.516(a), CMS strikes "statistics" and "other" so that the provision references information generally. Also, in response to comments, CMS is replacing the reference to "doctor-patient relationship" with "provider-patient relationship" to reflect the need for confidentiality between patients and their entire healthcare team. The provision is therefore amended as follows: "Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the ~~doctor-patient~~ provider-patient relationship, ~~statistics and other~~ information". In addition, CMS is making amendments to those sections to clarify its authority regarding reporting and data collection on MA and Part D plan procedures related to coverage, utilization in the aggregate, and beneficiary-level utilization (including the steps beneficiaries may need to take to access covered benefits).

Selected Comments/Responses. Many comments were in support of robust data collection to strengthen the agency's oversight of MAOs and Part D plan sponsors and to ensure enrollees have meaningful access to care. Some suggested incorporating collected data into plan audits and enforcement actions, while others suggested the agency publish the data on public websites to improve transparency and plan accountability. CMS agrees that collecting more detailed standardized data from MAOs and Part D plan sponsors is needed to improve transparency and that they will consider comments related to increasing oversight and transparency of the MA and Part D programs for developing future processes for making collected plan data public.

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

An MA plan enrollee may file with an MA organization, Part D plan sponsor, or an IRE an appeal regarding benefits. An MA organization (and Part D plan sponsor) is statutorily required to provide for reconsideration of a determination upon request by the enrollee, not later than 60

[82] CMS cites authority under sections 1857(e)(1), 1860D-12(b)(3)(D), and 1856(b) of the Act, as well as reporting requirements at §§422.516(a), 422.514(a), 422.504(f)(2), 423.505(f)(2), and 423.505(f)(3).
[83] Part C Reporting Requirements are at https://www.cms.gov/medicare/healthplans/healthplansgeninfo/reportingrequirements and Part D Reporting Requirements are at https://www.cms.gov/medicare/prescriptiondrugcoverage/prescriptiondrugcovcontra/rxcontracting_reportingoversight.

days after the date of receipt of the request.[84] The timeframe by which an enrollee must file an appeal is determined by regulation, and the filing deadline is set at 60 calendar days (which may be extended by the plan for good cause) from the date of the notice of the determination.

CMS finalizes its proposed amendments to the regulations to specify that a request for a Part C reconsideration, Part D determination, Part D at-risk determination, or a Part D IRE reconsideration must be filed within 60 calendar days after receipt of the written determination notice. The date of receipt by an enrollee of the determination will be presumed to be 5 calendar days after the date of the written determination, unless there is evidence to the contrary. For purposes of meeting the filing deadline, the appeal request will be considered filed on the date it is received by the plan, plan-delegated entity, or Part D IRE specified in the written determination. In addition, CMS finalizes amendments to clarify long-standing guidance and explicitly state a 60-calendar day timeframe for filing an expedited plan appeal for it to be considered timely.

T. Authorized Representatives for Parts C/D Elections (§§422.60 and 423.32)

CMS finalizes its proposal to codify its longstanding sub-regulatory guidance on authorized representatives making Parts C and D elections on behalf of beneficiaries.[85] Specifically, the agency will define the term "authorized representative" as those with legal authority under the state law of the state in which the beneficiary resides to act and make health care decisions on behalf of a beneficiary. Any mention of the beneficiary in the election, enrollment, or eligibility regulations will be considered to include the authorized representative of the beneficiary acting on behalf of the beneficiary.

U. Open Enrollment Period for Institutionalized Individuals (OEPI) End Date (§422.62(a)(4))

The open enrollment period for institutionalized individuals (OEPI) is continuous.[86] The OEPI is available to individuals if they move into, reside in, or move out of an institution and may be used by such an individual to enroll in, change, or disenroll from a plan. Sub-regulatory guidance states that the OEPI ends two months after an individual moves out of an institution.[87]

CMS finalizes its proposal to codify the sub-regulatory guidance and specifically state that the OEPI ends on the last day of the second month after the month the individual ends residence in a long-term care facility setting included in the definition of "institutionalized" at §422.2.

In response to a commenter requesting clarification about whether the OEPI permits institutionalized individuals to enroll in a SNP or PACE plan, CMS responds that the OEPI allows institutionalized individuals to enroll in an MA plan, including a SNP, or discontinue

[84] This requirement is applied to MA plans under section 1852(g)(2)(A) of the Act and pursuant to section 1860D-4(g)(1) of the Act is applied to part D plans.
[85] This proposal was finalized with a technical change to add the language as new paragraphs §§422.60(i) and 423.32(j) instead of §§422.60(h) and 423.32(h).
[86] Section 1851(e)(2) of the Act establishes the continuous OEPI.
[87] Chapter 2, section 30.3 of the Medicare Managed Care Manual.

enrollment in an MA plan and enroll in Traditional Medicare. It further clarifies that PACE is addressed in separate regulations and that individuals enrolling in a PACE plan do not require an election period.

V. Beneficiary Choice of C/D Effective Date if Eligible for More Than One Election Period (§§422.68 and 423.40)

Regulations do not currently address what an MA organization or Part D plan sponsor is to do when a beneficiary is eligible for more than one election period, which results in more than one possible effective date for the election. Sub-regulatory guidance provides that the MA organization or Part D plan sponsor determines the effective date based on the election period for which the beneficiary is eligible, and if the beneficiary is eligible for more than one election period, the MA organization or Part D plan sponsor allows the beneficiary to choose the election period that results in the desired effective date.[88] That guidance instructs MA organizations and Part D plan sponsors to attempt to contact the beneficiary and document those attempts to determine their choice of election period. If a beneficiary makes an election to enroll in an employer or union group health plan (EGHP) using the group enrollment mechanism, the beneficiary is assigned an effective date according to the SEP EGHP unless the beneficiary requests a different effective date allowed by another election period for which the beneficiary is eligible. The guidance also provides that if the beneficiary does not make an election, the organization or sponsor assigns an election period based on a specified ranking of election periods.

CMS finalizes its proposal to codify the sub-regulatory guidance. Specifically, if a beneficiary applying to enroll or disenroll in an MA plan or Part D plan is eligible for more than one election period, which results in the possibility of more than one effective date, the MA organization or Part D plan sponsor will be required to:

- Permit the beneficiary to choose the election period that results in the desired effective date;
- Attempt to contact the beneficiary (and document the attempts) to determine the beneficiary's choice;
- Use the ranking of election periods ((1) ICEP/part D IEP, (2) MA-OEP, (3) SEP, (4) AEP, and (5) OEPI) to assign an election period if the beneficiary does not make a choice. With the exception of the SEG EGHP (consistent with the sub-regulatory guidance), if a beneficiary is simultaneously eligible for more than one SEP and they do not make an election, including after the contact attempts, the MA organization or PDP sponsor should assign the SEP that results in an effective date of the first of the month after the enrollment request is received; and
- Assign an election period that results in the earliest disenrollment, in the case of a disenrollment request where the beneficiary's desired disenrollment effective date cannot be obtained.

[88] This guidance can be found in chapter 2, section 30.6 of the Medicare Managed Care Manual and chapter 3, section 30.4 of the Prescription Drug Benefit Manual.

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

A. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (§§422.2274(g) and 423.2274(g))[89]

Background on Proposal. CMS believes when a beneficiary calls a company based on an advertisement, they are only expecting to connect with that particular company, not to have return calls made to their personal home or cell number from other companies. However, it notes that the selling and reselling of beneficiary contact information occurs and that beneficiaries are unaware that by placing the call or clicking on the web-link they are unwittingly agreeing for their contact information to be collected and sold to other entities and providing consent for future marketing activities.

In the December 2022 Proposed Rule, CMS proposed to add to §§422.2274(g) and 423.2274(g) a new prohibition on the distribution of personal beneficiary data collected by a TPMO to other TPMOs.

In the final rule, CMS describes a number of protections under the authority of the Office of Civil Rights (OCR), the Federal Communications Commission (FCC), and the Federal Trade Commission (FTC) that apply to individual information collected during marketing or enrollment and clarifies the policies in the proposed rule would supplement, not replace those existing protections. CMS describes in detail that MAOs and Part D sponsors are covered entities subject to the HIPAA Privacy Rule and that it is the responsibility of the TPMO to understand whether it is a covered entity or a business associate when collecting personal beneficiary data that is protected health information, and thus whether it too is subject to the HIPAA Privacy Rule. In addition, the agency points to the Second Report and Order,[90] which amended the FCC consent rules for robotexts and robocalls governed by the Telephone Consumer Protection Act (TCPA). The new FCC rules will apply to TPMOs operating in the MA and Part D marketplace that contact Medicare beneficiaries through advertisements or telemarketing messages that use an automatic telephone dialing system or an artificial or prerecorded voice. The rules require telemarketing texts and calls that result from consumer consent to be "logically and topically associated with the interaction that prompted consent." The rules also will require lead generators and comparison-shopping websites to receive one-to-one consent with a disclosure from the individual for each seller.

Selected Comments/Responses. Many comments received expressed concern that beneficiaries should be able to consent to having their information shared, rather than have a strict prohibition against sharing their information. CMS recognizes the right of beneficiaries to choose to share their personal information and therefore modifies its proposal to provide beneficiaries with the option to consent to having their personal information shared in a clear and understandable way.

[89] The policies in this section were proposed during the cycle for Contract Year 2024.

[90] https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.

In response to comments, the agency clarifies that MAOs and Part D sponsors are not TPMOs and therefore TPMOs may share personal beneficiary data with MAOs and Part D sponsors without being in noncompliance with this proposal. Though, those entities are covered entities and business associates and as such would need to comply with HIPAA privacy rules.

Final Action. CMS is not finalizing its policy as proposed, but is instead finalizing a revised policy that permits TPMOs to share personal beneficiary data with other TPMOs for marketing or enrolling a beneficiary into an MA or Part D plan only if the TPMO first obtains express written consent from the beneficiary. Prior express written consent must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO. CMS indicates that the revised regulation text is generally consistent with the one-to-one consent structure announced by the FCC in the Second Report and Order, and thus should make it simple and less arduous for a TPMO to comply with both rules, when applicable. This finalized policy will apply beginning October 1, 2024.

B. Marketing and Communications Requirements for Special Supplemental Benefits for Chronically Ill (SSBCI) (§422.2267)

Beginning January 1, 2022, CMS requires a model disclaimer to be used in marketing materials that mention SSBCI benefits (referred to as the SSBCI disclaimer). Currently, §422.2267(e)(34) requires MA organizations to include the SSBCI disclaimer in any material copy that mentions SSBCI benefits, which must convey that the benefits are a part of special supplemental benefits and that not all members will qualify for the benefits. CMS, however, continues to be concerned about misleading marketing that may lead beneficiaries to believe they can automatically receive all SSBCI available by enrolling in a plan, and not understand that eligibility requirements that apply to these benefits.

CMS finalizes, with modifications noted below, to clarify that MAOs must include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI and to expand the required SSBCI disclaimer, requiring that the MAO clearly state what must occur for an enrollee to be eligible for the SSBCI, i.e., the beneficiary must have the required chronic condition, must meet the definition of chronically ill enrollee, and must be determined by the MAO to be eligible to receive a particular SSBCI under the plan's coverage criteria. In response to comments, CMS modifies its proposal to clarify that the SSBCI the MAO advertises must be tied to the applicable MA plan or plans that offer that SSBCI and that the disclaimer used must communicate that coverage depends on the enrollee being a chronically ill enrollee and on the applicable MA plan's coverage criteria (whereas before the proposed language was not plan specific but MAO specific). This modification is to clarify that if there are differences in terms of types of SSBCI offered or types of eligible chronic conditions for the SSBCI between plans offered by an MAO, the MAO must make those differences clear.

Specifically, in the SSBCI disclaimer, the MAO will need to comply with each of the following:

- List the top 5 chronic condition(s) the enrollee must have to be eligible for the SSBCI. In response to comments, the agency makes modifications to clarify the following:

    - When only one type of SSBCI is mentioned, if there are 5 or fewer conditions, all conditions will need to be listed; if there are more than 5, then the top 5 conditions (as determined by the MAO) need to be listed.
    - When multiple types of SSBCI are mentioned, if there are 5 or fewer conditions, all conditions will need to be listed, and if relevant, a statement included that these conditions may not apply to all types of SSBCI mentioned; if there are more than 5 conditions, then the top 5 conditions (as determined by the MAO) will for which one or more listed SSBCI is available will need to be listed.
    - If there are more than 5 conditions that may be eligible for the benefit, in addition to listing the top 5, there must be a statement that there are other eligible conditions not listed.
- Clearly and accurately convey that even if the enrollee has a listed chronic condition, the enrollee may not receive the benefit because coverage of the item or service depends on the enrollee being a chronically ill enrollee and on the MA organization's coverage criteria for the specific SSBCI item or service. MAOs are not required to conform with a standardized template, but are required to accurately provide the required information. The agency provides the following as an example of SSBCI disclaimer language that may be used: "Eligibility for this benefit cannot be guaranteed based solely on your condition. All applicable eligibility requirements must be met before the benefit is provided. For details, please contact us."
- Comply with formatting requirements specified by the agency; for print ads the disclaimer must be in 12-point font (as currently required) and for non-print media (i.e., television, online, radio) and outdoor advertising (i.e., billboards) the disclaimer would be read at the same pace (or displayed in the same font size) as the contact information mentioned in the ad.

These finalized SSBCI disclaimer requirements will apply to all contract year 2025 marketing and communications beginning October 1, 2024, and in subsequent years.

Selected Comments/Responses. The majority of commenters overwhelmingly supported CMS's proposal to strengthen and add more specific requirements to the SSBCI disclaimer. However, some commenters expressed concern about the amount of information being required to be included in the disclaimer, including because it could overwhelm the ad, make the beneficiary disinterested or confused in the benefit being offering, or deter MAOs from promoting SBCI that could be beneficial to beneficiaries. CMS believes that the benefit of providing accurate and complete information to aid the beneficiary in making an informed choice outweighs the potential for the concerns raised.

A few commenters raised concerns that the chronic condition list would be difficult for MAOs to implement and could lead to beneficiary confusion, including noting that if only 5 eligible conditions (rather than all, for example) are required to be provided, beneficiaries who may be eligible but don't have one of the conditions listed in the subset of eligible conditions may incorrectly believe they are ineligible. CMS addresses these concerns with the modifications described above.

Some commenters expressed concern that the disclaimer could be confusing for dually eligible individuals who may be unaware they could access some of the same benefits through Medicaid. CMS does not include SSBCI disclaimer language specifically for dually eligible individuals or D-SNPs, but does clarify that under statutory and regulatory authority, MAOs may not distribute marketing material to MA-eligible individuals (including dually eligible individuals) unless the material has been submitted to CMS and the agency has not disapproved the material.[91] It notes that accordingly, MAOs are required and expected to have SSBCI disclaimers that are accurate and not misleading, in accordance with agency rules. However, given the different levels of access to Medicaid benefits (such as with respect to full-benefit versus partial-benefit dually eligible individuals and state differences in waiver categories and eligibility) the agency does not believe it is practical for MAOs to tailor the SSBCI disclaimer in a manner that describes which SSBCI would be covered under Medicaid in each potential situation.

Other commenters expressed concern about giving MAOs discretion to determine the top 5 eligible chronic conditions to include in the list on the disclaimer. CMS believes MAOs are in the best position to make this determination and references examples of what an MAO may consider, including which conditions are more common among the enrollee population, which are most prevalent in the service are of the plan offering the SSBC, or which are used most commonly in determining eligibility for SSBCI.

C. Agent Broker Compensation

CMS is required under section 1851(j)(2)(D) of the Act to ensure compensation paid to agents and brokers incentivizes them to enroll individuals in the MA plan that is intended to best meet their health care needs. Regulations at §422.2274 permit MA plans to establish the amount paid to agents and brokers, but specify maximum compensation (excluding administrative costs) that may be paid to agents and brokers for initial enrollment and renewals. Payment to agents and brokers for administrative costs (such as training and operational overhead) are permitted outside of those limits if the payment is not more than fair market value of those services.

CMS notes that the MA marketplace has become increasingly consolidated, which provides a greater opportunity for larger parent organizations to use financial incentives provided to agents and brokers to enroll individuals in their plan. The agency has received complaints that current regulatory limitations on compensation are being circumvented by agents and brokers being provided "administrative payments" (which do not fall under regulatory caps)[92] rather than "compensation" (which does fall under the caps) or by being paid add-on payments that individually do not exceed the maximum compensation limitations (but cumulatively would exceed such limitations). CMS believes these financial incentives are contributing to behaviors that are resulting in a marked increase in MA marketing complaints to CMS in recent years related to beneficiaries being encouraged or pressured to join an MA plan and not receiving from such plan what was expected or explained. The agency also notes that it has observed similar additional payments made by MA organizations to Field Marketing Organizations (FMOs), which employ agents and brokers to complete MA enrollment activities and may conduct

[91] See section 1851(h)(1) and (2) of the Act and §422.2262.
[92] Note that fraud and abuse laws, including the Federal anti-kickback statute, place limitations on compensation arrangements.

additional marketing activities on behalf of MA plans. CMS describes how these incentives paid to FMOs create an unlevel playing field that favors larger, national plans.

CMS finalizes the following policies with modifications (with further details provided below) regarding agent and broker compensation:

- Prohibit contract terms between MAOs and agents, brokers, or other third-party marketing organizations (TPMOs) that directly or indirectly interfere with the agent's or broker's ability to objectively assess and recommend which plan best meets the health care needs of the beneficiary;
- Set a single agent and broker compensation rate for all plans and revise the scope of what is considered "compensation; and
- Eliminate the regulatory framework that allows for separate payment to agents and brokers for administrative services.
- Make conforming changes to the PDP agent broker compensation rules.

In response to several comments expressing concern that the 2025 contract year effective date could result in agents and brokers, who have already begun training, testing, and state appointments, being in noncompliance before the AEP has even begun, CMS clarifies that these policies related to the compensation rates are effective October 1, 2024. The updates will coincide with the beginning of marketing activities for the 2025 contract year. Any arrangements that are not in compliance with the proposals will not be subject to remedial action for activities engaged in before October 1, 2024, regardless of whether they are related to 2025 contract year plans.

1. Limitation on Contract Terms

Specifically, CMS finalizes its proposal that, beginning in contract year 2025, MAOs are required to ensure that no provision of a contract with an agent, broker, or TPMO creates an incentive that would reasonably be expected to inhibit their ability to objectively assess and recommend the plan that best meets the health care needs of a beneficiary. Examples of the prohibited anti-competitive contract terms include: (i) Those that specify renewal or other terms of the contract contingent upon preferentially higher rates of enrollment; (ii) Those that make a contract with an FMO or reimbursement for marketing activities contingent on agents and brokers employed by the FMO meeting enrollment quotas; (iii) Terms that provide bonuses with the understanding the money be passed to agents or brokers based on enrollment volume; and (iv) Terms for an FMO to provide an agent or broker leads or other incentives based on previously enrolling beneficiaries into specific plans (other than to best meet the health care needs of the beneficiary).

To enforce this requirement, the agency expects to review contracts as part of routine monitoring as well as relying on investigation of complaints and work of the Office of Inspector General. CMS may also seek additional data collection as part of the Part C reporting requirements process in future years.

2. Compensation Rates

CMS finalizes its proposal to require that all payments to agents or brokers that are related to initial enrollments or renewals in MA plans or are for services conducted as part of the relationship associated with enrollment in an MA plan be included as compensation, including payments for activities that are currently excluded under paragraph (ii) of the definition of compensation at §422.2274(a) (i.e., administrative payments), and therefore be regulated by compensation requirements. CMS is changing the caps on compensation payments to set the rates that would be paid by all plans across the board so they would not vary between plans. Agents and brokers will be paid at the same amount whether from the MA plan or by an FMO. CMS is removing the annual reporting requirement for MA organizations to report specific rates and range of rates paid to agents and brokers since all agents and brokers would be paid the same compensation in a year.

3. Administrative Payments

To ensure that MA organizations cannot circumvent the FMV caps on agency and broker compensation, CMS finalizes its proposal to eliminate the separate regulatory authority at §422.2274(e)(1) that provides for separate payments for administrative services, thus prohibiting separate administrative payments. As all payments (including administrative) would be included in "compensation," CMS will adjust the FMV for compensation to take into account costs for certain appropriate administrative activities. CMS acknowledges this approach does not enable agents and brokers to directly recoup administrative costs (such as overhead) unless the agent has a certain volume of business. After consideration of comments received (and discussed below), CMS finalizes this proposal with a modification to increase, beginning in 2025, the base compensation rate by $100 (instead of by $31, as proposed), to be updated annually, to reflect administrative costs included under compensation, including administrative cost of the licensing and training and testing requirement and the recording requirements.

Selected Comments/Responses. In response to comments raised, CMS clarifies that this policy is not intended to eliminate the ability of a plan to not pay compensation for an enrollment. Therefore, the agency clarifies in the final rule that a plan would not be in violation of the policy if the plan chooses at any time to communicate to its agents and broker that it will not compensate them for enrollments into the plan.

Concern was raised that setting a uniform compensation rate may have a negative impact on smaller MAOs and Part D plan sponsors, which would be at a disadvantage for negotiating below the compensation cap. However, CMS believes that because the administrative fees paid per enrollee greatly exceed the compensation paid for the enrollment, the benefits of removing the continual increase in administrative payments and thus increased payments to agents, brokers, and TPMOs will offset any financial losses caused by the increase to compensation expenses.

Other comments expressed concern that the $31 increase to the flat-rate compensation amount would not be enough to cover the administrative activities listed in the rule (call recording and training and testing) not to mention other business expenses and services provided. The agency

responds that it is not its intent to undervalue activities of agents and brokers or drive them out of the industry. However, CMS also believes the MA program and its funds should not be used to subsidize other programs and industries and therefore, it is reasonable for MA compensation rates to reflect less than 100 percent of the cost of purchasing or licensing, for example, tools used by agents and brokers when those tools are used for purposes and programs that are not limited to only the MA program. Therefore, CMS supports updating the compensation rate increase to better reflect the costs of MA agent and broker services, but notes that most administrative expenses are based on data and contracts to which CMS does not have access. The agency continues to believe that a uniform, flat rate for calculating the increase is appropriate to create parity regardless of plan, plan type, or Medicare enrollment type. Taking all comments on recommended dollar amount flat rate increases into account, the agency concludes that increasing the FMV rate for new enrollments by a total of $100 (and the consequent application to enrollment renewals, which are paid at a maximum amount of 50 percent of the total compensation amount) would provide agents and brokers with sufficient funds to continue to access necessary tools and training to perform their services and provide adequate services to Medicare beneficiaries.

4. Agent Broker Compensation for Part D Plans

CMS finalizes its proposal to apply each of the policies, as finalized as described in paragraphs 1, 2, and 3 above to the sale of stand-alone Part D plans by agents and brokers.

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

A. Introduction

CMS uses the Part C and Part D 5-star rating system to publicly disseminate comparative information, including on quality, about MA plans and Part D plans to beneficiaries. The system is used to determine quality bonus payment ratings for MA plans and the amount of MA beneficiary rebates. CMS has moved elements of the Part C/Part D star rating system to use "Universal Foundation" measures,[93] consistent with the agency's National Quality Strategy. The provisions in this section apply to the quality ratings for MA plans, cost plans, and Part D plans.

In its December 27, 2022 MA/Part D proposed rule, CMS proposed several changes to the star ratings system that the agency anticipated finalizing for the 2024 measurement period, but deferred finalizing these proposals until now (effective for the 2025 measurement period). CMS specifically proposed to:

- Remove the stand-alone Part C Medication Reconciliation Post-discharge measure;
- Add the updated Part C Colorectal Cancer Screening measure with the National Committee for Quality Alliance (NCQA) specification change;
- Add the updated Part C Care for Older Adults—Functional Status Assessment measure with the NCQA specification change;

[93] https://www.nejm.org/doi/full/10.1056/NEJMp2215539

- Update the Medication Therapy Management (MTM) program completion rate for comprehensive medication review (CMR) measure (Part D);
- Add the Part D Concurrent Use of Opioids and Benzodiazepines measure;
- Add the Part D Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults measure; and
- Add the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measure.

The agency also proposed a series of technical clarifications of the existing rules related to Quality Bonus Payment (QBP) appeals processes and weighting of measures with a substantive specification change.

Along with these proposals from the December 2022 proposed rule, CMS is also finalizing Star Ratings proposals it promulgated in its November 2023 Part C/Part D proposed rule, also for the 2025 measurement period/2027 Star Ratings. In that rule, CMS proposed to:

- Revise the process for identifying data completeness issues and calculating scaled reductions for the Part C appeals measures (addressed in VII.E Data Integrity section, below),
- Add that a sponsor may request CMS review its contract's administrative claims data used for the Part D patient safety measure no later than the annual deadline set by CMS for the tar ratings year (section VII.F, below),
- Update how the CAI and HEI rewards are calculated in the case of contract consolidations (sections VII.G and VII.H, below), and
- Revise an aspect of the QBP appeals process (section VII.I, below).

B. Adding, Updating, and Removing Measures (§§422.164 and 423.184)[94]

1. Proposed Measure Update

a. Medication Reconciliation Post-Discharge (Part C)

CMS proposed to remove the stand-alone Medicine Reconciliation Post-Discharge (MRP) measure as the agency determined that it is duplicative of the MRP component of the Transitions of Care (TRC) measure included in the 2024 Star Ratings. CMS indicates that most commenters supported the proposed removal of this measure and will remove it effective with the 2025 measurement year/2027 Star Ratings.

b. Colorectal Cancer Screening (Part C)—Substantive Change Colorectal Cancer Screening (Part C)—Substantive Change

In response to guidance from the U.S. Preventive Services Task Force (USPTF), the National Committee for Quality Assurance (NCQA) expanded its Colorectal Cancer Screening measure to adults aged 45–49, for an updated age range of 45–75. In December 2022, CMS proposed

[94] CMS lists the measures used for the star ratings each year in the Medicare Part C and D star ratings Technical Notes or similar guidance issued with publication of the star ratings.

incorporating this change for the 2024 and subsequent measurement years. Most commenters supported CMS's proposal; the agency finalizes the proposal and is including the updated colorectal cancer screening measure beginning with the 2025 measurement year/2027 Star Ratings.

c. Care for Older Adults (COA)—Functional Status Assessment (Part C)—Substantive Change

For HEDIS data reported in 2021, NCQA changed its existing COA – Functional Status Assessment measure. Previously, the measure specifications permitted noting that at least three out of four elements of the patient's cognition (ambulation, hearing/vision/speech, or other functional independence) were assessed as adherence to the measure (in addition to assessing ADLs and IADLs through standardized patient assessment instruments). The 2021 change removed the notation component of the specification, given the clinical community's movement toward standardized assessment instruments. Because this was a substantive change to the measure, CMS moved the measure to "display" status for two years beginning with the 2022 Star Ratings.

In December 2022, CMS proposed adding back the COA – Functional Status Assessment measure to the Star Ratings system. Given that most commenters supported the CMS proposal, CMS is finalizing its proposal to add the measure back to the Star Ratings beginning with the 2025 measurement year/2027 Star Ratings.

d. MTM Program Completion Rate for CMR (Part D)

Part D sponsors are required (per Section 1860D-4(c)(2) of the Social Security Act) to have an MTM program that is designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used and to reduce the risk of adverse events.[95] Targeted beneficiaries are Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary.[96] In the December 27, 2022 proposed rule,[97] CMS proposed changes to the MTM program targeting criteria that would (1) require plan sponsors to target all core chronic diseases identified by the agency; (2) lower the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and require sponsors to include all Part D maintenance drugs; and (3) revise the methodology for calculating the cost threshold to be commensurate with the average annual cost of 5 generic drugs. At the time, CMS estimated that if finalized, these changes would impact the number of Part D enrollees eligible for MTM services from 9 percent to an estimated 23 percent and, therefore, substantially increase the number of enrollees included in the denominator of the MTM Program Completion Rate for the CMR measure.[98]

[95] Section 1860D-4(c)(2) of the Act.
[96] Targeting criteria is codified at §423.153(d)(2).
[97] This is the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications" (87 FR 79452).
[98] Table GB1 in the rule provides a summary of the proposed revised individual star rating measure for performance periods beginning with 2025.

Therefore, CMS proposed that if these changes to eligibility proposed in the December 27, 2022 rule were finalized in a future rule, to move the MTM Program Completion Rate for CMR star rating measure to a display measure for at least two years (by reason of substantive measure updates) before using the updated measure to calculate and assign star ratings. For example, if the changes were to be finalized for 2025, the measure would be moved to the display page for at least two years before using the updated measure (*i.e.*, the measure would be removed from the star ratings for the 2025 and 2026 measurement years and return no earlier than the 2027 measurement year for the 2029 star ratings). The star rating measure would not be updated if the changes to eligibility for MTM programs described above and in the December 27, 2022 proposed rule were not finalized.

Because CMS did not finalize the proposed MTM changes in its April 2023 MA/Part D final rule, it is following through on its proposal to move the MTM Program Completion Rate for CMR measure to display status for at least two years (2025 and 2026). CMS acknowledges the concerns of some commenters who note that this would leave a gap in the measures applicable to MA-PD plans and/or the Part D summary Star Rating; however, the agency indicates that there is no legacy measure that could take the place of the MTM Program Completion Rate for CMR measure, but that new MTM-related measures could be considered in future rulemaking.

e. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D)

CMS proposed to add these three Part D measures to the 2026 Star Ratings (2024 measurement year), asserting that they would help plans identify enrollees who are at risk of respiratory depression or fatal overdoses, cognitive decline, or falls and fractures, respectively, and help plans encourage appropriate prescribing when medically necessary. These measures are calculated from Prescription Drug Event (PDE) or CMS administrative data, so they do not require any new data collections. The measures have been on display since 2021, and thus meet the §423.184(c)(3) and (4) requirement that measures be put on display for a minimum of two years before becoming Star Rating measures.

Although a few commenters supported moving these three measures from display status to the Star Ratings, the majority of commenters did not, particularly focusing on potential overlap between the two polypharmacy measures. Other commenters expressed concern that these measures could lead to tighter utilization management of the encompassed drugs and pose greater administrative burden on prescribers, pharmacists, *et cetera*.

In response, CMS asserted that it continues to believe that these measures are important areas of focus for the Part D population from a clinical perspective, and cited the evidence it reviewed to support this assertion. The agency did conduct an analysis to evaluate overlap between the COB measure and the two polypharmacy measures, however, finding relatively high overlap between the COB and Poly-CNS measures, and much lower overlap between the COB and Poly-ACH measures. CMS rebutted commenters' assertion that these measures would pose additional administrative burden, and contends that any small additional burden would be outweighed by

the better clinical outcomes related to improved patient safety and the reduction of medication errors.

As a result, CMS will finalize its proposal to move the COB and Poly-ACH measures to the 2027 Star Ratings beginning with the 2025 measurement year, but will maintain the Poly-CNS measure on the display page.

A summary of the new and revised Star Measures for performance periods beginning on or after January 1, 2025, is presented in Table VII.1 of the rule, reproduced below.

Table VII.1. Summary of New and Revised Individual Star Rating Measures for Performance Periods Beginning on or after January 1, 2025

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Colorectal Cancer Screening (COL)*	Percent of plan members aged 45 to 75 who had appropriate screenings for colorectal cancer.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	00139-02-C-PARTC	Clustering	MA-PD and MA-only
Care for Older Adults (COA) – Functional Status Assessment*	Percent of Special Needs Plan enrollees 66 years and older who received a functional status assessment	Managing Chronic (long term) conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	00109-01-C-PARTC	Clustering	Special Needs Plans
Part D Measures								
Concurrent Use of Opioids and Benzodiazepines (COB)	The percentage of individuals ≥18 years of age with concurrent use of prescription opioids and benzodiazepines.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year		Clustering	MA-PD and PDP

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)	The percentage of individuals ≥65 years of age with concurrent use of ≥2 unique anticholinergic medications.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year		Clustering	MA-PD and PDP
Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR)**	The percent of MTM program enrollees, 18 years or older, who received a CMR during the reporting period.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Part D Plan Reporting Requirements	The calendar year 2 years prior to the Star Ratings year	00454-01-C-PARTD	Clustering	MA-PD and PDP

* Revised Measures
** Effective for the 2027 measurement year.

C. Non-substantive Measure Updates (§§422.164(d)(1)(v) and 423.184(d))

In the December 2022 proposed rule, CMS proposed revised language to clarify that an expansion in data sources used is considered a non-substantive measure update, regardless of whether to expansion is in the form of adding alternative data sources or expanding the modes of data collection (*e.g.*, administering the Consumer Assessment of Healthcare Providers and Systems survey in a web-based mode). CMS characterized this proposal as only adding another example to the non-exhaustive list of non-substantive measure changes that the current regulations permit to be done through the Advance Notice/Rate Announcement process.

CMS received comments both supporting and opposing this proposal. Opponents of the proposal argued that a new mode of data collection should be considered a substantive change, especially if the new modality had the potential to produce different results from an existing survey. CMS disagreed with this position in its response, stating that the use of a web-based survey to augment a mail-in survey "in no way changes the numerator or denominator of the measure." Therefore, CMS is finalizing the clarification to the regulation text at §§422.164(d)(1)(v) and 423.184(d)(1)(v), and will apply it immediately on the effective date of the final rule and for measures in the 2025 Star Ratings where CMS has complied with §§422.164(d)(1) and 423.184(d)(1) in adopting the non-substantive change.

D. Measure Weights (§§422.166(e)(2) and 423.186(e)(2))

In the December 2022 proposed rule, CMS proposed to modify the regulation text to codify that substantively updated measures are treated like new measures for weighting purposes upon their return to the Star Ratings from the system's display page. A weight of 1 is assigned for the updated measure's year of return, and in subsequent years the measure receives the weight associated with its category.

The proposed regulation text reflects the process currently in use by CMS. A substantively updated measure is removed from the ratings and placed on the display page for 2 years, after which it may return to the Star Ratings once its return is adopted through rulemaking.

All commenters supported this proposal, so CMS is finalizing the proposed change to the regulation text in the 2025 final rule.

E. Data Integrity (§§422.164(g) and 423.184(g))

When CMS determines that a contract's measure data are incomplete, inaccurate, or biased, it reduces the measure rating in accordance with requirements specified at §§422.164(g) and 423.184(g). CMS uses statistical criteria to reduce a contract's appeals measures for missing Independent Review Entity (IRE) data such that it uses scaled reductions to account for the degree to which the data are missing. Beginning with the 2020 measurement year, CMS removed the only two Part D appeals measures because of low statistical reliability. Therefore, since the Part D appeals measures are no longer part of the star ratings, CMS proposed to remove the regulatory provisions that address how the Part D appeals measures had been used in calculating scaled reductions.

Currently, CMS uses data from the Timeliness Monitoring Project (TMP) to determine whether the IRE data used to calculate the Part C appeals measures are complete. CMS also proposed, beginning with the 2025 measurement year/2027 star ratings, to expand the sources of data for determining the completeness of data to include data from MA organizations, the IRE, and CMS administrative sources.

Part C contracts must send partially favorable and unfavorable decisions to the IRE within applicable timeframes specified by regulation.[99] CMS collects information at the contract level from MA organizations about the number of partially favorable reconsiderations and unfavorable reconsiderations, and these data are subject to data validation to confirm they are reliable, valid, complete, and comparable. Currently, a contract is subject to a possible reduction because of a lack of IRE data completeness if the calculated error rate is at least 20 percent and the projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

In its November 2023 proposed rule, CMS proposed, for purposes of determining if a contract is subject to a potential reduction for the Part C appeals measures' star ratings, to compare:

(A) The total number of appeals (regardless of their disposition) received by the IRE (including appeals that are dismissed for reasons other than the plan's agreement to cover the services and withdrawn appeals), to
(B) The total number of appeals that were supposed to go to the IRE, which would be equal to the sum of the number of partially favorable reconsiderations and the number of unfavorable reconsiderations from the Part C Reporting Requirements during the measurement year.

CMS proposed to then calculate the error rate as 1 minus the quotient of the above ratio. This error rate would be based on 12 months (rather than the current projected number of cases not forwarded to the IRE in a 3-month period). That is, the requirement for a minimum number of cases would be satisfied if the total number of cases that should have been forwarded to the IRE, minus the total number of cases received by the IRE ((B) described above minus (A) described above), is at least 10 for the measurement year.

CMS also proposed that the two Part C appeals measure star ratings be reduced to 1 star if the agency does not have accurate, complete, and unbiased data to validate the completeness of the measures.

Commenters generally supported these proposals. A few commenters asked for clarifications of CMS's methodological or procedural policies; the agency adjudicated these requests in its responses in this final rules. A few commenters asked for a transition year so that plan sponsors could accommodate the new approach for scaled reductions; CMS responded that a transition is unnecessary given that these updates continue to use data already submitted by plans through established processes.

[99] §422.590(a) through (e).

After consideration of the public comments received CMS is finalizing as proposed the updated approach for making scaled reductions at §422.164(g)(1)(iii), (1)(iii)(A)(*1*) and (*2*), (1)(iii)(H), (1)(iii)(K)(*2*), and (1)(iii)(O) for the 2027 Star Ratings (2025 measurement year) with a modification to clarify that the numerator is the total number of cases received by the IRE that should have been sent at §422.164(g)(1)(iii)(H). CMS here also finalizes the removal of the Part D related provisions at §422.164(g)(1)(iii)(B), (1)(iii)(F), and (1)(iii)(I), and § 423.184(g)(1)(ii), and the removal of the provision at §422.164(g)(1)(iii)(J) without modification.

F. Review of Sponsor's Data (§§422.164(h) and 423.184(h))

Currently, an MA organization, a cost plan organization, and a Part D plan sponsor may request a review of the contracts' appeals data and complaints tracking module data before star ratings are calculated.

CMS proposed in the November 2023 proposed rule, beginning with the 2025 measurement year/2027 star ratings, to expand the scope of data that Part D sponsors may request for CMS to review for star ratings to include administrative data used for their contract's Part D star rating safety measures, including prescription drug event, diagnosis code, and enrollment data. Beginning with the 2025 measurement year/2027 star ratings, CMS proposed that any requests by an MA organization, cost plan 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—established in this final rule for measurement year 2025 as May 18, 2026. Subsequent years' deadlines would be announced in advance via annual Advance Notice and Rate Announcement or by a HPMS memorandum.

CMS indicates that most commenters supported the agency's proposal to set an annual deadline for MA organizations and Part D sponsors to request reviews of its administrative data for the Patient Safety measures (May 18, 2026 for the 2025 measurement year), and thus finalizes these policies as proposed.

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

The categorical adjustment index (CAI) adjusts for the average within-contract disparity in performance associated with the percentages of enrollees who receive a low-income subsidy or are dually eligible for Medicare and Medicaid (LIS/DE), or who have disability status. Currently, in the case of a contract consolidation, the percentage of LIS/DE enrollees and of disabled enrollees for the surviving contract that are used to determine the CAI adjustment factor are calculated using enrollment data for the December for the measurement period of the star ratings year for the surviving contract.

CMS proposed, beginning with the 2027 Star Ratings, to instead, in the case of a contract consolidation, calculate the percentage of LIS/DE enrollees and of disabled enrollees used to determine the CAI adjustment factor for the surviving contract for the first two years following the consolidation, based on the combined contract enrollment data across all contracts in the consolidation for the December for the measurement period of the star ratings year.

CMS indicates that while one commenter raised concerns about this proposal (e.g., transparency of information, and whether this policy would encourage contract consolidations), most commenters supported the proposal, and thus the agency is finalizing the revision at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) as proposed.

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

The 2027 star ratings will be the first star ratings to include the health equity index (HEI) reward, which rewards contracts for obtaining high measure-level scores for enrollees with specified social risk factors (SRFs). Current regulations do not address how CMS is to calculate the HEI when contracts consolidate.

CMS proposed that, beginning with the 2027 star ratings, for the first year following a contract consolidation, the surviving contract of the consolidation would be assigned 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. Contracts that do not meet the minimum percentage of enrollees with the specified SRF thresholds or the minimum performance threshold would have a reward value of zero. For the second year following a consolidation, to calculate the HEI score for the surviving contract, the patient-level data used in calculating the HEI score would be combined across the contracts included in the consolidation before calculating the HEI score. The HEI score for the surviving contract would then be used to calculate the HEI reward for the surviving contract in accordance with the current methodology described in §§422.166(f)(3)(viii) and 423.186(f)(3)(viii).

CMS indicates that most commenters supported its proposed approach to calculating the HEI reward (with some asking for methodological clarifications), and thus the agency is finalizing the addition of §§422.166(f)(3)(viii)(A) and (B) and 423.186(f)(3)(viii)(A) and (B) as proposed, with a modification to clarify that total contract enrollment from July of the most recent measurement year is used in calculating the enrollment weights in the first year following the consolidation.

I. Quality Bonus Payment Appeals Rules (§422.260)

Under sections 1853(n) and 1853(o) of the Act, MA organizations that achieve at least 4 stars in a 5-star quality rating system receive quality bonus payments (QBP). Also, section 1854(b)(1)(C) of the Act associates the share of savings that MA organizations must provide to enrollees as the beneficiary rebate with the level of the MA organization's QBP rating. Regulations at §422.260(c) provide for an administrative review process for an MA contract to appeal its QBP status, which includes a request for reconsideration and a request for an informal hearing on the record.

CMS proposed in the November 2023 proposed rule to provide the CMS Administrator with the opportunity to review and modify the hearing officer's decision within 10 business days of its issuance, and proposed that if the Administrator does not do so within the timeframe the hearing officer's decision would be final and binding. This policy would apply for all QBP appeals after the effective date of the final rule.

CMS indicates most commenters supported this proposal, and is thus finalizing as proposed the revision of §422.260(c)(2)(vii) to state that the CMS Administrator has the discretion to review and modify the hearing officer's decision on a QBP appeal within 10 business days of its issuance by the hearing officer.

The prior December 2022 proposed rule also contained proposed revisions and additions to regulation text language dealing with the administrative review process for QBP status appeals that are finalized in this rule. These provisions would clarify the permissible bases for administrative review, adding language at §422.260 (c)(1)(i) would explicitly limit requests for reconsideration to circumstances where the alleged error could impact one or more measure values or the overall Star Rating and would explicitly state that the review process could result in a measure or overall Star Rating going up, going down, or staying the same. CMS also proposed adding language addition at §422.260 (c)(2)(v) would explicitly state that the burden of proof of calculation or data errors by CMS rests with the MA organization and that the applicable evidentiary standard is "a preponderance of evidence" rather than "clear and convincing evidence."

CMS also proposed expanding the limits on requesting an administrative review at §422.260 (c)(3) to provide that a review request could not be based on data inaccuracies from the following data sources: HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources. Lastly, CMS proposed to add language to §422.260(d) to clarify the potential outcomes of reopening a QBP determination.

In this rule, CMS is finalizing the proposed clarifications at §422.260(c)(1)(i), (c)(2)(v), (c)(3)(iii), and (d) with a small revision to paragraph (d) to clarify that information provided during the administrative review process may include information from other MA organizations and slight reorganization to §422.260(c)(3)(iii) to improve the clarity of the regulation. CMS is applying these changes immediately on the effective date of this final rule and to the 2025 Star Ratings.

VIII. Improvements for Special Needs Plans

A. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§422.2)[100]

Institutional Special Needs Plans (I-SNPs) are MA SNPs that restrict enrollment to MA eligible individuals who are institutionalized or institutionalized-equivalent. The term institutionalized means, with respect to a special needs individual and for an open enrollment period, an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care facility setting, such as a skilled nursing facility (SNF), nursing facility (NF), an intermediate care facility for individuals with intellectual and developmental

[100] The policies in this section were proposed during the cycle for Contract Year 2024 in the December 2022 proposed rule.

disabilities, a psychiatric hospital or unit, rehabilitation hospital or unit, a long-term care hospital, and a swing-bed hospital. The term "institutionalized-equivalent" means an MA eligible individual who is living in the community, but who requires an institutional level of care. The regulations include specific limitations on how an assessment is made to determine whether an individual meets the definition.

CMS proposed to add the following four definitions to §422.2: a definition of I-SNPs and three additional definitions for each of the current I-SNP types that correspond to CMS' current MA application process. As part of the definitions for I-SNPs that enroll special needs individuals who are institutionalized, CMS proposed to codify current policies that address the need for the I-SNP to contract with the institutions where such special needs individuals reside. The proposed definitions would clarify that MAOs may offer SNPs that are limited to institutionalized beneficiaries, institutionalized-equivalent beneficiaries, or both.

The agency also proposed to codify a requirement (at §422.101(f)(2)) for I-SNP models of care; specifically, that contracts with long-term care institutions would have to contain terms and conditions that permit I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized. Under the proposal, I-SNP clinical and care coordination staff could be employed by the MAO offering the I-SNP or under contract with the I-SNP to furnish healthcare, clinical care, or care coordination services. CMS would interpret the term "access" broadly to encompass information sharing, admission to physical facilities to see enrollees, and other issues.

CMS proposed to define I-SNPs as SNPs that restrict enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent. It also proposed to add definitions for the three types of I-SNPs:

- *Facility-based Institutional special needs plan (FI-SNP)* means a type of I-SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized; owns or contracts with at least one institution, specified in the definition of institutionalized in this section, for each county within the plan's county-based service area; and must own or have a contractual arrangement with each institutionalized facility serving enrollees in the plan.
- *Institutional-equivalent special needs plan (IE-SNP)* means a type of I-SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent.
- *Hybrid Institutional special needs plan (HI-SNP)* means a type of I-SNP that restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent in this section. HI-SNPs must meet the standards specified in the definitions of FI-SNP and IE-SNP.

In response to these proposals, some commenters sought clarifications from CMS regarding the proposed definitions, and some expressed concerns generally about SNPs that were somewhat oblique to the specific proposals in the NPRM. In general, commenters supported CMS's proposed definitions of I-SNPs and the codification of specified beneficiary protections. One commenter suggested applying level of care requirements similar to those proposed for I-SNPs

here, to "institutionalized equivalent" enrollees of Part D plans; CMS did not act on this suggestion given that this set of proposals pertained only to SNPs, and the agency had not made corresponding proposals for Part D plans.

CMS is finalizing definitions of the terms Facility-based Institutional special needs plan (FI-SNP), Hybrid Institutional special needs plan (HISNP), Institutional special needs plan (I-SNP), and Institutional-equivalent special needs plan (IE-SNP) at § 422.2 largely as proposed, with a slight modification of 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 also revising the definition of FI-SNP by replacing "with the plan's county-based service area" with "in the plan's service area." This revision better aligns with the definition of Service Area in 42 CFR 422.2 "Service area."

In this rule, CMS is also finalizing revisions to § 422.101 to add a new paragraph (f)(2)(vi) as proposed to require the model of care for each I-SNP to ensure that contracts with long-term care institutions contain requirements allowing I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized.

B. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (§422.101)[101]

All SNPs must implement care management requirements that have two explicit components: an evidence-based model of care (MOC) and a series of care management services. In the December 27, 2022 proposed rule, CMS proposed to codify several of its policies on MOCs.

1. Model of Care Scoring Requirements for SNPs (§422.101(f)(3)(iii))

All SNPs must submit their MOCs to CMS for evaluation by the National Committee for Quality Assurance (NCQA), and MAOs offering multiple SNPs must develop separate MOCs to meet the needs of the targeted population for each SNP type it offers. In 2021, CMS added requirements for plan implementation of enrollee care management practices and established a minimum benchmark score of 50 percent for each element of a plan's MOC. In the December 2022 NPRM, the agency proposed to codify the current SNP MOC scoring protocols established in subregulatory guidance.

For a SNP MOC to be approved, each element of the MOC would have to meet a minimum benchmark score of 50 percent, and each MOC must meet an aggregate minimum benchmark score of 70 percent. The SNP MOC would only be approved if each element of the model of care meets both the minimum benchmark and the aggregate minimum benchmark.

The period of approval for a C-SNP MOC that receives a passing score would be one year. For I-SNPs and D-SNPs, CMS proposed different approval periods based on the aggregate minimum benchmark score as follows:

[101] The policies in this section were proposed during the cycle for Contract Year 2024 in the December 2022 proposed rule.

Approval Periods for MOCs for I-SNPs and D-SNPs	
Aggregate Minimum Benchmark Score	**Period of Approval**
85% or greater	3 years
75% to 84%	2 years
70% to 74%	1 year

If an MOC fails to meet a minimum element benchmark score of 50 percent or fails to meet the aggregate minimum benchmark of 70 percent, the MAO would have a one-time opportunity to resubmit a corrected MOC for reevaluation. An MOC that is corrected and resubmitted using this cure period would be approved for only one year. This opportunity to cure deficiencies in the MOC would only be available once per scoring cycle for each MOC.

The comments CMS reports receiving on these proposals were either requests for clarification, or suggestions for changes to SNPs that were outside of the scope of the proposals in the December 2022 NPRM.

CMS is finalizing its proposals to amend §422.101(f)(3)(iii) substantially as proposed. As finalized, §422.101(f)(3)(iii) establishes the aggregate minimum benchmark score for a MOC to be approved, the time period of approval, and the opportunity for an MA organization to submit a corrected MOC for re-evaluation if the MOC is scored below the minimum benchmarks on NCQA's first review.

2. Amending SNP MOCs after NCQA Approval (§422.101(f)(3)(iv))

CMS proposed to codify current policies and procedures for MAOs to amend their MOCs after NCQA approval, which is referred to as the "off-cycle MOC submission process." Currently, a D-SNP or I-SNP that seeks to make substantive revisions to their existing approved MOC may submit a summary of their off-cycle MOC changes, along with the red-lined MOC, in the Model of Care module in HPMS for NCQA review and approval. Generally, C-SNPs may not submit a revised MOC through an off-cycle submission.

Under the proposal, off-cycle revisions (*e.g.*, updates or corrections) to a SNP MOC could only be submitted for NCQA review between June 1st and November 30th of each calendar year. Where an update or correction is necessary to comply with applicable law, the submission period would be dictated by CMS.

The agency also proposed to codify its guidance relating to which MOC changes require submission to CMS and how SNPs should submit their MOC changes to CMS. Specifically, CMS proposed to codify a list of reasons for when a SNP must use an off-cycle submission of a revised MOC for review and approval as follows:

- Substantial changes in policies or procedures pertinent to the health risk assessment (HRA) process; revising processes to develop and update the Individualized Care Plan (ICP); the integrated care team process; risk stratification methodology; or care transition protocols;
- Target population changes that warrant modifications to care management approaches (*e.g.*, adding Diabetes to a Cardiovascular Disease and Congestive Heart Failure C-SNP);

- Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations;
- Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical *vs*. non-clinical personnel); or
- Changes to quality metrics used to measure performance.

SNPs would not be allowed to implement any changes to its MOC until NCQA has approved the changes; any revised MOC would not be rescored during the off-cycle review of changes. Additionally, the MOC's original approval period (*i.e.*, 1-year or multi-year) would not be modified because of NCQA's approval of the changes.

C-SNPs would only be eligible to submit an off-cycle MOC submission when CMS requires one to ensure compliance with applicable law.

When a deficiency is identified in the off-cycle revisions to the MOC, the SNP would have one opportunity, between June 1st and November 30th of each calendar year, to cure the deficiency. If the revised version is not acceptable after the second NCQA review, the SNP would have to continue implementing its approved MOC without any revisions for the remainder of its MOC approval period.

In making these proposals, CMS emphasized that it is largely codifying current subregulatory policies, and that because plans are following the current subregulatory guidance, CMS did not expect that any further burden would be imposed by codifying these standards.

CMS reports in the final rule that one commenter objected to including "changes to quality metrics used to measure performance" on the list of reasons requiring off-cycle submission and approval, and another commenter suggested imposing deadlines for the NCQA review process (with a commensurate increase in resources to NCQA to adhere to these deadlines).

CMS is finalizing new paragraph (f)(3)(iv) (for requirements on off-cycle changes to an approved MOC) largely as that regulation text was proposed, but with very minor modifications to clarify and improve paragraph (f)(3)(iv).

C. Amending the Definition of Severe or Disabling Chronic Condition; Defining C-SNPs and Plan Types; and Codifying List of Chronic Conditions (§422.2)[102]

MA SNPs are coordinated care plans specifically designed to provide targeted care and limit enrollment to special needs individuals, who are institutionalized (or institutionalized-equivalent) individuals; dual eligible individuals; or individuals with a severe or disabling chronic condition and who would benefit from enrollment in a specialized MA plan. The BBA of 2018 made

[102] The policies in this section were proposed during the cycle for Contract Year 2024 in the December 2022 proposed rule.

several changes to the statutory provisions relating to Chronic Condition Special Needs Plans (C-SNPs), which CMS proposed to codify in its December 27, 2022 proposed rule.

1. Amending the Definition of Severe or Disabling Chronic Condition

Effective January 1, 2022, the BBA of 2018 amended section 1859(b)(6)(B)(iii) of the Act by adding a new definition of special needs individuals with severe or disabling chronic conditions. That definition requires the individual to "have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed by a panel of clinical advisors (under section 1859(f)(9)(A) of the Act)."

Additionally, every five years, CMS must convene a panel of clinical advisors to review and revise a list of chronic conditions for C-SNPs that meet two sets of criteria:

- Conditions that meet the new definition of special needs individuals with severe or disabling chronic conditions; and
- Conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a SNP and either (1) as a result of enrollment in a C-SNP, the enrollee with the condition would have a reasonable expectation of meeting a certain standard regarding health status, outcomes and costs compared to other coverage options, or (2) the condition has a low prevalence in the general population of Medicare beneficiaries or a disproportionally high per-beneficiary cost.

In addition, the statute also requires the following:

- The list of severe or disabling chronic conditions used for C-SNPs must include HIV/AIDS, end stage renal disease (ESRD), and chronic and disabling mental illness.
- The panel must consider the availability of varied benefits, cost-sharing, and supplemental benefits under the Medicare Advantage Value-Based Insurance Design (VBID) model being tested by the Center for Medicare and Medicaid Innovation (CMMI).

CMS proposed to codify, effective January 1, 2025, the statutory definition in its regulations without substantive change and the 22 chronic condition categories identified by the panel of clinical advisors mentioned above (see the final rule text for the full list of newly added or revised chronic condition categories at 87 FR 79562). Three of the new categories (conditions that cause similar functional challenges, conditions that impair the senses, and conditions that require continued therapy services) differ from how the current list of severe or disabling chronic conditions uses categories as a single condition or set of related diseases; these three new categories are focused on impacts on health and functionality rather than an underlying disease or condition. This is designed to permit C-SNPs to create benefit packages and care coordination services to address the needs of beneficiaries who share the same functional needs even if their specific disease or chronic condition may differ.

Commenters generally supported the revised and updated list of chronic conditions, although individual commenters made minor comments regarding specific conditions individually. The Medicare Payment Advisory Commission (MedPAC), however, opposed expanding the list of qualifying chronic conditions, arguing that many of the conditions are not specific enough to incentivize the kinds of specific interventions that C-SNPs were envisioned to bring to bear.

Deferring to the recommendations of its clinical panel, CMS is finalizing the definition for the term "severe or disabling chronic condition" as proposed with minor modifications to the formatting of the regulatory text to improve the clarity of the definition.

D. Chronic Condition Special Needs Plan Definition, Scope and Eligibility (§§422.2, 422.4, and 422.52)[103]

CMS asserted that it would be helpful to codify a definition of C-SNP that reflects the statutory requirement that they are limited to serving special needs individuals who have a severe or disabling chronic condition and that distinguishes them from D-SNPs, and proposed the following definition:

> "Chronic Condition Special Needs Plan (C-SNPs) means a SNP that restricts enrollment to MA eligible individuals who have one or more severe or disabling chronic conditions, as defined under this section, including restricting enrollment based on the multiple commonly co-morbid and clinically-linked condition groupings specified in §422.4(a)(1)(iv) of this chapter."

The proposed definition would codify then current guidance on ability of MAOs to offer a C-SNP that focuses on single or multiple chronic conditions. It would also limit C-SNPs that focus on multiple chronic conditions to the list of CMS-approved group of commonly co-morbid and clinically linked conditions. CMS identified five combinations of commonly co-existing chronic conditions that may be the focus of a C-SNP, which the agency proposed to codify at §422.4(a)(1)(iv).[104] The clinical panel discussed above recommended three additional pairings as permissible groupings of severe or disabling chronic conditions.[105] CMS proposed to add these to §422.4(a)(1)(iv), and proposed to clarify that enrollees need only have one of the qualifying conditions to be eligible for enrollment in the listed approved groupings.

CMS proposed to remove a C-SNP plan application option that is currently available. MAOs would no longer be able to sponsor a C-SNP to apply for their own customized group of multiple chronic conditions. Noting an historical lack of interest from MAOs, beneficiaries, and patient advocacy groups in this option, the agency anticipated only minimal impact from this proposal, given the limited take-up of this option.

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[103] The policies in this section were proposed during the cycle for Contract Year 2024 in the December 2022 proposed rule.

[104] Diabetes mellitus and chronic heart failure; chronic heart failure and cardiovascular disorders; diabetes mellitus and cardiovascular disorders; diabetes mellitus, chronic heart failure, and cardiovascular disorders; and stroke and cardiovascular disorders.

[105] Anxiety associated with COPD, chronic kidney disease and post-renal organ transplantation, and SUD and chronic and disabling mental health conditions

The agency expected that any changes from current plan and enrollment practices would most likely be seen in connection with chronic condition categories like ESRD, where the proposal would somewhat revise enrollment qualifications. Because it proposed to use the condition category "Chronic kidney disease (CKD)" and to include ESRD as part of that condition category, the agency anticipated that current ESRD C-SNPs would be permitted to enroll, in addition to those with ESRD, beneficiaries with CKD Stages 1–4 if this proposal were finalized. CMS asserted that its proposals would not add any burden for MAOs that sponsor C-SNPs.

Comments on these proposals were generally supportive.

CMS is finalizing the revised definition of the term "chronic condition special needs plan (C-SNP)" at §422.2, the revisions to §422.4(a)(1)(iv) to establish how C-SNPs may target specific and specific groupings of severe or disabling chronic conditions, and the special eligibility rule for C-SNPs at § 422.52(g) as proposed.

E. Verification of Eligibility for C-SNPs (§422.52(f))

Each MA special needs plan (SNP) must employ a process approved by CMS to verify the eligibility of an individual enrolling in the SNP. In its November 2023 MA/Part D proposed rule, CMS proposed to codify its longstanding guidance on the procedural steps that MA plans must take to verify an individual's eligibility for enrollment in a chronic condition SNP (C-SNP).

Under this proposal, the MAO would have to contact the individual applicant's current physician (either primary care or the specialist treating the qualifying condition) to confirm that the enrollee has the specific severe or disabling chronic condition(s). The contact with the physician would occur before enrollment, or if the MAO uses a Pre-enrollment Qualification Assessment Tool (PQAT) prior to enrollment, verification may be made after enrollment but no later than the end of the individual's first month of enrollment in the C-SNP. If a C-SNP using a PQAT could not confirm the enrollee has the qualifying condition(s) before the end of that first month, it would have the first 7 days of the following month to notify the enrollee that they will be disenrolled effective at the end of the second month of enrollment—unless confirmation of the chronic condition(s) is made before the end of the second month. If the individual is disenrolled because the person's eligibility cannot be verified, the C-SNP would have to recoup any agent/broker compensation.

Verification would be done in a form and manner authorized by the agency, which currently includes a note from a provider or the provider's office or documented telephone contact with the physician or physician's office confirming that the enrollee has the specific severe or disabling chronic condition.

The proposed requirements for the PQAT would include a pre-enrollment assessment and a post-enrollment confirmation by the C-SNP using the information from the applicant's physician. The PQAT would have to include a set of clinically appropriate questions relevant to the chronic condition(s) on which the C-SNP focuses, and it must collect information on the applicant's past medical history, current signs and/or symptoms, and current medications that would provide reliable evidence that the applicant has the applicable condition(s). Requirements for the

physician's signature and the date and time of the assessment would also be codified. C-SNPs would be required to track the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment, and the data and supporting documentation would have to be made available to CMS upon request.

Because this proposal would be a codification of procedures currently followed by MAOs, CMS asserted that there would be no new or additional burden impacts related to the SNP eligibility verification procedures from those that have already been accounted for under OMB control number 0938–0753.

CMS rebutted a number of comments asserting that these verification processes would result in undue burdens on physicians (health care providers) or plans, and made no change to the proposed regulation text in response to these comments. However, in response to other comments, CMS has changed "physician" in §422.52(f)(1) to include: (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). Additionally, it has changed references to "physician" elsewhere in § 422.52(f) to "health care provider."

Thus, the agency is finalizing its proposal to add new paragraph (f)(1) to §422.52 largely as proposed, but with modifications to specify that an applicant's current health care provider, who may be a physician, nurse practitioner or physician's assistant, provides the verification of the applicant's chronic condition. In addition, CMS is finalizing revisions in paragraphs (f)(1)(i), (f)(1)(ii)(A)(4), (f)(1)(ii)(B) and (f)(1)(iii) to be consistent with the revisions in paragraph (f)(1) and to clarify the post-enrollment verification process when the C-SNP uses the PQAT.

F. I-SNP[106] Network Adequacy (§422.116)[107]

SNPs, including I-SNPs are coordinated care plans and are subject to current network adequacy requirements.

CMS proposed new definitions for different types of I-SNPs, one of which was a facility-based institutional special needs plan (FI-SNP). An FI-SNP refers to a type of I-SNP that (1) restricts enrollment to MA eligible individuals who meet the definition of institutionalized; (2) owns or contracts with at least one institution, specified in the definition of institutionalized, for each county within the plan's county-based service area; and (3) owns or has a contractual arrangement with each institutionalized facility serving enrollees in the plan.

MAOs have complained that the network adequacy requirements are not appropriate for FI-SNPs. They state that many FI-SNPs have difficulty contracting with providers outside their facilities, due to their model of care, and I-SNP enrollees will not routinely seek care with these

[106] See VIII.A above for definition of I-SNP.
[107] The policies in this section were proposed during the cycle for Contract Year 2024 in the December 2022 proposed rule.

providers since they generally do not travel away from the facility for care. In response, in the November 2023 proposed rule, CMS proposed to adopt a new exception from the network evaluation requirements only for FI-SNP plans. Under the proposal, an FI-SNP could ask for an exception from the network adequacy requirements under either of the following situations:

- The FI-SNP is unable to contract with certain specialty types required under §422.116(b)[108] because of the way enrollees in FI-SNPs receive care.
- The FI-SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (under §422.135[109]) when using telehealth providers of the specialties currently listed in regulations at §422.116(d)(5).[110]

For the first exception, CMS would consider the inability to contract to mean the MAO could not successfully negotiate and establish a contract with a provider, which would include individual providers and facilities. Citing the noninterference clause, CMS indicated that it cannot judge the bona fides of contract negotiations between the MAO and the providers. However, approval of this type of exception would be based on whether the FI-SNP submits evidence of the inability to contract with certain specialty types required under the network adequacy rules due to the way enrollees in FI-SNPs receive care.

For the second exception, CMS proposed requiring (1) substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits and (2) coverage of out-of-network services furnished by a provider in person when requested by the enrollee, with in-network cost sharing for the enrollee.

An MAO receiving the exception provided for FI-SNPs would have to agree to offer only FI-SNPs on the contract that receives the exception, which means they would be prohibited from establishing additional plans (or plan benefit packages) that are not FI-SNPs with respect to that contract. CMS also notes that FI-SNPs would still be subject to §422.112 regarding access to covered benefits, including, for example, coverage of any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

Commenters were overall supportive of these proposals; thus CMS is finalizing the establishment of the two new exceptions from the network adequacy evaluations under §422.116(b) through (e) for certain FI-SNPs, the factors and evidence CMS will consider in whether to grant the exceptions, and the new requirement that an MA organization that receives an exception for its FI-SNP(s) only offer FI-SNPs under the contract that receives the exception approval.

[108] https://www.ecfr.gov/current/title-42/part-422/section-422.116#p-422.116(b)
[109] https://www.ecfr.gov/current/title-42/section-422.135
[110] https://www.ecfr.gov/current/title-42/part-422/section-422.116#p-422.116(d)(5)

G. 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)

There are a significant number of enrollees who receive Medicare services through one managed care entity and Medicaid services through a different entity (misaligned enrollment), rather than from one organization delivering both Medicare and Medicaid services (aligned enrollment). CMS believes aligned enrollment, and especially exclusively aligned enrollment (*i.e.*, enrollment in a parent organization's D-SNP is limited to individuals who are also enrolled in that organization's Medicaid MCO), is a critical part of improving experiences and outcomes for dually eligible individuals. CMS seeks to increase enrollment in integrated D-SNPs, such as fully integrated dual eligible special needs plans (FIDE SNPs), highly integrated dual eligible special needs plans (HIDE SNPs), and applicable integrated plans (AIPs). FIDE SNPs and AIPs require exclusively aligned enrollment (EAE).

In November 2023, CMS made the following proposals:

- To replace the current quarterly special enrollment period (SEP) with a monthly SEP for dually eligible individuals and other LIS eligible individuals to elect a standalone PDP;
- To create a new integrated care SEP to allow dually eligible individuals to elect an integrated D-SNP on a monthly basis;
- To limit enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO); and
- To limit the number of D-SNPs an MAO, its parent organization, or an entity that shares a parent organization with the MAO, can offer in the same service area as an affiliated Medicaid MCO in order to reduce "choice overload" of D-SNP options in certain markets. (An affiliated Medicaid MCO is a Medicaid MCO offered by the MAO, the same parent organization, or another subsidiary of the parent organization.)

The proposals would create a new SEP and revise the duals/LIS SEP, but otherwise would not change the remaining SEPs. Table HC1 of the proposed rule (reproduced below) summarizes the combined effects of the proposals.

TABLE HC1: ENROLLMENT SCENARIOS UNDER CURRENT RULES AND PROPOSED AMENDMENT—INDIVIDUAL PERSPECTIVE

(NOTE: This table does not include other applicable SEPs)

Scenarios for Dually Eligible Individuals	Current Rules under Quarterly Dual SEP	Proposed Monthly Dual/LIS SEP, Integrated Care SEP, and Enrollment Limitations for Non-Integrated MA-PD Plans
Elect any MA plan during initial coverage election period (ICEP) or annual election period (AEP), or switch between any plans during MA open enrollment period (MA-OEP)	Permitted	Permitted, except individuals in Medicaid MCOs would not be able to select a misaligned D-SNP where applicable

Scenarios for Dually Eligible Individuals	Current Rules under Quarterly Dual SEP	Proposed Monthly Dual/LIS SEP, Integrated Care SEP, and Enrollment Limitations for Non-Integrated MA-PD Plans
Elect Medicare fee-for-service (FFS) and standalone prescription drug plan (PDP), mid-year	One change permitted per quarter, except last quarter	Permitted each month
Elect an integrated D-SNP (FIDE SNP, HIDE SNP, or AIP) as eligible, mid-year		Permitted each month, but must be aligned enrollment
Elect a non-integrated D-SNP or other MA plan, mid-year		Not permitted
Scenarios for LIS individuals without Medicaid	**Current Rules**	**As Proposed**
Elect any MA plan during ICEP or AEP, or switches between any plans during MA-OEP	Permitted	Permitted
Elect Medicare FFS and standalone PDP, mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an MA plan, mid-year		Not permitted

1. Changes to the SEPs for Dually Eligible Individuals and Other LIS Eligible Individuals

The continuous dual SEP allows eligible beneficiaries to make Part D enrollment changes for Part D plans, including MA-PD plans, once a quarter for each of the first three quarters of a plan year. In contrast, other Part D enrollees generally may switch plans only during the AEP or via other applicable SEPs each year. CMS has reservations about this policy, including the impact of aggressive marketing focused on dual eligibles, the inability to enroll in an integrated D-SNP after having exhausted opportunities permitted by the quarterly dual SEP, and complexity for states, enrollment counselors and individuals. CMS proposed two new SEPs:

- First, the quarterly dual SEP would be replaced with a new dual/LIS SEP, which would allow dually eligible and other LIS-enrolled individuals to enroll once per month into any standalone prescription drug plan. The proposed dual/LIS SEP would not allow enrollment into MA-PD plans or changes between MA-PD plans, although such options would still be available where another election period permits.
- Second, a new integrated care SEP would permit enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans.

Effectively, the two new SEPs would permit a monthly election to (1) leave an MA-PD plan for Medicare FFS by enrolling in a standalone PDP, (2) switch between standalone PDPs, or (3) enroll in an integrated D-SNP (*e.g.*, a FIDE, HIDE, or AIP). An eligible individual could use both SEPs within the same month, in which case the application date of whichever SEP is elected last in time would be the SEP effectuated the first of the following month. A downside to such a policy proposal is that some states have few or no integrated plans or have integrated D-SNPs that only serve a limited geographic region, which means dually eligible individuals in

those states would not be able to change MA-PD plans outside of the AEP, MA-OEP, or other available SEPs. Anytime disenrollment could dissuade MA plans from offering D-SNPs, and it could complicate care coordination by plans. The new dual/LIS SEP could limit the ability of an LIS individual without Medicaid to use an SEP as compared to the current SEP.

2. Enrollment Limitations for Non-integrated Medicare Advantage Plans

CMS noted that states may use their state Medicaid agency contracts (SMAC) to limit enrollment in D-SNPs to enrollees in an affiliated Medicaid MCO and to arrange their Medicaid managed care programs. For example, they may use Medicaid MCOs to cover a comprehensive scope of Medicaid benefits or use prepaid health plans to cover a smaller scope of Medicaid benefits. CMS recognized that states have their own policy interests and goals for their Medicaid managed care programs and noted that the agency has traditionally deferred to states to use SMACs to align Medicare and Medicaid plan offerings consistent with their policy priorities. However, because it is concerned about the growing number of dual eligible individuals who are not enrolled in plans with aligned enrollment, CMS proposed new regulations for how MAOs offer and enroll eligible individuals in D-SNPs.

Specifically, starting with the 2027 plan year, when an MAO[111] also contracts with a state as a Medicaid MCO that enrolls dually eligible individuals in the same service area, D-SNPs offered by the MAO would have to limit new enrollment to individuals enrolled or enrolling in the D-SNP's affiliated Medicaid MCO. This would apply when *any* part of the D-SNP service area(s) overlaps with any part of the Medicaid MCO service area. Further, only one D-SNP could be offered by the MAO, its parent organization, or another MAO with the same parent organization in the same service area with the aligned Medicaid MCO.

Additionally, under this proposal starting in 2030, these D-SNPs could only enroll (or continue to enroll) individuals enrolled or enrolling in the affiliated Medicaid MCO. The effect of this proposal would be to require integrated D-SNPs to disenroll individuals who are not enrolled in both the D-SNP and Medicaid MCO offered under the same parent organization. However, D-SNPs could use a period of deemed continued eligibility to retain enrollees who temporarily lose Medicaid coverage (as described in §422.52(d)). Further, where an enrollee is temporarily disenrolled from the affiliated Medicaid MCO but is expected to be re-enrolled in the affiliated Medicaid MCO within the period of deemed continued eligibility, the D-SNP would not have to disenroll that enrollee during that period. The proposed regulations would apply at the parent organization level.

CMS would establish two exceptions to the proposed new requirements §422.514(h)(3). The first exception would be to allow states that currently have different integrated D-SNP programs based on age or benefit design to continue to operate these programs or to design future integrated D-SNP programs with eligibility nuances. Under the proposal, an MAO[112] could offer

[111] References to an MAO in this sentence include references to its parent organization and to an entity that shares a parent organization with the MAO.
[112] References to an MAO in this paragraph include references to its parent organization and to an entity that shares a parent organization with the MAO.

more than one D-SNP for full-benefit dually eligible individuals in the same service area as that MAO's affiliated Medicaid MCO if the SMAC requires it. This exception would only be available where the SMAC requires different eligibility groups for the different D-SNPs that are offered by the same MAO.

The second exception would permit an MAO to offer, or continue to offer, both HMO and PPO D-SNPs under the condition that they no longer accept new full-benefit dually eligible enrollees in the same service area as the D-SNP affected by the proposed new regulations at §§422.504(a)(20) and 422.514(h). Under this proposed exception, the MAO could only accept new enrollment in one D-SNP for full-benefit dually eligible individuals in the same service area as an affiliated Medicaid MCO, and that new enrollment would be limited to the full-benefit dually eligible individuals who are enrolled or enrolling in the affiliated Medicaid MCO. Table HC2 in the proposed rule (reproduced above) contains enrollment scenarios that illustrate the combined effects of the proposed SEP changes and enrollment limitations, and examples are shown in Tables HC3 and HC4.

CMS also proposed to establish a new crosswalk exception to allow one or more MAOs that share a parent organization and offer D-SNPs subject to these proposed new limits to crosswalk enrollees (within the same parent organization and among consistent plan types) when the MAO elects not to renew or to consolidate its current D-SNPs to comply with the new rules.

Summary of Comments and CMS Responses

CMS received extensive comments[113] on its proposals aimed at increasing the number of dually eligible managed care enrollees who receive Medicare and Medicaid services from the same organization.

Summary of Comments: Increasing the Percentage of Dually Eligible Managed Care Enrollees Receiving Integrated Services

Many commenters, including MedPAC and MACPAC, generally supported the proposals to increase the percentage of dually eligible individuals who receive Medicare and Medicaid services from the same organization for multiple reasons – including, reducing administrative burden, supporting Medicaid agencies' ability to coordinate care, creating more efficient program management, making it easier to navigate integrated care, and strengthening integrated care plans so that Medicare and Medicaid feel like one program.

Commenters supporting the goal of increasing enrollment in truly coordinated organizations highlighted that this would reduce administrative burdens, support care coordination, create more efficient program management, and strengthen integrated care plans. There was strong support for measures that would simplify enrollment processes and enhance the integration of Medicare and Medicaid services, ensuring that dually eligible individuals receive cohesive care. Some

[113] Comments and responses on this topic composed over 70 pages of the public inspection version of this final rule. Only the highest-level summary of these comments is provided here, given that comments were generally supportive, and that CMS is proceeding to finalize its proposals largely as proposed with only minor modifications.

commenters expressed concerns about the existing landscape of D-SNPs, with many not providing the level of integration necessary for effectively coordinating Medicare and Medicaid services.

CMS response
CMS appreciated the comments supporting the increase in integrated care for dually eligible individuals and agreed that aligned enrollment is a critical part of improving experiences and outcomes for these individuals. CMS shared its vision for a future where integrated care models, such as FIDE SNPs and HIDE SNPs, become more prevalent and accessible.

Summary of Comments: SEP Changes
A number of commenters, again including MedPAC and MACPAC, also supported CMS's proposal to (1) replace the quarterly dual/LIS SEP with a monthly dual/LIS SEP that allows individuals to enroll in Traditional Medicare and a PDP, and (2) create the new monthly integrated care SEP. They believed that this would reduce aggressive marketing tactics and simplify the enrollment process for dually eligible individuals by limiting the movement of these individuals only into integrated plans (and not "integration-only" D-SNPs). Some commenters also supported the new monthly integrated care SEP, highlighting its potential to reduce complexity for Medicaid agencies and improve access to needed services for those with complex chronic care needs. Still other commenters noted that the monthly dual/LIS SEP would improve freedom of choice for individuals whose current plan "does not work for them."

Other commenters, however, raised concerns that the proposed changes to SEPs could actually have undesirable effects, such as opening up dually-eligible beneficiaries to more, rather than less, plan marketing. Commenters expressing concerns about the proposed SEP changes also raised the possibility of increased administrative burdens on states, and confusion among beneficiaries or their representatives. Some commenters posited that CMS's proposed SEP changes could result in discontinuity of care, or result in dually eligible/LIS beneficiaries leaving coordinated care environments for Traditional Medicare, which lacks such benefits, and also expose some of these beneficiaries to greater financial liability if they were not able to obtain a Medigap plan upon disenrolling from Medicare Advantage. In such instances, this disenrollment could potentially undermine plan investments in care coordination.

Some commenters argued that more frequent enrollment/disenrollment could also adversely affect an MAO's Star Ratings; CMS indicated that the agency does not have any evidence to support this assertion, and instead argued that the greater integration of care afforded by these proposals could actually positively impact D-SNPs' Star Ratings.

CMS response:
CMS responded that the proposed SEP changes aim to streamline the enrollment process and protect dually eligible individuals from potentially misleading marketing, without significantly restricting their ability to switch plans in response to changing needs. CMS underscored that efforts to enhance transparency and provide clear, comprehensive information to beneficiaries about their enrollment options will be an essential part of CMS' strategy to mitigate confusion and ensure informed decision-making.

CMS acknowledged some of the potential adverse unintended consequences of its SEP proposals, but asserted that the benefits of the agency's SEP proposals would outweigh these potential drawbacks.

In response to the issue of aggressive marketing, CMS proposed modifications to the enrollment and eligibility policies to safeguard dually eligible individuals from such practices, and to foster an environment where the choice of plan is driven by the quality of care and integration of services, rather than marketing pressure.

Summary of comments: Enrollment Limitations for Non-integrated Medicare Advantage Plans

Some commenters expressed concern that limiting enrollment changes could inadvertently restrict dually eligible individuals' access to the most suitable plans for their needs. Suggestions were made for maintaining a level of flexibility that would allow beneficiaries to respond to changes in health status, provider networks, or plan performance without being confined to the annual election periods.

CMS response
CMS is finalizing the integrated care SEP with a narrower scope so that dually eligible individuals may use the SEP to enroll in a FIDE SNP, HIDE SNP, or AIP if they are enrolled in or in the process of enrolling in the sponsor's affiliated Medicaid managed care plan. CMS is finalizing §423.38(c)(35) largely as proposed but with a modification that the SEP is available only to facilitate aligned enrollment, as that term is defined in §422.2. As a result of this limitation, this SEP will effectively be limited to full-benefit dually eligible individuals because "aligned enrollment" is defined by reference to full-benefit dual eligibility.

Summary of Comments: Concerns for Partial-Benefit Dually Eligible Individuals
A number of commenters raised concerns that the SEP proposals would limit the options available to partial-benefit dually eligible individuals. They noted that these individuals have similar health care needs as full-benefit dually eligible individuals and should have access to the same enrollment opportunities.

CMS response
In response to concerns about partial-benefit dually eligible individuals, CMS noted that these individuals would still have the opportunity to disenroll from an MA-PD plan to Traditional Medicare and switch between standalone PDPs on a monthly basis. CMS acknowledges that the SEP proposals limit opportunities for partial-benefit dually eligible individuals and LIS eligible individuals to enroll in MA-PDs and coordination-only D-SNPs, but notes that partial-benefit dually eligible individuals and LIS eligible individuals would still have the ability to make changes to their MA plan or non-integrated D-SNPs during the AEP, MA-OEP, or where another SEP permits.

Summary of Comments: Clarification Requests and Suggestions for Modifications to SEP Proposals
Several commenters requested clarifications on the SEP proposals and suggested modifications to address various concerns. Some suggested retaining the quarterly dual/LIS SEP in states

without integrated D-SNPs, allowing enrollment into additional MA-PDs outside of the AEP or MA-OEP, and considering exceptions or modifications to accommodate unique state circumstances.

CMS response
CMS provided clarifications on the availability of current SEPs and confirmed that the proposed changes to the dual/LIS SEP and the adoption of a new integrated care SEP would not affect the ability of individuals to access other applicable SEPs.

is finalizing without modification its proposed amendment at §423.38(c)(4) on the dual/LIS SEP. The agency is finalizing with modifications its proposed amendment at §423.38(c)(35) to add a new integrated care SEP; narrowing the scope so that the SEP is available only to facilitate aligned enrollment as defined at §422.2 (this limitation is reflected in a new paragraph at §423.38(c)(35)(ii)) and clarifying in §423.38(c)(35)(i) that the SEP is available only for full-benefit dually eligible individuals.

H. Comment Solicitation: Medicare Plan Finder and Information on Certain Integrated D-SNPs

While information on D-SNPs that also provide Medicaid benefits for dual eligible individuals is available on the Medicare Plan Finder (MFP) tool, in the November 2023 proposed rule, CMS solicited suggestions on how to make it easier for dually eligible beneficiaries to use the tool to assess MA plans that cover the full array of Medicare and Medicaid services. It noted that information about Medicare benefits covered by integrated D-SNP plans is robust, but less information is available on the scope of Medicaid benefits, which results in confusion or misleading information.

At the time of the publication of the proposed rule, the agency was considering, for Applicable Integrated Plans (AIP), adding a limited number of specific Medicaid-covered benefits (*e.g.*, dental, non-emergency medical transportation, or certain types of home and community-based services) when those services are available to enrollees through the D-SNP or the affiliated Medicaid MCO. It would not include Medicaid benefits that are only available through a separate carve-out. The agency was also considering whether to indicate those services that are Medicare supplemental benefits and which are Medicaid, although it is concerned about additional operational complexity.

Another challenge is that CMS does not currently capture the necessary information for AIPs or other D-SNPs in a systematic manner to populate the plan finder with information about Medicaid benefits covered by D-SNPs. The agency noted that the information it does get from SMACs is neither standardized nor submitted early enough for CMS to review for its release in October. CMS sought comment on ways to get the necessary information to report it. Any changes would not require rulemaking.

In this final rule, CMS does not respond to each specific comment submitted in response to the solicitation in the NPRM, but will consider comments on an ongoing basis.

Commenters were generally supportive of improving the MPF for dually eligible beneficiaries, but recognized the operational challenges of adding Medicaid benefits to the MPF. Some agreed with CMS's thoughts about excluding carved-out Medicaid benefits; one commenter suggested that MPF include Medicaid FFS benefits. Some commenters expressed concerns about the accuracy of Medicaid benefit data, and about CMS's ability to continuously update these data. Several commenters suggested general improvements to the MPF's search functionality that would benefit fully dually eligible beneficiaries. However, CMS has not committed to any immediate action in response to these suggestions.

I. Comment Solicitation: State Enrollment Vendors and Enrollment in Integrated D-SNPs

There are often technical challenges that complicate enrollment in integrated D-SNPs. These include misalignment of Medicare and Medicaid enrollment processes, start dates, and related operational challenges for states and plans, as well as potentially confusing non-integrated enrollee communication materials. Under the Financial Alignment Initiative (FAI), eligibility and enrollment functions for Medicare-Medicaid Plans (MMPs) were delegated to states, and many use state Medicaid enrollment vendors to carry out these functions. Outside of the FAI, dually eligible individuals elect MA plans, including D-SNPs, by enrolling directly with the plan, through Third-Party Marketing Organizations, or via 1-800-Medicare and the Medicare Online Enrollment Center. Some states are interested in using state enrollment vendors, including enrollment brokers as described in section 1903(b)(4) of the Act, to effectuate exclusively aligned enrollment for integrated D-SNPs and their affiliated Medicaid MCOs.

In the November 2023 NPRM, CMS sought to (1) promote enrollment in integrated D-SNPs and reduce the likelihood of misaligned Medicare and Medicaid managed care enrollment for beneficiaries, (2) move to an integrated D-SNP enrollment process that is operationally practical for both CMS and States, (3) align to the extent feasible Medicare and Medicaid managed care enrollment start and end dates, (4) protect beneficiaries from abusive enrollment practices without creating barriers to enrollment into a plan of choice, and (5) streamline beneficiary messaging and communication related to enrollment.

The agency sought feedback on the feasibility of requiring integrated D-SNPs to contract with state enrollment brokers as well as specific concerns with states implementing it. Specific comment was requested on the following issues related to enrollment in integrated D-SNPs:

- Challenges for individuals trying to enroll.
- States' rationale(s) for having a specific Medicaid managed care enrollment cut-off date.
- Operational or systems barriers that states and Medicaid managed care plans face to align the Medicaid enrollment cut-off date with the Medicare managed care enrollment start date or to align disenrollment dates with Medicare.
- Concerns about CMS determining effective dates for Medicare enrollments that occur in the context of the proposed SEP for integrated care.
- Concerns with states requiring D-SNPs to route enrollment through the state enrollment vendor via the SMAC.
- The type of technical assistance related to effectuating MA plan and D-SNP enrollment and eligibility processes that would be helpful to States.

- Concerns about potential abusive enrollment practices.
- Current state requirements and policies related to agents and brokers.
- Other aspects of the integrated enrollment and disenrollment processes in FAI that should apply to D-SNPs.

As with the MFP comment solicitation, CMS is here not responding to each comment submitted.

A number of commenters expressed support for the idea of states requiring DSNPs to contract with state enrollment vendors for enrollment in integrated D-SNPs, believing that this approach could better align enrollment between a D-SNP and an affiliated Medicaid managed care plan and reduce the potential for misalignment. Some commenters emphasized that such an approach would require robust oversight, monitoring, and training for state enrollment vendors. Other commenters suggested that additional resources be invested in State Health Insurance Assistance Programs (SHIPs) as an alternative to requiring D-SNPs to contract with State enrollment vendors. A commenter noted that SHIPs are uniquely positioned to help dually eligible individuals understand their enrollment choices, and recommended CMS require SHIP contact information be included on all plan outreach to beneficiaries. CMS described a handful of other comments specific to the bullets above, but is not taking any immediate actions or making specific future proposals in response to these comments.

J. Clarification of Restrictions on New Enrollment into D-SNPs via State Medicaid Agency Contracts (SMACs) (§§422.52 and 422.60)

Many states add eligibility categories and criteria to their SMACs that restrict new D-SNP enrollment to prioritize and promote integrated care. Others only allow D-SNPs to enroll individuals who are also in an affiliated Medicaid managed care plan creating exclusively aligned enrollment.

CMS proposed to clarify that to be eligible to elect a D-SNP, an individual must also meet any additional eligibility requirements established in the SMAC. It would also be more explicit in its regulations that MAOs may restrict enrollment in alignment with §422.52(b)(2).

CMS indicates in this final rule that several commenters were supportive of this proposal, but cautioned that it would take time to implement, given the need to educate states, to avoid the inclusion of enrollment restrictions within the SMAC that would put a D-SNP at odds with MA enrollment requirements.

Thus in this rule CMS is finalizing without modification its 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. The agency is also finalizing without modification its 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).

K. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§422.514)

A look-alike D-SNP is not a SNP, but it has levels of dual eligible enrollment that are virtually indistinguishable from D-SNPs, and far above those of a typical MA plan. It is not an integrated care plan and is not subject to the laws or regulations governing D-SNPs, which means it is not required to coordinate Medicare and Medicaid benefits for its dual eligible enrollees. It does not have a contract with a state Medicaid agency, which specifies a D-SNP's responsibilities to better integrate care for dually eligible beneficiaries and provide for accountability for their care. To address the proliferation and growth of D-SNP look-alike plans, CMS established the following contracting limitations:

- Beginning with plan year 2022, CMS will not enter into a contract for a new non-SNP MA plan that projects, in its bid, that 80 percent or more of the plan's total enrollment are Medicaid beneficiaries. (See §422.514(d)(1))
- Beginning with plan year 2023, CMS will not renew a contract with a non-SNP MA plan that has actual enrollment, determined using the January enrollment of the current year, consisting of 80 percent or more of Medicaid beneficiaries, unless the MA plan has been active for less than 1 year and has enrollment of not more than 200 individuals at the time of the determination. (See §422.514(d)(2))
- Beginning with plan year 2024, the prohibitions above apply to individual segments of an MA plan.

1. Reducing Threshold for Contract Limitation on D-SNP Look-Alikes

In the November 2023 proposed rule, CMS stated that it set the threshold at 80 percent based on a 2019 MedPAC analysis that showed the proportion of dually eligible individuals in most geographic areas did not exceed the 80-percent threshold. At that time, no MA plan service area had more than 50 percent dual eligible beneficiaries; thus, dual eligible enrollment of 80 percent or greater would not be the result of any plan that had not intended to achieve high enrollment of dually eligible individuals. Some commenters have previously expressed concern that an 80 percent threshold could be gamed by MAOs by keeping enrollment of dually eligible beneficiaries just below 80 percent, and thresholds as low as 50 percent were suggested as an alternative.

CMS has noted significantly increased growth in non-SNP MA plans with a percentage of dually eligible enrollees between 50 and 80 percent of total enrollment,[114] suggesting that MAOs are offering plans for dually eligible individuals but circumventing rules for D-SNPs. The agency proposed to lower the D-SNP look-alike threshold as follows:

- For contract year 2025, 70 percent.
- For contract year 2026, 60 percent.

[114] The rate of growth from 2017 to 2023 in the number of non-SNP MA plans with 50 to 60 percent (544 percent increase), 60 to 70 percent (900 percent), and 70 to 80 percent dually eligible individuals as a percent of total enrollment (1,400 percent) exceeded the rate of enrollment growth for all MA-PD plans (109 percent) over the same period of time.

The lower thresholds would apply to new and existing non-SNP MA plan bids. CMS selected the 60 percent threshold because it exceeds the share of dually eligible individuals in any given MA plan service area currently; thus, it would not be the result for any plan that simply reflected the concentration of dually eligible enrollees in its service area.

In the proposed rule, CMS estimated that the lower threshold would impact 30 non-SNP MA plans with dually eligible individuals representing 70 to 80 percent of total enrollment and 40 non-SNP MA plans with dually eligible individuals representing 60 to 70 percent of total enrollment.

2. Amending Transition Processes and Procedures for D-SNP Look-Alikes

a. Background

To ensure a smooth transition for enrollees from a plan that is discontinued for failure to meet the 80 percent thresholds described above, CMS established regulations (at §422.514(e)) for transitioning enrollees from a discontinued D-SNP look-alike plan to another MA plan, which would be effective for coverage effective January 1 of the next year.

An MAO may transition enrollees in a plan that is being discontinued because it does not meet the proposed 80 percent thresholds into another MA-PD plan or plans (including a D-SNP for enrollees eligible for a D-SNP) offered by the MAO, or by another MAO that shares the same parent organization as the MAO. The individual must be eligible to enroll in the MA-PD plan, meaning they would have to reside in the plan service area and meet other requirements.

The MA-PD plan receiving enrollment from the discontinued D-SNP look-alike plan must satisfy certain requirements. First, in the case of a plan that is not a SNP plan, the resulting total enrollment of the receiving plan may not exceed the 80 percent threshold for dual eligibles. CMS makes this determination prospectively; it adds the cohort of enrollees the MAO proposes to enroll into a different non-SNP plan to the April enrollment numbers and calculates the resulting percentage of dual eligibles. Second, an MA-PD plan receiving transitioned enrollment from a D-SNP look-alike must have a combined Part C and D beneficiary premium of $0 after application of the premium subsidy for full subsidy eligible individuals (as described at §423.780(a)). Third, the receiving plan must be of the same plan type (for example, HMO or PPO) of the D-SNP look-alike out of which enrollees are transitioned.

MAOs may transition individuals without requiring the individual to file an election form if the individual is eligible to enroll in the MA plan and the MAO describes changes in MA-PD benefits and information about the MA-PD plan into which the individual is enrolled in the Annual Notice of Change. The notice describing the change in plan enrollment and any differences must be provided at least 15 days before the annual election period (AEP). If the MAO does not transition current enrollees, it must send a written notice to enrollees who are not transitioned following the rules for notice of non-renewal of plans. An enrollee may make an affirmative choice for another MA plan or standalone Part D plan of their choosing during the AEP preceding the year for which the transition is effective. If a transitioned enrollee elects to

enroll in a different plan during the AEP, enrollment in the plan the enrollee selected takes precedence over the plan into which the MA organization transitioned the enrollee.

b. Proposals

First, CMS proposes what is essentially a conforming amendment to the transition rules to apply the lower thresholds described above (*i.e.*, 70 percent for contract year 2025 and 60 percent for contract year 2026).

Additionally, starting with contract year 2027, the transition process and procedures would be limited to D-SNP look-alikes transitioning dually eligible enrollees into D-SNPs. The agency's experience with D-SNP look-alike transitions effective for plan year 2023 shows the vast majority of enrollees are transitioned to other MA-PDs under the same parent organization as the D-SNP look-alike, and it expects a similar pattern for transitions effective for plan year 2024. CMS notes that MAOs can use other regulatory processes to transition D-SNP look-alike enrollees to non-D-SNPs.

Numerous commenters, including MACPAC and MedPAC, supported the proposal overall to lower the threshold used to identify D-SNP look-alikes to 70 percent dually eligible individuals for plan year 2025 and 60 percent dually eligible individuals for plan year 2026 and subsequent years, and limit the D-SNP look-alike transition pathway to D-SNPs starting in plan year 2027. These commenters expressed concern that D-SNP look-alikes undermine efforts to develop integrated plans for dually eligible individuals by encouraging them to enroll instead in plans that provide many of the same extra benefits as D-SNPs but do not integrate Medicaid coverage. MACPAC noted that D-SNP look-alikes act at cross purposes to State and Federal efforts to integrate care by drawing dually eligible individuals away from integrated products and avoiding the additional requirements that D-SNPs must meet. Commenters also noted that the CMS proposals would simplify choices for dually-eligible beneficiaries, and potentially reduce aggressive marketing tactics on the part of plan sponsors.

CMS also indicates that a number of commenters responded to its solicitation of feedback on the idea of lowering the threshold to 50 percent, and that these commenters were generally supportive of this idea, with some going so far as to suggest lowering the threshold to 40 percent. CMS reports "widespread" support for its proposal to limit transition options available to D-SNP lookalike plans.

By contrast, some commenters opposed these proposals, arguing that they could inappropriately limit plan choices available to dually-eligible beneficiaries, especially for partial-benefit dual-eligibles, or those residing in rural areas. CMS indicated the agency understood these commenters' concerns, but did "not find them to be sufficiently persuasive to change our position." A number of commenters also suggested that CMS exclude partial-benefit dually-eligible beneficiaries from the calculation of the D-SNP lookalike threshold, arguing that a number of states have standing policies that prohibit partial-benefit dual-eligibles from enrolling in D-SNPs; other commenters suggested that CMS develop separate thresholds for fully-dually eligible and partially-dually eligible beneficiaries. Still other commenters suggested that CMS delay the lowering of the thresholds proposed in the November 2023 proposed rule. Again, CMS

understood these arguments, but did not find them compelling enough to cause the agency to change its proposal.

CMS is finalizing revisions to §§422.514(d)(1)(ii), 422.514(d)(2)(ii), and 422.514(e), as proposed.

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

PPOs generally have higher cost sharing for out-of-network services than for the same services obtained from network providers, which is designed to incentivize use of in-network providers. The amount of cost sharing for out-of-network services in D-SNP PPOs are often significantly higher than the cost sharing for the same services under Medicare FFS, while cost sharing for in-network services largely tracks Medicare FFS cost sharing requirements. However, the large majority of enrollees in D-SNP PPOs are protected from being billed for covered Medicare services by Medicare providers, including out-of-network providers, with state Medicaid agencies paying, or the provider foregoing the payment of, cost sharing. Providers may receive less than they would have received under Medicare FFS if the state Medicaid agency limits payment of Medicare cost sharing. This runs counter to the statutory requirement under section 1852(a)(2)(A) of the Act that out-of-network providers receive no less than the FFS amounts, including applicable cost sharing.

CMS proposed, beginning January 1, 2026, to require D-SNP PPOs (both local and regional) to cap out-of-network cost sharing for professional services at the cost sharing limits for those services established at §422.100(f)(6)[115] when furnished in network. The term "professional services" would have the meaning given it in section 422.100(f)(6)(iii), which includes primary care services, physician specialist services, partial hospitalization services, and rehabilitation services.

A D-SNP PPO with a catastrophic limit set at the mandatory maximum out-of-pocket (MOOP) limit in 2026 and subsequent years would have cost sharing for a visit with an out-of-network psychiatrist or other specialist (*i.e.*, cost sharing subject to paragraph (f)(6)(iii)) that is capped at 30 percent coinsurance. If the catastrophic limit is set at the intermediate MOOP limit in 2026 and subsequent years, the coinsurance cap would be set at 40 percent. If the catastrophic limit is set at the lower MOOP limit in 2026 and subsequent years, the coinsurance cap would be 50 percent. The rules CMS uses under §§422.100(f)(6) and 422.100 (j)(1) to assess that copayments are actuarially equivalent to coinsurance would apply here as well.

CMS also proposed to require that cost sharing for out-of-network acute and psychiatric inpatient services be limited by the cost sharing caps under §422.100(f)(6) for in-network benefits. Thus, the cost sharing limit for a D-SNP PPO with a catastrophic limit set at the mandatory MOOP limit would not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay in an out-of-network inpatient or psychiatric hospital. For catastrophic limits equivalent to the intermediate and lower

[115] https://www.ecfr.gov/current/title-42/part-422/section-422.100#p-422.100(f)(6)

MOOP amounts, higher cost sharing for out-of-network cost sharing for inpatient and psychiatric stays could be charged as described at §422.100(f)(6)(iv)(D)(2) and (3), respectively.[116]

CMS proposed to apply to D-SNP PPOs the regulatory requirements under 422.100(f)(1)[117] that list specific benefits for which cost sharing under a plan may not exceed cost sharing under Medicare FFS, including chemotherapy administration services, skilled nursing facility services, home health services, and durable medical equipment.

As an alternative, CMS also considered whether to limit all D-SNP PPO out-of-network cost sharing to no greater than Medicare FFS, or to use an incremental approach to establish a limit specifically for physician services, including psychiatric and other mental health services. This would apply instead of the caps on cost sharing under §422.100(f)(6). The agency also considered proposing out-of-network cost sharing limits for D-SNP PPOs only for services for which the Medicaid payment of cost sharing did not result in a total payment that was at least equivalent to the payment under Medicare FFS. However, that approach would create a complex system of cost sharing limits that differed both by State (depending on whether State policy limited cost sharing for specific services), by service, and in some cases by individual provider; At the time it published the proposed rule, CMS believed this approach would likely be unworkable.

In this final rule, CMS indicates that "the vast majority" of commenters on this topic (including MedPAC) supported the agency's proposal to impose limits on the out-of-network cost sharing for Parts A and B benefits in the benefit packages offered by D-SNP PPOs, with some going further to suggest that CMS impose the cost sharing limits for plan year 2025 (rather than 2026, as proposed), and others supporting CMS's alternative proposal to cap all D-SNP PPO out-of-network cost sharing at traditional FFS levels. (Other commenters opposed the alternative proposal, however, and CMS, recognizing their concerns, declined to impose more stringent cost-sharing limits in this final rule.). CMS notes that many other comments on this section of the NPRM were beyond its scope.

In light of general support expressed in comments received, CMS is finalizing its proposed amendment at §422.100(o)(1) that, starting in 2026, for an MA organization offering a local PPO plan or regional PPO plan, cost sharing for out-of-network services under D-SNP PPOs will be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans, as described in §422.100(f)(6). CMS is also finalizing, with minor technical edits, its 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).

[116] https://www.ecfr.gov/current/title-42/part-422/section-422.100#p-422.100(f)(6)(iv)(D)
[117] https://www.ecfr.gov/current/title-42/part-422/section-422.100#p-422.100(j)(1)

IX. Changes to the Programs of All-Inclusive Care for the Elderly (PACE)

As noted in the table of contents, all but two of the decisions made in this section of the final rule relate to policies in the December 2022 proposed rule for the MA-PD 2024 contract year to update and revise requirements for PACE. The last two provisions in this section relate to proposals made for the MA-PD 2025 contract year. The finalized policies include modifications to application requirements, requirements for medical clearance for PACE staff, timeframes for coordinating care, interdisciplinary team (IDT) requirements for care coordination and plans of care, expansion of participant rights, modifications to the grievance process, notice of performance issues or deficiencies, and service requests made before the participant's initial plan of care is developed. Some of the policies are based on requirements that apply to nursing homes and to MA organizations and Part D sponsors. CMS believes the policies add details about the agency's expectations.

In this section of the summary, unless otherwise specified, a reference to a PACE participant includes a reference to the designated representative of the participant.

A. PACE Past Performance (§§460.18 and 460.19)

CMS proposed to add an evaluation of past performance as a new criterion in the review of applications submitted by a PACE organization (PO) seeking to offer a PACE program or to expand an approved program by adding a geographic service area and/or PACE center site(s). This is intended to allow the agency to deny an application based on past performance. The proposal was modeled after the MA and Part D review regulations, which has long considered past performance in reviewing applications from MAOs or Part D sponsors. The agency also proposed to permit the denial of an application if the PO's agreement was terminated or not renewed during the 38-month period preceding the date the application was first submitted to CMS, and to make a number of related conforming changes to other parts of the PACE regulations in conjunction with the policy proposals.

CMS finalizes all the proposals without modification. Additional details on the final policies are as follows.

During a 12-month review period, the following specific factors will be applied to PACE organizations as a basis for denying an initial or service area expansion (SAE) application:

- The organization was subject to the imposition of an enrollment or payment sanction under §460.42(a) or (b) for one or more of the violations specified in §460.40;[118]
- The organization failed to maintain a fiscally sound operation consistent with the requirements of §460.80(a)[119] after the end of the trial period;
- The organization filed for or is currently in state bankruptcy proceedings; or

[118] Violations in §460.40 include the failure of the PACE organization to provide medically-necessary services, discrimination in enrollment or disenrollment of individuals eligible to enroll in a PACE program based on health status or need for health services, and involuntary disenrollment of a PACE participant in violation of §460.164.
[119] Section 460.80(a) requires PACE organizations to have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities.

- The organization exceeded CMS' threshold for compliance actions, which under the PACE regulations is 13 points determined as follows for the performance period:
    - 6 points for each corrective action plan issued under §460.19(c)(3).
    - 3 points for each warning letter issued under §460.19(c)(2).
    - 1 point for each notice of noncompliance issued under §460.19(c)(1).

These factors are based on those applied to an MA or Part D application, which were tailored for use under the PACE program.

Selected Comments/Responses. Some commenters objected to the 13-point compliance threshold, arguing that it would disproportionately impact larger organizations with many PACE center sites or because of the size and geographic spread of the organization. CMS disagrees. It notes that past performance is determined at the legal entity level, not the parent organizational level. Further, CMS expects all POs to comply with established requirements, regardless of size. Another commenter believes the policy to deny an application because the organization was under a sanction in the past should not be applied once the sanction has been lifted. Noting that sanctions are issued for serious violations, CMS believes an organization with a sanction should continue to focus on compliance even when the sanction is lifted, and including sanctions that have been lifted during the twelve-month look-back period in evaluating past performance is an important protection for the PACE program and participants of the PO.

Some commenters objected to the 12-month look-back period (suggesting a six-month period instead), as well as to applying the look-back period before January 1, 2025. Others suggested delaying implementation of the policies because of the COVID-19 Public Health Emergency (PHE). CMS rejects the objections and suggestions. Noting that the timing is only a concern for those organizations with current noncompliance, the agency believes it is exactly these organizations whose applications should not be approved. It also observes that the COVID-19 PHE expired in May 2023. The agency also disagrees with those who believe POs need more time to train employees. Finally, CMS rejects arguments that it should not consider the fiscal soundness of a PO that has a high-quality program when evaluating past performance, noting that an expansion will occasion additional costs that would likely further challenge the organization's net worth.

The agency may also deny an application from an organization that does not hold a PACE program agreement at the time of the submission, if the applicant's parent organization or another subsidiary of the same parent organization would be denied under the past performance criteria. CMS reported that it receives more initial PACE applications that represent unique and distinct legal entities that are part of a broader parent organization, and it is concerned about troubled performance history of the parent organization or its subsidiaries. However, it finalizes an exception: If a PACE organization acquires an organization that would have an application denied based on any of the factors described above, the acquiring PACE organization will be provided a 24-month grace period. This means the acquiring PACE organization may still enter into new agreements or expand its programs under other agreements for which there are no performance issues for 24 months following the acquisition.

CMS also codifies (at §460.19(c)) the compliance actions it currently issues for PACE organizations. A notice of noncompliance (NONC) may be issued for any failure to comply with

the requirements of the PACE organization's current or prior PACE program agreement; it is typically used to document small or isolated problems and is the lowest form of compliance action. A warning letter may be issued for serious and/or continued noncompliance with the requirements of the PACE organization's current or prior program agreement. It is an intermediate level compliance action, which contains warning language about the potential consequences to the organization should the noncompliant performance continue. A corrective action plan (CAP) is issued for particularly egregious or continued noncompliance and is the most serious type of compliance action, which includes requirements to implement a plan for corrective action.

The CAP at §460.19(c)(3) differs from corrective actions issued under §460.194(a)(2), which require PACE organizations to take action to correct deficiencies that CMS or the state administering agency (SAA) identified through reviews and audits of the PACE organization under §460.194(a)(2). These CAPs are routinely requested, and PACE organizations submit them to CMS as a means of addressing deficiencies identified during reviews or audits; no proposal was made to change that process. CMS clarifies, in response to comments, that corrective actions resulting from audits and reviews issued under §460.194 are not considered as part of the past performance methodology, and it adds conforming language to clarify this point at §460.18(c)(1)(D)(1)(i).

CMS also codifies (at §460.19(b)) the factors it currently applies in determining whether to issue a compliance action and what level of action to issue, which is based on an assessment of the circumstances surrounding the noncompliance and includes all of the following factors:

- The nature of the conduct.
- The degree of culpability of the PACE organization.
- The actual or potential adverse effect on beneficiaries which resulted or could have resulted from the conduct of the PACE organization.
- The history of prior offenses by the PACE organization or its related entities.
- Whether the noncompliance was self-reported.
- Other factors which relate to the impact of the underlying noncompliance or to the PACE organization's inadequate oversight of the operations that contributed to the noncompliance.

Among the rationale provided for finalizing these policies is the recent growth in the number of PACE organizations, which is attributed in part to a recent legislative change that allowed for-profit entities to operate PACE programs, and the agency's concern for what it describes as the most vulnerable Medicare patient population.

B. PACE Determining that a Substantially Incomplete Application is a Nonapplication (§§460.12 and 460.20)

Current regulations require that an entity submitting application to establish a new PACE program (an initial applicant) or to expand an existing program's service area (which includes expansion of the program's geographic service area, adding a new PACE center, or both) must include certain documents as part of that application. One of those required documents is the

state assurances document, which is a template that includes standard statements on the state's roles and duties as well as the physical address of the proposed PACE center, geographic service area, or both, as applicable, depending on the type of application. The state assurances document must be signed by an official in the applicable (SAA and is confirmation of the state's support for the application.

An application that lacks a state assurances document is not considered a complete application and therefore is not reviewed. Further, applicants are instructed to withdraw applications for problems with the state assurances document, including the lack of a signature by the state, providing the document after the designated submission date, a change in the location of the proposed PACE center, or the use of the corporate address as a placeholder.

CMS proposed to treat any PACE application that does not provide a signed and dated state assurances document that includes accurate service area information and the physical address of the PACE center as incomplete and invalid. Such an application would not be subject to review or reconsideration. Entities that submit an application without a complete and valid state assurances document would have their application withdrawn from the Health Plan Management System (HPMS) and would have to wait until the next quarterly submission date to submit the application with the state assurances included, and would not be entitled to a hearing on an application that is withdrawn on that basis.

CMS also proposed a change to the PACE regulations at §460.12(a) to clarify that it will only accept applications that are submitted within the timeframes established by CMS (e.g., the quarterly submission dates currently in effect).

For initial applicants, CMS proposed to codify its current practice of requiring the submission of a separate Part D application as part of the application to establish a new PACE program. It would also codify its current practice of treating a Part D application as substantially incomplete if it lacks responsive material for one or more sections. Any such application would not be reviewed or subject to reconsideration. Existing PACE organizations submitting applications to expand their service area are not currently required to complete a Part D application, and CMS does not propose to change this policy.

CMS finalizes its proposals without modification. Some commenters objected to requiring the state assurance form as part of a PACE application submission, asking that applicants be allowed to amend the state assurance document after application submission. Noting that a state is a party to the 3-way agreement among the PO, CMS and the state, CMS says a correct state assurance form is necessary at the time the application is submitted to evaluate the application.

C. Personnel Medical Clearance (§§460.64 and 460.71)

CMS has found that PACE organizations do not implement consistent methods for assessing or detecting communicable diseases for staff to meet the program requirements to be medically cleared for communicable diseases. Sections 460.64(a)(5) and 460.71(b)(4) each currently require that PACE staff be medically cleared for communicable diseases and have "all immunizations up-to-date" before engaging in direct participant contact. It proposed amending

those requirements to require all POs to develop and implement a comprehensive medical clearance process with minimum conditions that the agency deems acceptable to meet the requirement of medical clearance.

1. Immunizations. CMS proposed separating the requirement for up-to-date immunizations from the requirement for medically cleared for communicable diseases. It proposed to specify that those immunizations include vaccinations for COVID-19, and it sought comment on which immunizations should be included in the reference to "all immunizations" in the regulatory text. It considered requiring all Advisory Committee on Immunizations Practices (ACIP) recommended immunizations for health care workers or a narrower set that would include the Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B.

Some commenters objected to the potential scope of immunizations. They expressed concern that the expansive list would be creating a new federal floor for PACE that was unlike that required of any other Medicare provider, which would impact hiring and retention of staff. Clarification was sought on whether religious and medical exemptions would apply. While CMS does not believe adding more vaccination requirements would impact the hiring ability of POs, it nonetheless does not finalize the proposal to specify in regulations all the specific immunizations that will be required of PACE staff. It leaves the current regulatory language "all immunizations must be up-to-date" in place. Further. The agency notes that in the LTC 2023 Final Rule[120] it removed requirements relating to COVID-19 staff vaccinations, including for PACE. As such, it does not finalize the proposal to include vaccinations for COVID-19 in the scope of required immunizations. CMS notes that it will continue to assess the need for vaccinations, and it may act in the future to impose specific vaccination requirements for staff.

2. Medical Clearance for Communicable Diseases. With respect to requirements for medical clearance for communicable diseases, the agency proposed to require these medical clearances on an annual basis and to specify in regulations what constitutes an acceptable process for medical clearance for the PACE population for staff engaging in direct patient contact. Mandatory annual physical examinations for these staff members conducted by a licensed physician, nurse practitioner (NP) or physician assistant (PA) were proposed; additionally, as part of the first annual physical examination, the staff member would have to be determined to be free of active Tuberculosis (TB) disease.

Some commenters objected to annual medical clearances, suggesting that this was burdensome especially for small POs. Concerns were also raised about the ability to contract with other health care providers who do not face similar medical clearance requirements. CMS agrees and does not finalize the requirement for an annual medical clearance for communicable diseases. Requirements for a medical clearance for communicable diseases still apply. As part of the initial physical examination, it must be determined that staff are free of active TB. Some commenters

[120] "Medicare and Medicaid Programs: Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Diseases (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements" (88 FR 36485).

worried that HIPAA would not permit colleagues to conduct health screenings. CMS responds that the HIPAA Privacy Rule does not apply to employment records held by a covered entity in its role as an employer; it also notes that its regulatory language is not intended to require POs to conduct these examinations. Rather, the agency sought to afford POs some flexibility. Additionally, CMS finalizes its proposal to limit the clinicians who may perform the medical examination to licensed physicians, NPs and PAs.

CMS also finalizes its proposal to permit POs to conduct an individual risk assessment as an alternative to a physical examination for staff with direct patient contact. If the risk assessment indicates the staff member does not require a physical examination to be medically cleared, that requirement is waived. CMS finalizes the following requirements for individual risk assessments:

- Policies and procedures for risk assessments must be based on accepted professional standards of care.
- The risk assessment must identify when a physical examination is required based on the results of the assessment.
- The results of the risk assessment must be reviewed by a registered nurse (RN) or by a licensed physician, NP, or PA.
- The risk assessment must:
    - Assess whether staff have been exposed to or have any symptoms of the following diseases: COVID-19, Diphtheria, Influenza, Measles, Meningitis, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Rubella, Streptococcal Infection, Varicella Zoster Virus, and any other infectious diseases noted as a potential threat to public health by the CDC; and
    - Determine if staff are free of active TB during the initial risk assessment.

D. Timeframes for Coordinating Necessary Care (§460.98(b)(4) and (c))

CMS has in the past considered creating a specific timeframe for the delivery of services to PACE participants, but it has declined to do so because of the vast array of services that PACE organizations provide. Instead, it requires that all services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's overall medical, physical, emotional and social needs.

Noting that over the past 4 years more than 80 percent of audited PACE organizations have been cited for a failure to provide services necessary to meet participant needs, CMS proposed establishing timeframes for arranging the provision of IDT-approved services for PACE participants. The proposal is finalized without modification.

All services must be scheduled or arranged (not actually furnished) as expeditiously as the participant's health conditions requires, but not later than:

- For medications, 24 hours after the medication is ordered; and
- For all other services, 7 calendar days after the date the IDT, or member of the IDT, first approves the service.

In the final rule, CMS provides examples of what it means for a service to be scheduled or arranged. For medications, it would mean the PO notified the participant's pharmacy or pharmacy service of the approved medication order and provided all necessary information for the pharmacy to fill the medication order to afford the participant timely access to the medication. However, the medication would not have to be delivered within 24 hours unless the participant's condition required delivery within that timeframe. For other services, the PO is expected to take affirmative steps to ensure the approved service is set up, scheduled, or arranged within the 7-day timeframe; this may involve scheduling an appointment and/or purchasing an item the IDT approved.

Some commenters objected to the single 24-hour timeframe for medications, recommending instead that there be different timeframes depending on whether the order involves emergency or non-emergency medications. CMS rejects this recommendation in part because it believes such a standard would be difficult and impractical. The agency reminds stakeholders that the timeframe applies to scheduling and arranging the dispensing of the medication—not the actual provision of the medication within 24 hours unless the participant's condition requires it.

Commenters also objected to the 7-day timeframe; they suggested 10 days for arranging or scheduling these services, citing problems communicating with external provider offices especially for specialists. The agency is not sympathetic, citing results of audits where it discovered instances where weeks passed between an order for a service and the actual scheduling of the appointment for that service.

The 7-calendar-day timeframe will not apply to routine or preventive services under certain conditions. Those conditions are (i) the PO was unable to schedule the appointment due to circumstances beyond its control (which it would have to document), (ii) the participant does not have a change in status that requires the service to be provided more quickly, **and** (iii) the PO provides the service as expeditiously as the participant's condition requires. The current standard requiring the PO to take into account the participant's overall medical, physical, emotional and social needs in assessing the participant's health condition continues to apply.

The final rule defines which services are IDT-approved services; they include services (i) approved by the full IDT or by a member of the IDT, (ii) services ordered by a member of the IDT, and (iii) care planned services.

E. Care Coordination (§460.102)

The IDT is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery, and it must document all recommendations for care or services and the reason(s) for not approving or providing recommended care or services. Oversight has shown that some organizations do not ensure the IDT is fully involved in coordination of care for participants across all care settings. CMS made several proposals to clarify the scope of IDT duties for the coordination of care across all care settings. It finalizes all the proposals, with the only modifications being to the proposed timeframes for the IDT to review, assess and determine whether service recommendations are necessary to meet the participant's medical, physical, social or emotional needs (described below).

CMS clarifies that these IDT duties apply to and must be fulfilled for each participant. The final rule regulation text specifies that the IDT duty for the coordination of 24-hour care applies across all care settings and that care coordination includes at a minimum the following activities:

- Ordering, approving, or authorizing all necessary care.
- Communicating all necessary care and relevant instructions for care.
- Ensuring care is implemented as it was ordered, approved, or authorized by the IDT.
- Monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs.
- Promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant.

Some commenters considered IDT involvement in daily care coordination activities for participants residing in care facilities to be functionally impractical and potentially harmful to participants. They believe having the IDT order all necessary care for these participants may delay the provision of necessary care. Another complained about the difficulty of ensuring daily communication between the IDT and care facilities with staffing shortages or other operational issues. CMS responds that the IDT is responsible for authorizing and approving all care, which does not mean the PO or the primary care practitioner must directly order all services for a participant residing in acute and long-term care settings. The agency reiterates that the PO is responsible for care coordination across all settings, even those settings where it is difficult to communicate with staff, and it expects to see documentation of communications with the facility that demonstrate the IDT's active monitoring and management of the participant's condition.

The appropriate member of the IDT must review, assess, and act on service recommendations from emergency or urgent care providers following participant discharge, as well as from employees and contractors, including medical specialists. CMS believes this policy is necessary based on information from 2021 audits, which showed that roughly 75 percent of audited PACE organizations were cited based on a failure to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. The following timeframes will apply for the IDT to review, assess and determine whether service recommendations are necessary to meet the participant's medical, physical, social or emotional needs:

- For recommendations from hospitals, emergency departments, and urgent care providers, within 48 hours of discharge (increased from 24 hours under the proposed rule); and
- For recommendations from other employees and contractors, within 7 calendar days from the date of the recommendation (increased from 5 days under the proposed rule).

CMS clarifies, in response to a comment, that to "act on" means, in addition to reviewing and assessing these recommendations, the IDT would decide whether it is appropriate to approve the service and would ensure the provision of any approved services. If the IDT determines a recommended service is not necessary, it must document the rationale for that determination. CMS also clarifies that the IDT can determine the appropriate IDT disciplines for reviewing recommendations, and it does not expect that the full IDT must be involved in all decisions relating to recommendations made by hospitals, emergency departments, or urgent care centers. With respect to expectations for documentation of oral recommendations the IDT receives and

reviews, CMS believes that the IDT must, at a minimum, document the recommendation in the participant's medical record as well as the result of any discussion regarding the recommendation to show the IDT assessed and considered the recommendation. Further, if the service is approved or ordered, that should be documented in the medical record; if the service was not approved, the rationale for that decision should be included in the medical record.

If the IDT, or a member of the IDT, authorizes or approves the service recommendation(s), it must arrange and schedule the service using the timeframes for coordinating necessary care under section IX.D. of the final rule (i.e., within 24 hours for medications, within 7 calendar days for most other services, other than certain routine and preventive services, and always as expeditiously as the participant's health condition requires). The IDT is not required to approve all recommendations, but an appropriate member of the IDT must review, assess, and act on each recommendation.

F. Plan of Care (§460.106)

CMS believes that PACE organizations are struggling with developing, implementing, monitoring, reevaluating, and revising plans of care. While it has observed more robust initial care plans, it has seen that care plans become sparser over time, and care initially included in the plan of care is omitted in subsequent revisions and handled through discipline-specific progress notes as the participant's enrollment continues. While these progress notes are appropriate, CMS believes they should not substitute for a single, comprehensive care plan that addresses the participant's needs. It has also noted minimal participant and caregiver involvement in the care planning process, which tends to occur after the development and/or revisions to the plan of care have been finalized and implemented by the IDT.

CMS proposed to rewrite section §460.106 in its entirety to further define the timeframes for care plan development and reevaluation, to define the minimum content in a plan of care, to emphasize the ongoing duties of the IDT to monitor and revise the plan of care to determine its effectiveness, and to define the involvement of the participant and/or their caregiver in the plan of care before it is finalized. Where possible, it sought to use regulatory language that is consistent with the long-term care facility regulation.

CMS finalizes its proposed rewrite of §460.106, with a clarification described below.

For the basic care plan requirement, the full IDT must develop, evaluate, and if necessary, revise a comprehensive person-centered plan of care for each participant, and each care plan must consider the most current assessment findings and identify the services required to attain or maintain the participant's highest practicable level of well-being. This standard to attain or maintain the participant's highest practicable level of well-being is from the nursing home regulations, which CMS considers to be appropriate in the context of its changes for PACE care plans. The initial plan must be completed within 30 days, which is consistent with current regulations. The full IDT must participate in the semiannual care plan evaluations (which is clarified to be at least once every 180 calendar days) as well as in revisions to the care plan due to change in the participant's status. In response to comment, CMS clarifies that the 180-day timeline restarts every time a new care plan is finalized.

Under the final rule, revisions to the care plan for a change in the participant's status must be completed within 14 calendar days. That 14-day timeframe begins when the PACE organization determines or should have determined that there was a change in the participant's status. If the participant is hospitalized during that 14-day window, the timeframe for the evaluation of and revision to the care plan must be completed by the end of the 14-day period that begins on the date of discharge. The term "change in the participant's status" is defined to mean "a major decline or improvement in a participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status and requires interdisciplinary team review or revision of the care plan, or both."

All needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring must be included in the required contents of a care plan for PACE participants. The final rule adds a high degree of specificity to requirements for the care plan; most of the content requirements are again based on the nursing home regulations though some are tailored to PACE. The care plan must address all of the following issues: vision; hearing; dentition; skin integrity; mobility; physical functioning, including activities of daily living; pain management; nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs; the participant's ability to live safely in the community, including the safety of their home environment; home care; center attendance; transportation; and communication, including any identified language barriers. Some commenters objected to the specificity required of PACE plans of care being based on long-term care facility requirements, noting the differences between PACE programs and those facilities. CMS seems to be prepared to err on the side of more specificity, disagreeing with claims of excessive burden on PACE programs. It also disagrees that its requirement to record diagnoses in both the participant's plan of care and the medical record is duplicative. CMS does agree with commenters that including acute diseases is not always appropriate in the plan of care, and it finalizes the proposed required content without including acute diseases or medications. The agency may consider proposing additional minimal care plan content in future rulemaking.

The plan of care must identify each intervention needed to meet each medical, physical, emotional and social needs (other than medications documented elsewhere in the medical record), and the IDT must specify a timeframe for the implementation of each service identified in the plan of care. Thus, the IDT must identify both how each service will be implemented and the timeframe in which it will be implemented. Finally, the participant's preferences and goals of care must be included in the care plan.

In lieu of the current requirement for the care plan to identify a measurable outcome for each intervention, CMS finalizes a requirement for the care plan to identify measurable goals for the service. The care plan must also identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified.

CMS also makes language changes to the requirements for IDT implementation of the care plan; specifically, it requires the IDT to continuously implement, coordinate, and monitor the plan of care, regardless of whether the services are furnished by PACE employees or contractors, across

all care settings. The agency views the plan of care as a comprehensive, living document that is updated per the participant's current status at any given point. The IDT must also continuously evaluate and monitor the participant's medical, physical, emotional and social needs, as well as the effectiveness of the plan of care. This should be accomplished through furnishing services, informal observation, input from participants or caregivers, and communications among members of the IDT and other employees or contractors.

In addition to the current requirement to collaborate with participants and their caregivers in the development of the care plan, the IDT must review and discuss each plan of care with the participant and/or caregiver before it is completed to ensure that there is agreement with the plan of care and the participant's concerns are addressed. Some commenters objected to this requirement, pointing out that many participants and their caregivers do not wish to participate in the care planning process. CMS responds that there are many ways for the IDT to involve participants. Where the participant is not interested in the care planning phase, the documentation must show that the care plan was fully reviewed with the participant, and that any concerns were addressed before the care plan is finalized. The agency believes it is critical that participants and/or caregivers are active in discussions regarding the participant's needs.

With respect to documentation, the final rule requires that the IDT establish and implement a process to document and maintain records related to all requirements for the plan of care in the participant's medical record, and ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

It also makes a conforming amendment to §460.104(e) (changes to plan of care due to participant reassessments) to require the IDT to reevaluate and revise (if necessary) the care plan after conducting a semiannual or unscheduled reassessment.

G. Specific Rights to Which a Participant is Entitled (§460.112)

PACE organizations must have in effect written safeguards of the rights of enrolled participants, including a patient bill of rights. Audit activity has revealed that some PACE organizations do not provide care that is meant to improve or maintain the participant's condition, but instead provide a palliative-like benefit. The proposals were intended to ensure participants understand that they are entitled to more than palliative care, comfort care, and end-of-life care services.

CMS finalizes its proposals without modification. Thus, in addition to specific rights previously established in regulations (§460.112), the following enumerated rights are added to clarify this issue and to address other concerns:

1. The right to appropriate and timely treatment for health conditions.

This includes the right to receive all care and services needed to improve or maintain the participant's health condition and to attain the highest practicable physical, emotional and social well-being. CMS believes the right to treatment is a separate and distinct right. It bases its regulatory language on nursing home regulations that require services to be furnished "to attain

or maintain the resident's highest practicable physical, mental, and psychosocial well-being" (§483.21(b)(1)(i)).

2. The right to have all information regarding PACE services and treatment options explained in a culturally competent manner.

This right to have treatment options explained in a culturally competent manner is currently listed at (§460.112(e)(1)), but CMS moves to it the paragraph relating to respect and nondiscrimination.

CMS expands upon the current participant right to be informed of the consequences of their decisions by specifying in regulation the right to be informed of the consequences their decisions may have on their health and/or psychosocial status.

3. The right to have information shared with their designated representative.

CMS adds new language establishing a right for the designated representative of a participant to have access to all information in §460.112. The rationale for this addition is that the designated representative should receive the same accurate, easily understood information the participant receives in order to make informed decisions on the participant's behalf.

4. The right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services.

Oversight activities have revealed that certain types of care offered by PACE organizations are not well-defined; some organizations use terms such as palliative care, comfort care, and end-of-life care, with little or no information on what those terms mean or how they are defined or implemented across PACE organizations.

In the final rule, CMS does not define these terms, but instead it directs PACE organizations to define them within their programs and to provide clear information to participants on what the terms mean. PACE organizations must fully explain the information and the treatment options contained in the written notification (described in paragraph 5 below) before the PACE organization implements palliative care, comfort care, or end-of-life care services.

A majority of commenters encouraged the agency to define these terms, noting that there is currently a definition of palliative care in the hospice regulations (§418.3). Others asked CMS to refrain from using the term comfort care because it is not a medical term, and most commenters urged CMS not to use these terms interchangeably. CMS is disinclined to define these terms at this time but may be convinced to do so in the future. For now, it encourages POs to consider using the definition of palliative at §418.3 because it is a national standard. The agency reiterates that the policy intent of this proposal was to ensure that POs define these terms and to explain them to participants.

5. The right to be fully informed, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services.

The written notification before implementation of palliative care, comfort care, or end-of-life care services must include a description of those services and how they differ from the care the participant is currently receiving to meet their individual needs. The written notification is intended to ensure participants are fully informed of their options for treatment and can make informed decisions about the care they wish to receive. Further, PACE organizations must explain in writing whether palliative care, comfort care, or end-of-life care services will be an added service or a substitute for the care the participant is receiving. Some participants may want comfort measures in addition to treatment meant to maintain their health condition while others may be at the end of their life and only seek treatment meant to reduce or control pain. The written explanation must include a detailed description of all treatment services that would be impacted if the participant elects palliative care, comfort care, or end-of-life care services.

The final regulatory text specifies the participant's right to revoke or withdraw consent to receive palliative care, comfort care, or end-of-life care services at any time, for any reason, and either verbally or in writing. PACE organizations must explain this right to participants both orally and in writing.

The PACE organization must receive written consent from the participant to change a treatment plan to include palliative care, comfort care, or end of life care. However, this requirement is not a substitute for any advance directive the participant may have and does not impact the existing duty for PACE organizations to explain advance directives and establish one if requested by the participant.

Some commenters objected to the requirement to obtain written consent before implementing palliative care on the grounds that it would be administratively burdensome and unnecessary because they believe palliative care is provided concurrently with curative care. CMS notes that because some PACE programs stop furnishing curative care when palliative care has been elected, it believes written notice and a clear explanation is necessary for participants to make informed decisions.

The agency also clarifies that when a participant who elected to forgo curative care in favor of palliative care subsequently changes that election to restart receiving curative care, that change of election should be treated as a change in participant status, which would require the PO to reassess the participant and re-evaluate the participant's plan of care.

6. The right to request services from the PACE organization, its employees, or contractors through the service determination process.

Existing participant rights include the right to voice grievances and the right to appeal; however, there is no mention of the right to request a service determination request, which is the first step in the appeals process. CMS adds the right to request services through the service determination process to the list of participants' rights.

H. Grievance Process (§460.120)

CMS finalizes almost all its proposed policies to modify its grievance process regulation; however, the proposal to establish an expedited grievance process[121] is not finalized. The policies finalized in this rule are designed to address concerns over participant confusion as well as inconsistency in how grievances are addressed by PACE organizations. Section 460.120 is rewritten in its entirety with the stated goal of providing more detailed processing requirements. While many of the provisions have been retained, the regulation is restructured and expanded or modified in several places, and new provisions are added.

The current requirement to have a formal written process for evaluating and resolving grievances is modified to require that the process promptly identify, document, investigate, and resolve those grievances.

The definition of a grievance is modified to clarify the following:

- A grievance may exist without regard to whether remedial action is requested.
- A grievance may be between participants and the PO or any other entity or individual through which the PO provides services to the participant.

Some commenters objected to including grievances for which no remedial action was requested in the definition, citing additional burden and the likelihood of more numerous complaints. They recommended a separate process for this type of grievance. CMS disagrees with concerns about additional burdens and notes that this final action was the result of requests from POs asking for clarification on this issue. It also believes excluding complaints that do not require remedial action would be inconsistent with other requirements within the PACE statute and regulation.

The current requirement to provide notice to participants about the grievance process will include significantly more detail. New requirements in the regulation for the notice include all of the following:

- The information must be presented in understandable language.
- The participant may voice a grievance without fear of discrimination or reprisal.
- Medicare beneficiaries may file written complaints with quality improvement organizations (QIOs) for Medicare covered services.
- Information must be provided on who may file a grievance, how to file a grievance, the organization's duty to conduct a thorough investigation, timeframes to resolve the grievance and notify the participant, requirements for expedited grievances, and the manner and content of the notification of grievance resolution.
- The organization must continue to furnish all required care and maintain the confidentiality of a grievance.

Grievances may currently be submitted by participants, family members or their representatives. CMS believes caregivers are often in the best position to advocate for services on behalf of

[121] CMS had proposed to require resolution of a grievance that could have "both an imminent and significant impact on the health or safety of the participant" by no later than 24 hours after receipt of the grievance. CMS did not define the terms "imminent" and "significant," leaving it to POs to define the terms as a part of their grievance procedures.

participants; thus, it finalizes its proposal to permit the participant's caregiver to submit grievances. The agency notes that it does not consider caregivers to include employees or contractors of the PO. Input of contractors or employees must already be taken into account by the IDT. Most commenters objected strenuously to including caregivers in the list of persons who may file grievances. Many concerns were raised, including the lack of a definition for "caregiver," outcomes that would not align with the participant's care goals, risks to HIPAA Privacy Rule compliance, and confusion when coordinating care for participants with support networks made of many individuals with complex dynamics. Commenters also asked why caregivers should have the right to file grievances when participants, their families, and their designated representatives may already submit grievances. In response, the agency says it is appropriate for caregivers to advocate for services because they are involved in the care planning process and are presumably providing at least some care to the participant. The agency also claims that the policy expansion will not "meaningfully" increase burden for POs.

Changes to the process for filing grievances are also finalized. For example, POs may not require a written grievance to be submitted on a specific form; letters and email correspondence are an acceptable form of written grievance. Further, a grievance may be made to any organization employee or contractor that provides care to a participant in the participant's residence, the PACE center, or while transporting participants.

PACE organizations must conduct a thorough investigation of each distinct issue within the grievance when the cause of the issue is not already known. Organizations have 30 calendar days to resolve the grievance, and they must notify the participant within 3 days of resolving the grievance. As noted above, CMS does not finalize its expedited grievance process proposal that would have imposed a 24-hour deadline for decisions on grievances that could have both an imminent and significant impact on the health or safety of the participant. However, the agency states that the IDT has a duty to triage grievances to determine which grievances must be processed more quickly in order to meet the participant's needs.

PACE organizations may provide a notice of grievance resolution orally or in writing, based on the participant's preference; however, the PACE organization must respond in writing for the resolution of any grievance related to quality of care, regardless of how the grievance is filed. The written notice for resolution of quality-of-care grievances must describe the right of Medicare participants to file a written complaint with a QIO regarding Medicare covered services. The grievance resolution notice must include at least the following three elements:

- A summary statement of the grievance, including all distinct issues.
- A summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation.
- For a grievance that requires corrective action, the corrective action(s) taken or to be taken by the PO as a result of the grievance, and when the participant may expect corrective action(s) to occur.

Some commenters objected to the requirement that grievance resolution notifications include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur. CMS believes the commenter

misunderstood the intent of the requirement. It says that the grievance resolution and notification timeframe requirements apply to taking action to resolve the grievance and notifying the individual who submitted the grievance of the resolution. Taking action does not require that all corrective actions be completely implemented within the timeframes for all grievances issues. Further, the regulations do not specify the level of detail the PO should provide in the resolution notification to describe the actions taken or when to expect the actions to occur.

Another topic of complaint was the proposal to include QIO rights in grievance resolution letters to Medicare participants with quality-of-care grievances about Medicare covered services. CMS notes that all Medicare beneficiaries, including Medicare PACE enrollees, have this right, which heretofore was not specified in the PACE regulations. It appears to view this addition as a technical, clarifying amendment.

A PACE organization may withhold notification of the grievance resolution in cases where the individual submitting the grievance specifically asks not to receive notification of the grievance resolution, and the PACE organization has documented the request in writing. The current requirement for PACE organizations to maintain confidentiality of a grievance is expanded to include a specific requirement to protect the identity of any individuals involved in the grievance from other employees and contractors when appropriate.

Minor modifications are made to the current recordkeeping requirements and to requirements for the maintenance, aggregation, and analysis of information on grievance proceedings as part of an organization's quality improvement program.

I. PACE Participant Notification Requirement for PACE Organizations with Performance Issues or Compliance Deficiencies (§460.198)

Unlike the regulations applicable to MAOs and Part D sponsors, Part 460 does not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies; this requirement for Part D sponsors (under §423.128) was waived for PACE. CMS now believes disclosure of this information would serve as an important protection for PACE participants.

In the final rule, CMS adds a new section §460.198, which authorizes the agency to require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS.

In response to a query, the agency anticipates limiting this requirement to those situations where an intermediate sanction is imposed on a PACE organization or other instances where a PACE organization has serious compliance or performance deficiencies about which CMS believes PACE participants should be informed. It will follow a disclosure process that is similar to the process in MA and Part D. CMS would provide the PACE organization with a letter template, and the organization would complete the required information in the template. CMS will then review and approve the notification and provide a date for the PACE organization to mail the notice to participants. The notice must also be posted on the organization's website.

J. PACE Participant Health Outcomes Data (§460.202)

Section 460.202 currently requires participant health outcomes data reported to CMS and the SAA to be specified in the PACE program agreement; however, CMS does not routinely update program agreements based on changes to the required participant health outcomes data. The health outcomes data that PACE organizations must report to CMS and the SAA are specified and routinely updated through the Paperwork Reduction Act (PRA) rather than the program agreement.

Thus, CMS finalizes its proposal to strike from §460.202(b) the following statement: "The items collected are specified in the PACE program agreement." It believes this change will eliminate confusion about where the data collection requirements may be found.

K. Corrective Action (§460.194)

Currently, pursuant to §460.194(b), CMS or the SAA must monitor the effectiveness of corrective action plans established by PACE organizations to correct deficiencies. Citing a growing number of PACE programs and its conclusion that such monitoring is not always necessary, CMS finalizes its proposal to change the regulation to permit CMS and SAAs to conduct such monitoring as opposed to being required to do so. Future monitoring efforts will prioritize participant health and safety and program integrity. The agency reminds PACE organizations of their oversight compliance program duties, which include a requirement that PACE programs ensure ongoing compliance with CMS requirements such as those imposed under a corrective action plan.

CMS believes that its implementation of the change will not increase PACE organization administrative burden. Because of the complexity and scope of potential corrective actions, it will not establish specific criteria or thresholds as determinants of whether CMS or the SAA will monitor the effectiveness of a particular corrective action. It further indicates that any corrective action monitoring threshold it may create will be internal to CMS and the SAA; this is to ensure it retains flexibility to reassess any thresholds, as needed, based on new information and changing data.

L. Service Determination Requests Pending Initial Plan of Care (§460.121)

CMS created the service determination request process, which it describes as a first level of appeal. A service determination request is a request to (1) initiate a service; (2) modify an existing service, including to increase, reduce, eliminate, or otherwise change a service; or (3) continue coverage of a service that the PACE organization is recommending be discontinued or reduced. CMS had finalized an exception to this definition when the request is made before the initial plan of care is completed. It explained that this exception would apply any time before the initial plan was finalized and discussions among the IDT ceased.

The agency states that it has found requests made by participants and/or caregivers before the initial care plan is finalized are often not discussed during the care planning process and are

therefore not considered by the IDT. While CMS does not want to elevate these requests to the level of service determination requests, it nonetheless expects PACE programs to consider them.

It finalizes its proposal to require that a service request made before developing the participant's initial plan of care must either be approved and incorporated into the participant's initial plan of care, or the rationale for why it was not approved and incorporated must be documented. Specifically, the IDT must (1) document the request, (2) discuss the request during the care plan meeting, and (3) either approve the requested service (and incorporate it into the participant's initial plan of care) or document why the service was not approved as part of the initial plan of care.

Some commenters requested that the requirement not apply to requests for services made by participants before the first day of their enrollment; CMS declines to do so. It believes the initial plan of care developed by the IDT should be a comprehensive document detailing all necessary services the participant should receive from the PACE organization. Thus, the IDT must not only consider the assessments conducted by members of the IDT, but also the participant's wishes. This includes any specific requests for services that the participant makes prior to that initial plan of care being developed regardless of when those requests were made. On the other hand, it reiterates that these requests for services received prior to the finalization of the initial plan of care are not to be processed as service determination requests. The agency also disagrees with the belief that documenting requests for services received prior to the finalization of the initial plan of care is overly burdensome or that this requirement holds no inherent value to the participant. CMS notes in the early part of a participant's enrollment into PACE, before an initial plan of care is finalized, participants are actively communicating the services they hope to receive from the PACE organization; the agency believes this should be documented.

X. Information Collection Requirements

Under the PRA, CMS must solicit public comment on any proposals that would require individuals or entities to submit information to the federal government before such information collection requirement is submitted to the Office of Management and Budget for approval. CMS provides a summary table of the provisions in the final rule for which it estimates potential burden and that would require an information collection review and approval under the PRA. Table J9 of the final rule identifies provisions that would contain collection of information requirements in the following areas:

- Network Adequacy in Behavioral Health
- Changes to an Approved Formulary Submission
- Part D Drug Management Program: Case Management, Enrollee Notification and CMS Notification
- SSBCI: Expectation of Health Improvement and Documentation
- Mid-Year Notification of Unused Supplemental Benefits
- Utilization Management Committee: Expertise in Health Equity
- Exceptions for Network Adequacy
- Increasing Enrollment in D-SNPs: Notification, Integrated SEP, Software, Policy Updates

- D-SNP Look-Alikes: Transitioning to other MA-PD Plans
- Marketing: Notice of Availability of Part C Update of Systems and Policies
- Marketing: Notice of Availability of Part D Update of Systems and Policies
- Medication Therapy Management: Comprehensive Medication Review (CMR)
- Involuntary Disenrollment from SNPs and MSAs
- Reinstatements from Cancellation of New Enrollments
- PACE: Personnel Requirements, Risk Assessment Tool, Service Delivery, Participant Rights Updates, Grievance Policy Updates, and Participant Notice of Past Program Performance Issues
- TPMO Sharing of Information

In total, CMS estimates that all of the information collection requirements would raise costs for plans and enrollees by a total of approximately $227 million in year one and would cost roughly $225 million in subsequent years. The Drug Management Program provisions are estimated to reduce paperwork burden by $3 million annually, saving $30 million over 10 years, but provisions relating to requirements for MTM comprehensive medication reviews and mid-year notification of unused benefits are estimated to increase burden by roughly $192 million and $23 million, respectively, each year.

XI. Regulatory Impact Analysis

CMS examined the impact of the final rule as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, Executive Order 14094 entitled "Modernizing Regulatory Review," the Regulatory Flexibility Act (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995, Executive Order 13132 on Federalism, and the Congressional Review Act.

CMS concludes that the final rule is a major rule that requires a Regulatory Impact Analysis because the total economic impact for the rule exceeds $200 million in several years. However, CMS certifies that the final rule does not have a significant economic impact on a substantial number of small rural hospitals. Further, the final rule is not anticipated to have an unfunded effect on state, local, or Tribal governments, in the aggregate, or on the private sector of $183 million or more. It also anticipates that a number of the provisions of the final rule will have no impact at all because they codify existing guidance or are technical provisions. The agency says it is unable to provide an estimate for a number of provisions.

Overall, CMS concludes that the provisions of the final rule in the aggregate provide significant savings. It estimates net annualized savings from the final rule over 10 years of approximately $200 million per year, which arise from increased enrollment in D-SNPs and will result in estimated reduced spending from the Medicare Trust Fund of $961 million for Part C, and $1,341 million for Part D over 10 years. Those savings are offset by the annual costs of the rule of approximately $224 million. The major contributors to the annualized cost estimates are a variety of mailings and notifications. Tables K5a and K5b of the final rule (reproduced below) provide more detail.

TABLE K5a: SAVINGS AND COSTS ($ Millions) BY PROVISION AND YEAR

Item	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers
Total Savings	4.0			4.0			4.0			4.0			4.0		
Total Costs		229.4			227.9			227.9			227.9			227.9	
Aggregate Total	225.4			223.9			223.9			223.9			223.9		
Savings of Medicare Trust Fund			0.7			0.7			13.3			25.6			37.6
DMP	3.0			3.0			3.0			3.0			3.0		
Multi Language Inserts		0.1			0.0			0.0			0.0			0.0	
Formulary Provisions	1.0			1.0			1.0			1.0			1.0		
Mid-Year Notice of Unused Supp. Benefits		23.7			23.7			23.7			23.7			23.7	
Utilization Committee		1.0			0.0			0.0			0.0			0.0	
SSBCI Provision		7.0			7.0			7.0			7.0			7.0	
D-SNP Look Alike Provision		0.1			0.1			0.1			0.1			0.1	
PACE Provisions		2.1			1.9			1.9			1.9			1.9	
Increasing D-SNP Enrollment, Paperwork burden		0.2			0.0			0.0			0.0			0.0	
Involuntary Disenrollment from D-SNPS		0.5			0.5			0.5			0.5			0.5	
TMPO Sharing of Information		1.7			1.7			1.7			1.7			1.7	
MTM		192.7			192.7			192.7			192.7			192.7	
Reinstatements from Cancellation of New Enrollments		0.3			0.3			0.3			0.3			0.3	
Increasing D-SNP Enrollment, Part C									5.5			10.9			15.9

Item	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers
Increased Enrollment in D-SNPS, Part D									7.0			13.9			21.1
Increasing Enrollee appeal rights			0.7			0.7			0.7			0.7			0.7

TABLE K5b: SAVINGS AND COSTS ($ Millions) BY PROVISION AND YEAR (Continued from Table K5a)*

Item	2030 Savings	2030 Costs	2030 Transfers	2031 Savings	2031 Cost	2031 Transfers	2032 Savings	2032 Cost	2032 Transfers	2033 Savings	2033 Cost	2033 Transfers	2034 Savings	2034 Cost	2034 Transfers	Raw 10 Year Totals
Total Savings	4.0			4.0			4.0			4.0			4.0			40.1
Total Costs		227.9			227.9			227.9			227.9			227.9		2280.6
Aggregate Total	223.9			223.9			223.9			223.9			223.9			2240.6
Savings of the Medicare Trust Fund			406.3			421.1			440.1			470.0			493.9	2,307.8
DMP	3.0			3.0			3.0			3.0			3.0			-30.5
Multi Language Inserts		0.0			0.0			0.0			0.0			0.0		0.1
Formulary Provisions	1.0			1.0			1.0			1.0			1.0			-9.6
Mid-Year Notification of unused Supplemental Benefits		23.7			23.7			23.7			23.7			23.7		236.9
Utilization Committee		0.0			0.0			0.0			0.0			0.0		1.1
SSBCI Provision		7.0			7.0			7.0			7.0			7.0		70.0

Item	2030 Savings	2030 Costs	2030 Transfers	2031 Savings	2031 Cost	2031 Transfers	2032 Savings	2032 Cost	2032 Transfers	2033 Savings	2033 Cost	2033 Transfers	2034 Savings	2034 Cost	2034 Transfers	Raw 10 Year Totals
D-SNP Look Alike Provision		0.1			0.1			0.1			0.1			0.1		0.6
PACE Provisions		1.9			1.9			1.9			1.9			1.9		19.2
Increasing D-SNP Enrollment, Paperwork burden		0.0			0.0			0.0			0.0			0.0		0.2
Involuntary Disenrollment from D-SNPs		0.5			0.5			0.5			0.5			0.5		5.1
TMPO Sharing of Information		1.7			1.7			1.7			1.7			1.7		17.2
MTM		192.7			192.7			192.7			192.7			192.7		1927.2
Reinstatements from Cancellation of New Enrollments		0.3			0.3			0.3			0.3			0.3		3.1
Increasing D-SNP Enrollment, Part C			170.8			175.3			180.3			195.7			206.9	961.4
Increased Enrollment in DSNPs, Part D			234.8			245.0			259.2			273.7			286.3	1340.9
Increasing Enrollee appeal rights			0.7			0.7			0.7			0.7			0.7	6.8

NOTES:

- Positive numbers in the annual cost columns reflect costs while positive numbers in the annual savings columns reflect savings. The aggregate row subtracts the savings from the cost and therefore lists the aggregate total as a cost expressed as a positive number. The raw total column (over 10 years) expresses costs as positive numbers and savings as negative numbers.
- Two line items affect the Trust Fund: Increased Enrollment in D-SNPs, Part C; and Increased Enrollment in D-SNPs, Part D. Over 10 years they save $961 million and $1,341 million, respectively.
- When the aggregate of line items for a provision is below $50,000—for example, the paperwork burden of $4929 associated with the provision for network adequacy of behavioral health, or the cost to CMS staff to perform certain tasks listed in this section—they were not included in the table (since they do not have an effect on numbers). However, when the aggregate of several provisions rounded to at least $0.1 million it was included.
- Line items belonging to one class of provisions in the COI Summary table are included under one line item in this RIA summary table. For example, the three line items contributing to the paperwork burden of Medication Therapy Management (MTM) are added together in one line in this RIA Summary table.

CMS also provides a summary table (duplicated below) of the costs, transfers, and benefits of the final rule.

TABLE A1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision	Description	Financial Impact
1. Part D Medication Therapy Management (MTM) Program: Eligibility Criteria	CMS is finalizing changes to the MTM eligibility requirements to (1) codify the 9 core chronic diseases currently identified in sub-regulatory guidance and adding HIV/AIDS for a total of 10 core chronic diseases; (2) require Part D sponsors to include all core chronic diseases in their MTM targeting criteria, and to include all Part D maintenance drugs when determining the number of drugs an enrollee is taking; and (3) revise the methodology for the MTM cost threshold to calculate the dollar amount based on the average annual cost of 8 generic drugs.	The revisions to the MTM targeting criteria being finalized in this rule have an estimated annual administrative cost of $192.7 million. CMS is unable to score this provision largely due to challenges with estimating Part A/B savings.
2. Improving Access to Behavioral Health Care Providers	CMS is finalizing changes to add a new facility specialty type called "Outpatient Behavioral Health" to the network adequacy standards under § 422.116(b)(2). For purposes of the network adequacy requirements, the new facility specialty type will be evaluated using time and distance and minimum number standards adopted in this rule. The new facility type will include MFTs, MHCs, OTP or other behavioral health and addiction medicine specialists and facilities. Based on comments from stakeholders CMS is also finalizing how an organization will determine when certain providers (NP, PA, CNS) may be utilized to meet network adequacy.	The new provision adds requirements for a new facility specialty type, which include providers some of which we have data for and some which are new and for which we lack data. Therefore, we cannot quantify the effects of this provision though we expect it may increase access which may qualitatively increase utilization.

Provision	Description	Financial Impact
3. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs)	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 express written consent is given by the beneficiary. Further, CMS is codifying that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure.	We do not expect any cost impact to the Medicare Trust Fund.
4. Enhance Guardrails for Agent/Broker Compensation	CMS is modifying agent/broker compensation requirements to further ensure payment arrangements and structure are aligned with CMS's statutory obligation to set limits on compensation to ensure that the use of compensation creates incentives for agents and brokers to enroll prospective enrollees in plans that best fit their needs.	This provision has no costs because CMS is transferring funds the MA plans are already paying Marketing Agencies directly to the agents and brokers with some reductions due to some funds possibly being used inconsistent with the requirements of the regulation.
5. Special Supplemental Benefits for the Chronically Ill (SSBCI)	CMS is finalizing changes to require MA organizations to establish bibliographies for each SSBCI they include in their bid to demonstrate that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. This will shift the burden from CMS to the MA organizations to demonstrate compliance with this standard and help ensure that SSBCI items and services are offered based on current, reliable evidence. In addition, CMS is finalizing new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility and coverage criteria. CMS is modifying and strengthening the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned.	The requirements for SSBCI are not expected to have any economic impact on the Medicare Trust Fund.
6. Mid-Year Enrollee Notification of Available Supplemental Benefits	CMS is finalizing requirements for MA plans to issue notices to enrollees who, by June 30th of a given year, have not utilized supplemental benefits, to ensure enrollees are aware of the availability of such benefits and ensure appropriate utilization.	Although these changes may result in increased utilization and ultimately create a savings to the Medicare Trust Fund, we cannot currently quantify this provision because it is new, and we lack data. See the Regulatory Impact Analysis for further discussion. The provision has an administrative cost of $23.7 million.

Provision	Description	Financial Impact
7. Annual Health Equity Analysis of Utilization Management Policies and Procedures	CMS is finalizing changes to the composition and responsibilities for the Utilization Management committee, to require: a member of the UM committee have expertise in health equity; the UM committee conduct an annual health equity analysis of prior authorization used by the MA organization using specified metrics; and require MA organizations to make the results of the analysis publicly available on its website.	We do not expect any cost impact to the Medicare Trust Fund.
8. Amendments to Part C and Part D Reporting Requirements	CMS is affirming our authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements and finalizing the proposed regulatory revisions to be consistent with the broad scope of the reporting requirements.	We do not expect any cost impact to the Medicare Trust Fund.
9. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services	CMS is finalizing regulations to (1) require QIOs to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF and (2) eliminate the provision requiring the forfeiture of an enrollee's right to appeal to the QIO a termination of services decision when they leave the facility.	The revisions to this provision have an estimated annual administrative cost of $683,910. This is a transfer from MA plans to QIOs; MA plans have a reduced cost while QIOs have a corresponding increased cost.
10. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products	CMS is finalizing regulations to permit Part D sponsors to immediately substitute authorized generics for corresponding brand name drug products, interchangeable biological products for their reference products, and unbranded biological products marketed for the brand name biological product marketed under the same biologics license application. We also are finalizing regulations to permit substitutions of all biosimilar biological products with 30 days advance notice.	We do not expect any cost impact to the Medicare Trust Fund.
11. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization	CMS is finalizing, with some modifications, policies to (a) replace the current dual/LIS quarterly SEP, (b) create a new integrated care SEP for full-benefit dually eligible individuals, (c) limit enrollment in certain D-SNPs to those full-benefit dually eligible individuals who are also enrolled in an affiliated Medicaid MCO, and (d) limit the number of D-SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO.	Over a 10-year horizon, we estimate a $1.3 billion savings to the Trust Fund for Part D plans and an additional $1 billion savings to the Trust Fund for Part C plans.

Provision	Description	Financial Impact
12. For D-SNP PPOs, Limit Out-of-Network Cost Sharing	CMS is finalizing a limitation on D-SNP PPOs' out-of-network cost sharing for certain Part A and Part B benefits, on an individual service level.	We do not expect any cost impact to the Medicare Trust Fund.
13. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes	CMS is lowering the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.	We estimate this provision will have an average annual impact of less than $1M for plan years 2025-2027 due to non-SNP MA plans meeting the lower D-SNP look-alike threshold transitioning enrollees into other plans. We also estimate this provision will have an average annual impact of less than $1M on MA plan enrollees for plan years 2025-2027 due to enrollees choosing a different plan. We expect cumulative annual costs to non-SNP MA plans and MA plan enrollees beyond plan year 2027 to also be less than $1M per year.
14. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process	CMS is revising when a medical record review determination and a payment error calculation appeal can be requested and adjudicated because RADV payment error calculations are based upon the outcomes of medical record review determinations. CMS is also finalizing other revisions to our appeals process to conform with these proposed changes. The changes could reduce burden on some MA organizations that, absent these revisions, will have otherwise potentially submitted payment error calculation appeals that could have been rendered moot by certain types of medical record appeals decisions. The potential reduction in burden to MA organizations cannot be quantified prior to the implementation of the new appeals process and until appeals have been fully adjudicated. While the MA RADV appeals regulations have been in place for a period of years, CMS did not issue RADV overpayment findings to MA organizations as we worked to finalize a regulation on our long-term RADV methodology. Therefore, any impact of these policies on MA organization behavior is further unquantifiable. The proposed changes do not impose any new information collection requirements.	The potential reduction in burden to MA organizations cannot be quantified prior to the implementation and execution of the appeals process pursuant to these changes.