CMS Final Rule on 2024 Policy and Technical Changes to Medicare Advantage and Medicare Part D

On April 5th, 2023, CMS released their annual Medicare Advantage (MA) and Part D Final Rule for 2024 (fact sheet) which governs requirements for MA and Part D plans. Among its provisions, the rule finalizes stricter prior authorization requirements, increases beneficiary marketing protections, better incorporates health equity into Star Ratings, provider directories, and quality improvement programs, and improves access to behavioral health. The proposed expanded eligibility criteria of the Medication Therapy Management (MTM) Program under Part D were not finalized at this time. **The summary below does not reflect a complete summary of the provisions of the rule. Rather, it includes a chosen subset of sections considered most relevant.**

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

A. Applying D-SNP Look-Alike Requirements to PBP Segments (section II.A, pgs. 20-37)

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

Finalized Changes

CMS finalized as proposed to amend § 422.503(e) to allow for CMS to sever a segment from an MA plan and allow the remaining segments of that MA plan to continue along with any other MA plans offered under the same contract. CMS also finalized as proposed to amend § 422.504(a)(19) to adopt a new contract term that MA organizations agree not to segment an MA plan in a way that results in a D-SNP look-alike.

CMS believed that by applying the D-SNP look-alike contracting limitations only at the MA plan level without applying it to segments of plans, their existing regulation has an unintended and unforeseen loophole through which D-SNP look-alikes could persist, contrary to the stated objectives in their prior rulemaking.

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

Finalized Changes

CMS finalized as proposed to amend § 422.514(d)(1) to apply it to both new and existing (that is, renewing) MA plans that are not D-SNPs and submit bids with projected enrollment of 80 percent or more enrollees of the plan's total enrollment that are dually eligible for Medicare and Medicaid.

3. Contract Limitations for D-SNP Look-Alikes as a Basis for MA Contract Termination

Finalized Changes

CMS finalized their proposed amendment to § 422.510(a)(4), which outlined the bases for termination of an MA contract. Specifically, they proposed to add language at § 422.510(a)(4) to add a new paragraph (a)(4)(xvi) that permits CMS to terminate an MA contract when the MA organization meets the criteria in § 422.514(d)(1) or (d)(2). This proposed amendment is consistent with how § 422.514(d) provides that CMS will not enter or renew an MA contract in certain circumstances.

Background/Rationale, All Sections:

Numerous commenters, including MACPAC and MedPAC, supported the CMS proposals overall to apply contracting limitations for D-SNP look-alikes to existing MA plans and MA plan segments. Some of the commenters emphasized their overall support for CMS' proposals and general approach to limiting D-SNP look-alikes, noting that D-SNP look-alikes detract from plans that integrate Medicare and Medicaid benefits. Several commenters supported CMS efforts to close unforeseen loopholes that have allowed D-SNP look-alikes to persist. CMS responded by stating that they agree with the commenters' concerns about D-SNP look-alikes. CMS believes the amendments that are still being finalized will allow CMS to more effectively implement Medicare-Medicaid integration requirements under the BBA of the 2018 along with other State and Federal requirements.

Some commenters recommended that CMS take action beyond implementing the proposals to lower the threshold used to identify D-SNP look-alikes. CMS responded by stating that the recommendations to reduce the enrollment threshold at § 422.514(d) are outside of the scope of the proposed amendments. CMS continues to monitor the level of dually eligible enrollment among non-SNP MA plans and will consider these comments for future rulemaking.

Some commenters suggested that CMS exclude or reconsider excluding partial-benefit dually eligible individuals when calculating the 80 percent threshold at §422.514(d). The recommendations to revise the definition of the enrollment threshold at § 422.514(d) are outside of the scope of CMS' proposed amendments; they believe that policy making on this issue would benefit from further study and engagement with interested parties. CMS will consider these comments for future rulemaking.

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes (section II.B, pgs. 37-40)

Finalized Changes

CMS finalized as proposed the SEP for Individuals Who Enroll in Part B During the Part B GEP to request enrollment in a Part D plan at § 423.38(c)(16). These revisions are needed to align the timeframe for use of this Part D SEP based on new Part B GEP enrollment effective date parameters.

In 2020, CMS codified a number of exceptional condition SEPs, including the SEP for Individuals Who Enroll in Part B During the Part B General Enrollment Period (GEP) (85 FR 33909). This SEP, as codified at § 423.38(c)(16), allowed individuals who are not entitled to premium-free Part A and who enroll in Part B during the GEP for Part B (January–March) to enroll in a Part D plan. This SEP begins April 1st and ends June 30th, with a Part D plan enrollment effective date of July 1st. This SEP effective date aligns with the entitlement date for Part B for individuals who enroll in Part B during the GEP.

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

Background/Rationale

All commenters supported the proposal to align the timeframe for use of this SEP based on the revised GEP effective date parameters established by the CAA. CMS thanked the commenters for their support of this proposed revision to align the timeframe for use of this SEP with the new parameter for GEP effective dates established under the CAA.

One commenter supported the proposal, but stated that current eligibility criteria do not require checking Part A status of payment, and requested clarification on whether CMS intends to require plans to validate Part A Entitlement Status Code in the Medicare Advantage Prescription Drug (MARx) system as part of eligibility verification for use of this SEP. CMS responded by stating that they did not propose any change to the criteria for use of this SEP, only the timeframe for its use, and the effective date of the coverage. Therefore, the actual enrollment process will not change.

One commenter stated that the individual's premium-Part A entitlement is a necessary component if one were to use the SEP to apply for Part D. CMS explained that the parameters for applying for premium-Part A in group-payer states are outside of the scope of this rule.

C. Alignment of Part C and D Special Enrollment Periods with Medicare Exceptional Condition Enrollment (section II.C, pgs. 40 – 45)

Finalized Changes

CMS finalized the MA SEP at §§ 422.62(b)(26) with a minor edit to the regulation text to clarify that this SEP applies to an individual submitting an application for Part B only if they are already entitled to Part A, or are enrolling in premium-free Part A within the timeframe of this SEP. CMS is finalizing the Part D enrollment SEP at 423.38(c)(34) as proposed without modification. These SEPs algin with new Medicare premium-Part A and B exception condition SEPs that CMS has finalized in 42 CFR 406.27 and 407.23.

Background/Rationale

All commenters supported the proposal to add corresponding exceptional condition SEPs for MA and Part D enrollment to align with the new Medicare premium Part A and B exceptional condition SEPs that CMS has finalized in 42 CFR 406.27 and 407.23.

One commenter expressed that, under the new requirements, a Part D plan would not know the date the applicant submitted their application to the SSA. Per current practice, the MA or Part D plan would need to confirm that the individual had enrolled in premium Part A and/or Part B, as applicable, prior to the individual's MA or Part D enrollment effective date. CMS clarified the timeframes to address the concern.

Another commenter stated that, although they support CMS' policy intent with this proposal, with increased prescription coverage for beneficiaries, this will likely exacerbate current reimbursement challenges at the pharmacy counter—where pharmacies are being paid below costs for many of the prescriptions they purchase and dispense. CMS noted this comment is outside the scope of the rulemaking.

D. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program (section II.D, pgs. 49-92)

1. Eligibility and Enrollment

Finalized Changes

CMS finalized as proposed to make LI NET a permanent program through § 423.2500. The program would begin January 1, 2024, where eligible individuals would be provided transitional coverage for Part D drugs. CMS also finalized eligibility, enrollment, and sponsorship requirement for LI NET beneficiaries and sponsors. CMS finalized two categories of individuals eligible to enroll in LI NET that encompass the previously noted categories of low-income individuals recognized by Part D in § 423.2504. The first category, "LIS-eligible," consists of individuals whose low-income status has been confirmed through CMS' records or demonstration of the individual's low-income status. The second category, "immediate need," consists of individuals whose low-income status has not been confirmed, because CMS' data do not yet reflect the individual's low-income status, but the individual has indicated that they are eligible for the LIS (although absence of documentation should not be a barrier to LI NET eligibility).

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

CMS finalized that immediate need beneficiaries whose eligibility cannot be confirmed can continue to fill prescriptions throughout their 2-month enrollment in LI NET in § 423.2504(a)(2)(i).

CMS finalized to codify LI NET enrollment, including autoenrollment, point-of-sale for immediate need individuals, direct reimbursement, and LI NET enrollment form in § 423.2504(b). CMS also finalized to automatically enroll those that are LIS-eligible and whose auto-enrollment into a Part D plan has not taken effect into the LI NET program unless they have actively declined enrollment by notifying CMS' systems. Therefore, when a beneficiary declines Part D enrollment, they are also opting out of LI NET enrollment. CMS also finalized to allow retroactive LI NET coverage beginning the date an individual is identified as full-benefit dual or an SSI benefit recipient, or 36 months before the individual enrolls in (or opts out of) Part D coverage, whichever is later. Under CMS proposal, LI NET enrollment ends once Part D coverage takes effect, consistent with section 1860D-14(e)(3) of the Act.

CMS also finalized § 423.2504 with the following revisions:

- Renumber proposed § 423.2504(a)(2)(i) to § 423.2504(a)(3) and add a heading that reads "Documentation of LIS Eligibility"
- Renumber the succeeding subsections under proposed § 423.2504(a)(2)(i) accordingly;
- Insert § 423.2504(a)(4) to say "CMS uses documentation submitted under paragraph (a)(3) of this section to confirm LIS eligibility"
- Renumber proposed § 423.2504(a)(2)(ii) to § 423.2504(a)(5) and revise to specify that "If CMS cannot confirm an immediate need individual's eligibility during the period of LI NET coverage, the individual will not be auto-enrolled into a standalone Part D plan in accordance with § 423.34(d) following their LI NET coverage"
- Finalize § 423.2504(b)(2) as follows: "(2) Point-of-sale enrollment. An individual who is not automatically enrolled in accordance with paragraph (b)(1) of this section and whose claim is submitted at the point-of-sale and accepted by the LI NET sponsor will be enrolled into the LI NET program by the LI NET sponsor"
- Finalize § 423.2504(b)(3) as follows: "(3) Direct reimbursement request. An individual described in paragraph (a)(1) of this section who is not automatically enrolled in accordance with paragraph (b)(1) or at the point-of-sale as provided in paragraph (b)(2) and who submits a direct

reimbursement request form, receipts for reimbursement for eligible claims paid out of pocket (with optional documentation of LIS eligibility listed in paragraph (a)(3)), will be retroactively enrolled into the LI NET program by the LI NET sponsor. The LI NET sponsor has 14 calendar days to reply with a coverage decision"

- Finalize § 423.2504(b)(4) as follows: "(4) LI NET application form. An individual who is not enrolled through one of the methods in paragraphs (b)(1) though (3) of this section may submit an LI NET application form to the LI NET sponsor (with optional documentation of LIS eligibility listed in paragraph (a)(3)). If no documentation is submitted and accepted, the LI NET sponsor will periodically check for eligibility and enroll applicants once LIS eligibility is confirmed."
- Recognizing that the SSA letter uses the terminology "Extra Help" instead of "LIS", CMS also added for clarity the term "Extra Help" to § 423.2504(a)(3)(ii).

2. Benefits and Beneficiary Protections

Finalized Changes

CMS largely finalized provisions as proposed, including the following:

- Codifying the requirement that the LI NET program provide access to all Part D drugs under an open formulary in § 423.2508(a).
- Establishing that a pharmacy is deemed to be in good standing if it is licensed, has not been revoked from Medicare under § 424.535, does not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs (unless the OIG waives the exclusion, which the OIG has authority to do in certain specified circumstances), and does not appear on the preclusion list as defined in § 423.100. CMS made a slightly revision to the definition of "good standing" in § 423.2508(b) to also include pharmacies against which the LI NET sponsor does not have a credible allegation of fraud as defined at § 423.4. With the addition of this element relying on the LI NET sponsor's determination, and noting that there are specific, objective standards comprising the definition of pharmacies that are in "good standing" for LI NET, it is unnecessary for CMS to decide about pharmacies' standings in this regard. Thus, CMS also removed the phrase "as determined by CMS" from § 423.2508(b)
- Applying the patient safety and appropriate medication dispensing regulations to the LI NET program and LI NET sponsor.
- Requiring that beneficiaries whose LIS-eligibility is established and who have not yet enrolled in a prescription drug plan or MA-PD plan, or who have enrolled in a prescription drug or MA-PD plan but coverage under such plan has not yet taken effect, would pay the applicable cost sharing for their low-income category as established in the yearly Announcement of Calendar Year Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.
- Clarifying that LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of the Part D regulations.

3. LI NET Sponsor Requirements

Finalized Changes

CMS finalized requirements for the LI NET sponsor when administering the LI NET program largely as proposed.

CMS finalized the cross reference to the good reference standard in § 423.2508(b) to say that the LI NET sponsor must adjudicate claims from out-of-network pharmacies that are in good standing (as defined in § 423.2508(b)) according to the LI NET sponsor's standard reimbursement for their network pharmacies.

CMS also finalized § 423.2512(c)(3) as proposed, except for an editorial change to more concisely say "conduct outreach plans" instead of "carry out outreach plans."

4. Selection of LI NET Sponsor and Contracting Provisions

Finalized Changes

CMS finalized selection of the LIE NET Sponsor and Contracting Provisions largely as proposed.

CMS noted an omission in § 423.2508(b) of the description of OIG's exclusion authority. OIG has the authority to exclude individuals and entities from Medicare and State health care programs under section 1156 of the Act. CMS omitted reference to State Health care programs in proposed § 423.2508(b), and added state health care programs to OIG's list of excluded entities under section 1156 of the Act.

5. Bidding and Payments to LI NET Sponsor

CMS finalized as proposed the methodology and formulas used to determine the amounts paid to the LI NET sponsor under the contract. CMS also finalized payments for the LI NET program be made from the Medicare Prescription Drug Account, as payments are made to other Part D sponsors. CMS also proposes providing advance monthly LI NET payments, on a per-member, per-month (PMPM) basis, equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid submitted annually.

CMS finalized requiring the sponsor to submit a bid and supplemental information in a format specified by CMS, with the same deadline as other Part D bids of no later than the first Monday of June each year.

CMS finalized specific provisions (§ 423.272(a), (b)(1), and (b)(4) regarding the review, negotiation, and approval of the LI NET bid.

6. Part D Program Waivers

Finalized Changes

CMS finalized the waiver of Part D program requirements as they were proposed, but they noted that they would consider whether they would waive the new Part D program requirements to the LI NET program when the new Part D program was adopted.

Background/Rationale, All Sections

CMS received many comments supporting the making of the LI NET program permanent, especially since it would simplify and expand access for the dually eligible population, in addition to the partial-benefit dually eligible population.

CMS also received comments asking whether each MA organizations needs to have programs tracking low-income beneficiaries' LI NET eligibility, benefits, and enrollment, to which CMS responded only the sponsor appointed by CMS must do so.

CMS also received comments to conduct additional LI NET beneficiary outreach during their temporary enrollment in LI NET to ensure they select the most appropriate Part D plan for themselves. CMS responded that LI NET beneficiaries receive information at the beginning of their enrollment and have many phone, text, and web communications to assist them in the process.

CMS also received comments saying that CMS was not intending to allow a letter from the Social Security Administration indicating a beneficiary's LIS eligibility to be sufficient evidence for enrollment into LI NET. CMS responded that a letter from SSA showing LIS status is sufficient, although they said that they would modify their proposal to clarify the list of documents to ensure eligibility at any point in time, from POS, direct reimbursement request, or by submitting an LI NET application form.

CMS also received comment that the proposed definition for point-of-sale enrollment in § 423.2504(b)(2) would not adequately capture the full range of POS enrollees, such as those who are eligible for LI NET but do not necessarily demonstrate an immediate need for medication. CMS agreed and struck "with an immediate need" from the description of point-of-sale enrollment. This makes it easier for those who are not in immediate need of prescriptions to take advantage of the POS enrollment system.

CMS received comment that the definition of pharmacies in good standing in LI NET should be expanded to also prohibit out-of-network pharmacies from submitting claims to the LI NET sponsor if they are under a current payment suspension by any Part D sponsor or have been terminated from the LI NET sponsor's network based on credible allegations of fraud. The commenter recommends this change to avoid a situation in which a pharmacy has been suspended or terminated from participation in a Part D plan's network but can still serve LI NET beneficiaries. CMS responded that they encourage Part D sponsors to use information CMS provides through the Health Plan Management System Program Integrity Portal and to perform their own investigations as well. They agreed and expanded the definition to also include the aforementioned non-credible pharmacies.

CMS received comments about a LI NET sponsor's ability to audit and recover overpayments from out-of-network pharmacies, which would not be contracted with the LI NET sponsor. CMS agreed that the requirement to adjudicate out-of-network claims would only apply to pharmacies in good standing and

updated the rule accordingly. CMS also reiterated that the LI NET sponsor has the ability to audit out-of-network pharmacies and subject them to overpayment recovery processes.

CMS also received comments regarding its Part D requirements that would be waived under the LI NET program and to clarify whether new requirements apply to the LI NET program as the Part D requirements are also introduced. CMS responded that they would consider at the time of Part D program adoption whether they should apply to the LI NET program or be added to the list of waived requirements.

CMS also received concerns about the time between sunsetting the demonstration program and when they would make LI NET permanent, pointing to potential glitches in the transition. CMS acknowledged these concerns and stated that they would work closely with the new sponsor to monitor the transition to limit beneficiary disruption.

E. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (section II.E, pgs 92-96)

Finalized Changes

CMS finalized their proposals to expand eligible of LIS to 150% of the FPL with one minor change, revising the regulatory text of proposed § 423.773(b)(2)(iii) by adding the word "plan" before "years", so that the provision as finalized in this rule refers to "plan years beginning on or after January 1, 2024". This change is consistent with the references to "plan years" in paragraphs (b)(1) and (d) of § 423.773, as revised by this final rule. Finalized provisions include:

- Amending § 423.773(b)(1) to add that to be eligible for the full subsidy for plan years beginning on or after January 1, 2024, an individual must have an income below 150 percent of the FPL.
- Amending § 423.773(d) to specify that the requirement that an individual have an income below 150 percent of the FPL to be eligible for the partial subsidy applies only to plan years beginning before January 1, 2024. This latter change is consistent with the IRA effectively sunsetting the partial LIS after 2023.
- Amending § 423.773 to state that the current resource limits applicable for the full subsidy at paragraph (b)(2)(ii) apply to years 2007 through 2023.
- Adding a new § 423.773(b)(2)(iii) to state that for years beginning on or after January 1, 2024, the resource limits at paragraph (d)(2) of § 423.773 – the resource standards currently applicable for the partial subsidy – would apply to full subsidy eligible individuals. This result of this change is that individuals can have a higher value of resources and still be eligible for the full subsidy.
- Amending § 423.780(d) to specify that the sliding scale premium amounts currently applicable for individuals with the partial subsidy apply with respect to plan years beginning before January 1, 2024. These individuals who have incomes between 135 and 150 percent of the FPL and who meet the resource requirements will now qualify for the full subsidy beginning in 2024, and will be entitled to a premium subsidy of 100 percent of the premium subsidy amount, as outlined in § 423.780(a).

Background/Rationale

The Part D low-income subsidy (LIS) helps people with Medicare who meet certain statutory income and resource criteria pay for prescription drugs and lowers the costs of prescription drug coverage. Individuals who qualify for the full LIS receive assistance to pay their full premiums and deductibles (in certain Part D plans) and have reduced cost sharing. Individuals who qualify for the partial LIS pay reduced premiums (on a sliding scale based on their income) and have reduced deductibles and cost sharing. Section 11404 of the IRA (Pub. L. 117-169), enacted on August 16, 2022, amended section 1860D-14 of the Act to expand eligibility for the full LIS to individuals who are determined to have incomes below 150 percent of the FPL and who meet either the resource standard in paragraph (3)(D) or paragraph (3)(E) of section 1860D-14(a) of the Act, with respect to plan years beginning on or after January 1, 2024. This change will provide the full LIS for individuals who currently qualify for the partial subsidy.

Commenters overwhelmingly supported our proposal to implement section 11404 of the IRA and expand eligibility for the Part D LIS. Commenters stated that this change will advance health equity, increase the affordability of prescription drugs, and facilitate access to care, especially for individuals with ESRD, and Black and Hispanic beneficiaries, who may disproportionately fall within the partial subsidy category. CMS appreciates the support for the proposal and agree that the expansion of the LIS benefit will increase beneficiaries' access to prescription drugs and improve treatment adherence, leading to better health outcomes.

While voicing their support, many commenters recommended that CMS explore opportunities to educate beneficiaries newly eligible for the full benefit, as well as those currently eligible for but not enrolled in the LIS. CMS agrees that it is vital that beneficiaries eligible for the low-income subsidy understand that extra help is available to them through low-income savings programs like MSP and LIS.

A few commenters expressed concern that beneficiaries with incomes between 135 percent and 150 percent of the FPL are not auto-enrolled into a benchmark plan. Individuals who currently qualify for the partial LIS subsidy and continue to qualify in 2024 will not have to take any action to transition to full subsidy status.

A few commenters, while supporting the proposal, noted concerns about how other changes to the Part D program will affect LIS beneficiaries. CMS thanked the commenters for expressing their concerns for how other upcoming changes to the Part D program may disproportionately have a negative effect on low-income beneficiaries.

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

A. Health Equity in Medicare Advantage (MA) (section III.A, pgs 97-146)

1. Ensuring Equitable Access to Medicare Advantage Services

Finalized Changes

CMS finalized the revisions to § 422.112(a)(8) as proposed. Currently, § 422.112(a)(8) requires MA organizations that offer coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees. CMS proposed changing the current paragraph heading from "Cultural considerations" to "Ensuring Equitable Access to Medicare Advantage (MA) Services" to more clearly reflect the protection that MA organizations must guarantee for all enrollees.

The second change that CMS proposed and finalized is adding more populations to the existing list of groups that appear in the regulation. The rule clarifies the list of populations that may require specific consideration to their needs by replacing the phrase replace the phrase "those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds" and after the word "including" add" "(i) people with limited English proficiency or reading skills; (ii) people of ethnic, cultural, racial, or religious minorities; (iii) people with disabilities; (iv) people who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (vi) people who live in rural areas and other areas with high levels of deprivation; and (vii) people otherwise adversely affected by persistent poverty or inequality."

Background/Rationale

Commenters generally supported the proposed changes for this provision. CMS did not receive any modification requests for the proposed heading change. Some commenters recommended that CMS include additional populations in the proposed list of groups such as adding intersectional conditions affecting some enrollees. CMS responded that the list of groups is not exhaustive, and CMS will not add additional groups at this time to avoid redundancy. Some commenters also recommended that CMS delay the finalization of the proposal to allow MA organizations to prepare for the changes. CMS responded that the requirement for MA coordinated care plans to ensure services are provided in a culturally competent manner to all enrollees has already been in effect for a significant amount of time and the proposal makes no changes to the regulation's current application.

2. Medicare Advantage (MA) Provider Directories

Finalized Changes

CMS finalized one of the two revisions as proposed at § 422.111(b)(3)(i). CMS finalized the proposal to mirror the provider directory requirements for Medicaid managed care plans at § 438.10(h)(1)(vii) by adding the phrase "each provider's cultural and linguistic capabilities, including languages (including

American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office" to paragraph (b)(3)(i). The addition would change this best practice to a required data element that all organizations must include in their provider directories.

CMS did not finalize the proposal to amend § 422.111(b)(3)(i) to add a new required provider directory data element for certain providers who offer medications for opioid use disorder (MOUD). CMS Specifically, the agency proposed to require organizations to identify certain providers in their directories who had obtained a waiver under section 303(g)(2) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)(2)(B)(i)-(ii)) from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) to treat patients with buprenorphine for opioid use disorder and who are listed on SAMHSA's Buprenorphine Practitioner Locator (BPL).

Background/Rationale

Comments on the proposal to identify providers' cultural and linguistic capabilities were largely favorable. Many commenters supported allowing enrollees to make informed decisions when choosing providers and expressed support for the benefit the proposal would provide for non-English speaking enrollees, individuals with limited English proficiency, and those seeking providers who use ASL or have an interpreter available. Many commenters stressed the importance of provider directory accuracy and were in favor of a national provider directory, recommending that CMS focus provider directory efforts on establishing a National Director of Healthcare Providers & Services (NDH). CMS responded that it is still considering the NDH concept and stated that this proposal is an important step to promoting transparency and equitable access to care. Several commenters expressed concern that the new proposed requirements would increase the burden on providers. CMS acknowledged the potential burden on providers and encouraged organizations to consider using their contracts with providers to require them to provide this information and keep it updated.

Comments on the proposal that would require organizations to identify MOUD-waivered providers pointed to recently enacted legislation that has made the proposal mute. Section 1262 of Division FF of the Consolidated Appropriations Act of 2023 (CAA) (Pub. L. 117-328) amended section 303(g) of the Controlled Substances Act to remove the statutory requirement for providers to obtain a valid waiver (commonly referred to as an "X-Waiver") from SAMHSA and the DEA to administer, dispense, or prescribe MOUD. As a result, any licensed provider can treat patients with MOUD without a waiver. Per commenters recommendations, CMS decided not to finalize this proposal.

3. Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth

Finalized Changes

CMS finalized the revisions with amendments. CMS proposed to add requirements for certain MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy. Specifically, CMS proposed to amend current continuity of care requirements for MA organizations offering coordinated care plans to "ensure continuity of care and integration of services through arrangements with contracted providers" at § 422.112(b), by adding a new

paragraph (9). The proposed paragraph would require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange. CMS finalized the policy but amended § 422.100 rather than § 422.112(b) as originally proposed to apply the requirement to all MA plans and not just coordinated care plans.

CMS also finalized as proposed the requirement for MA organizations to make information about their required digital health literacy screening and digital health education programs available to CMS upon request at proposed § 422.112(b)(9)(i) (finalized at § 422.100(n)(1)). The proposed rule would allow CMS to monitor the impact of the new requirement for these programs on MA organizations, providers, enrollees, and the MA program. CMS is finalizing language providing a non-exhaustive list of the information CMS may request from MA organizations under this policy. CMS initially proposed that this requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, and evaluations of effectiveness of digital health literacy interventions. CMS initially solicited comments on whether it should require regular reporting of this data from all MA organizations alongside Part C reporting requirements. CMS did not finalize this proposal.

Background/Rationale

Most comments were generally supportive of the proposals, especially because the proposal would provide MA organizations with flexibility in implementing the digital education program. Many commenters requested additional information on MA organization compliance under this policy, and CMS acknowledged the logistic challenges that MA organizations will face and reaffirms that MA organizations have discretion to enact practices that meet their needs. Many commenters also requested CMS define digital health literacy and suggested it establish standardized reporting metrics; however, CMS expressed concern that establishing standardized definitions for digital health literacy and reporting metrics would detract from the flexibility it intends to provide MA organizations. Based on comments it received, CMS indicated that it would consider convening an industry workgroup to study standards and effective methods for improving digital health literacy. In response to recommendations from commenters, CMS expanded the proposal to require all MA organizations, and not just coordinated care plans, to implement a digital health education program.

4. Quality Improvement Program

Finalized Changes

CMS finalized as proposed its amendments to the MA Quality Improvement (QI) program at § 422.152(a) to require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees.

Background/Rationale

CMS received several comments expressing overwhelming support for requiring MA organizations to incorporate one or more activities that reduce disparities in health and health care among MA enrollees into their QI program, and recommended that CMS finalize the provision as proposed.

A few commenters requested that CMS allow MA organizations to have broad discretion regarding the types of activities they can implement to meet the new QI program requirement. CMS reiterated that the requirement that is being finalized is not prescriptive in the types of activities MA organizations must or can implement to meet the requirement.

A few commenters encouraged CMS to exercise appropriate oversight to ensure that MA organizations are implementing activities that are reducing disparities, clearly and measurably. CMS noted that various aspects of the QI program require that MA organizations have processes in place to evaluate participant outcomes, the effectiveness of QI programs, report the status of CCIP results to CMS as requested, report quality performance data, etc. CMS' current oversight efforts include these requirements, and therefore, they do not believe it is necessary to impose additional means of oversight.

B. Behavioral Health in Medicare Advantage (MA) (section III.B, pgs 146-171)

1. Behavioral Health Specialties in Medicare Advantage (MA) Networks

Finalized Changes

CMS finalized the proposal, with some modifications, adding Clinical Psychology and Licensed Clinical Social Work as provider specialty types, subject to network adequacy evaluations, and eligible for the 10% telehealth credit. CMS is not finalizing the proposal to add the Prescribers of Medication for Opioid Use Disorder, including Opioid Treatment Programs, to the provider specialty types and subsequent other requirements.

Background/Rationale

CMS received numerous comments that were generally supportive of adding new behavioral health specialty provider types to expand access to behavioral health services and providers for Medicare enrollees. Some commenters opposed including the new provider types in network adequacy standards, citing industry-wide behavioral health professional shortages, which could hinder the ability of plans to meet standards. CMS believes that the network adequacy standards were developed according to an established process, based on the current supply and distribution of providers, which should allow plans to meet the standards, or request an exception.

Numerous commenters noted that the Consolidated Appropriations Act of 2023 eliminated the X-waiver requirement for medication for opioid use disorder prescribers, and therefore recommended CMS not finalize or develop alternative standards for OTPs and prescribers. CMS concurred with these comments and is not finalizing this part of the proposal.

2. Behavioral Health Services in Medicare Advantage (MA)

Finalized Changes

CMS finalized as proposed adding behavioral health services to the general access to services standards at § 422.112. This includes provisions to codify wait times for primary care and behavioral health services, clarify that some behavioral health services may qualify as emergency health services and are therefore not subject to prior authorization, and extend current requirements for MA organizations to establish behavioral health care coordination programs.

Background/Rationale

All the comments were generally supportive of this proposal. Some commenters suggested CMS clarify that MA organizations may not issue denials based on medical necessity when an enrollee has an emergency medical condition, via prior authorization, retrospective authorization, or other medical necessity review processes. In response CMS emphasized that MA organizations are required to cover inpatient and outpatient emergency services needed to evaluate or stabilize an emergency medical condition and may not be retrospectively denied by MA plans. However, MA organizations are not responsible for unrelated non-emergency services provided during treatment in emergency situations.

3. Medicare Advantage (MA) Access to Services: Appointment Wait Time Standards

Finalized Changes

CMS is finalizing, largely as proposed the revisions to § 422.112(a)(6)(i) to codify wait time standards for primary and behavioral health care services, as previously established in the Manual. CMS is modifying the finalized rule to clarify that the standard is based on business days.

Background/Rationale

CMS received many comments in support of the proposal to codify the existing standards and extend them to behavioral health. Some commentors did not support the proposal, expressing concern about MA plans' ability to meet the standards given provider shortages, alignment with NCQA and QHP standards, or requesting pilots or additional analyses before finalizing the proposal. While CMS appreciated the comments, they believe the proposed approach supports parity between behavioral and physical health services and strengthens CMS's requirements to ensure MA plans are meeting standards for these services. However, they did choose to update the standards using business days, based on this feedback.

C. Medicare Advantage (MA) Network Adequacy: Access to Services (section III.C, pgs 171-183)

Finalized Changes

CMS finalized as proposed the changes to § 422.112(a)(1) and (a)(3) to more clearly state the scope of the MA organization's obligation to ensure adequate access to medically necessary covered benefits and reflect longstanding policy. Specifically, CMS will require MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, at in-network cost sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

CMS has not been made aware of any issues of MA organizations non-compliance with this policy, and as such, believes that MA organizations have been complying with this longstanding guidance. Therefore, as stated in the proposed rule, the proposed amendment to § 422.112(a)(1) and (a)(3) would not impose new information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements), and CMS has not provided burden estimates in the Collection of Information section of the proposed rule. In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

Background/Rationale

CMS noted that the majority of comments were supportive of the proposal, notably many expressed appreciation for ensuring adequate access to medically necessary covered care for more vulnerable enrollees. After considering the comments received, CMS is adding the phrase "and cover," thus revising § 422.112(a)(3) to read, "Arrange for and cover any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs."

Some commenters requested more guidance around the policy. Specifically, one commenter suggested CMS clarify the policy through definitions of "unavailable," "arrange for," and "necessary specialty care." Another commenter suggested CMS should establish timelines as a requirement to ensure services are available within one business day of an approved authorization. CMS noted that they are not adding any definitions to the regulatory text, however clarified the definitions of the phrases the commenter highlighted in their response. CMS also acknowledged the concern around timelines of access to care, and shared that while MA organizations may not have the same level of control, they expect MA organizations to make their best effort to ensure that out-of-network care they arrange for is provided timely.

A few commenters opposed this proposal, citing that when CMS requires MA organizations to allow for out-of-network providers to be seen at in-network cost sharing, it limits the MA organization's ability to control utilization, quality, and costs. Another commenter stated that out-of-network providers should not be required to accept in-network reimbursement for their services, and MA organizations should be required to reimburse out-of-network providers at a rate that accurately reflects the services provided.

CMS noted that requiring MA organizations to allow out-of-network providers to be seen at in-network cost sharing has been a longstanding policy, and highlighted the option for MA organizations to enter into a case-by-case agreement or limited contract with the non-contracted provider if they wish to have more control over elements such as utilization, quality, and costs.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Contract Terminations (section III.D, pgs 183-204)

Finalized Changes

CMS finalized as proposed the changes to § 422.111(e) to remove "good faith effort" beneficiary notification requirements for no-cause provider contract terminations and require MA organizations to provide notice to beneficiaries at least 30 days before the termination effective date, as required under § 422.111(e). Moreover, CMS finalized as proposed the clarifications of the existing notification requirements for all other specialty types (besides primary care and behavioral health providers) in section § 422.111(e)(2). For these provider types, notifications will continue to be required to be provided at least 30 days in advance, through written notice only, and only to affected enrollees. CMS additionally finalized a modified proposal to include behavioral health providers to the notification requirements § 422.111(e) and add new requirements for notifications related to behavioral health and primary care providers. Revisions to the proposed changes include:

- In § 422.111 (e)(1)(i), removing the phrase "both written and telephonic" and adding "written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have opted out of calls regarding plan business as described in § 422.2264(b)."
- In § 422.111 (e)(1)(iii), adding the phrase "are currently assigned to that primary care provider and to enrollees who" and removing the word "ever" and adding the phrase "within the past three years."

Finally, CMS finalized changes to § 422.2267(e)(12) as proposed.

Background/Rationale

CMS noted that comments were mixed, with about half in support of the proposal and half opposed to it.

CMS received comments pertaining to enrollee notification requirements, the proposed lookback period for identifying enrollees, the addition of required telephonic notification, and the proposed timeframes for written notice of the provider contract termination and removal of the "good faith effort" standard. In response, CMS disagreed with extending requirements for contract termination because of the "special considerations" applicable to the primary care and behavioral health space, implemented a three-year look back period as a middle ground solution, defended the additional requirement of one phone call, and emphasized the importance of greater notice beyond that of "good faith" in behavioral and primary care.

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (section III.E, pgs 204-306)

1. Coverage Criteria for Basic Benefits (209 – 251)

Finalized Changes

CMS finalized the removal of the reference to "original Medicare manuals and instructions" and clarified that MA organizations must comply with general coverage and benefit conditions included in Traditional Medicare laws, as applicable to the inpatient only list, unless superseded by laws applicable to MA plans, when making coverage decisions.

CMS finalized their proposal that MA organizations must make medical necessity determinations based on coverage and benefit criteria and may not deny coverage for basic benefits based on coverage criteria. This means that when an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies.

CMS finalized their proposal that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available to enhance transparency requirements related to use of internal coverage criteria. In creating these internal policies, CMS is finalizing that MA organizations must follow similar rules that CMS and MACs follow when creating NCDs or LCDs. Specifically, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations.

CMS finalized that MA organizations must follow a somewhat similar process when creating internal plan coverage criteria by providing a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. CMS also finalized a requirement that an MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature.

CMS finalized that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate.

CMS finalized a narrower policy that permits MA organizations to continue to choose who provides Part A and Part B benefits through the creation of their contracted networks, but limits MA organizations' ability to limit when and how covered benefits are furnished when Traditional Medicare will cover different provider types or settings. MA organizations may not deny authorization based on internal MA

organization clinical criteria that go beyond Medicare coverage rules or addressing standards for when MA internal coverage rules are permissible.

CMS finalized that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only when the prior authorization processes are consistent. They also finalized to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary, or to ensure that the furnishing of supplemental benefits is clinically appropriate.

CMS made two modifications in finalizing its proposals:

- Clarifying the scope of the requirements in § 422.101(b)(2) and to explicitly state the applicability of the inpatient-only list.
- When coverage criteria are not fully established, clarifying that the obligation to make information publicly accessible applies to the internal criteria in use, to enhance transparency requirements related to the use of internal coverage criteria. Based on the scope of these modifications and clarifications, CMS addressed when Medicare coverage criteria are not fully established and the procedural and transparency requirements that apply when an MA organization adopts internal coverage criteria for basic benefits.

Background/Rationale

CMS received several comments in support of the clarifications that MA plans must comply with coverage and benefit conditions in Traditional Medicare. Several commenters requested CMS clearly specify that MA plans must follow the Inpatient Only (IPO) list and "two-midnight rule" presumption and benchmark for inpatient admissions. Additional commenters requested CMS explicitly state additional coverage criteria are prohibited when the IPO list and two-midnight rule are applicable. Other commenters expressed concern that the proposed rules limit MA plans' ability to adequately assess whether a covered item or service is medically necessary. Some commenters expressed concerns that Medicare coverage guidelines are not specific enough to be relied upon to make medical necessity determination and suggested CMS provide additional clarity regarding what plans should do when there are no CMS guidelines applicable to a service and to provide examples regarding what is permissible under these circumstances.

CMS responded that when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, MA plans may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available.

CMS received several comments asking to prohibit use of commercial and proprietary criteria by MA plans. Many commenters stated that MA plan coverage criteria are often inconsistent, outside the scope of reasonable standards of practice, and more restrictive than Traditional Medicare guidelines. Some commenters requested that CMS not prohibit use of proprietary coverage criteria and tools, stating that that these tools help plans consolidate Medicare regulations and assist plans in making evidence-based, clinically appropriate medical necessity determinations.

CMS stated that they understand that utilization management tools are created to assist the plans, providers and others, in clinical review processes and to help guide medical necessity determinations and that these products were created with the intention of serving as a single source that consolidates clinical data, medical literature, and CMS guidance and coverage policies to assist MA plans in making medical necessity determinations. However, use of these tools, in isolation, without compliance with requirements in this final rule is prohibited. Further, if an MA plan uses the coverage criteria in these tools, they will need to understand the external clinical evidence relied upon in these products and how that evidence supports the coverage criteria applied by these tools.

Several commenters expressed concern that requiring MA plans to strictly adhere to Traditional Medicare coverage policies undermines MA plans' ability to appropriately manage care. Commenters also stated that the proposed policies would restrict a plan's ability to direct patients to clinically equivalent, lower-cost alternative treatments or therapies first which could lead to increased costs and duplicative and unnecessary services. Other commenters stated that the proposal will undermine the transition to value-based care and similar payment models.

CMS responded that MA organizations must make medical necessity determinations based on coverage and benefit criteria and may not deny coverage for basic benefits based on coverage criteria that are not specified. This means that when an MA organization is making a coverage determination on a Medicare covered item or service and that item or service has fully established coverage criteria, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. However, this rule does not mean that an MA organization must deny coverage of all other treatment alternatives for an MA enrollee, since MA plans may have supplemental benefits that cover of items and services that are not covered under Parts A or B. CMS believe this policy provides enough flexibility for MA organizations to manage care so long as that management is grounded in current evidence in widely used treatment guidelines or clinical literature and made publicly available.

Some commenters expressed concern about the appropriateness of Traditional Medicare coverage guidelines. These commenters suggested that these guidelines may need to be updated and are not in line with current medical standards. CMS responded that because Traditional Medicare follows a process of expert consultation and public review and comment to stay up-to-date and align with current medical standards and practices as it develops the coverage guidelines governing Traditional Medicare's basic benefits, they believe that these processes are sufficient in creating appropriate coverage guidelines

Some commenters expressed concern about MA plans' ability to provide a summary of evidence for all services and asked CMS clarify what exactly is meant by summary of the evidence that was considered. Other commenters requested CMS provide guidance on how this information should be shared publicly, noting that some resources may be behind a paywall. A few commenters suggested that CMS also require MA plans to make any internal coverage criteria publicly available and that this information should be available at least 30 days prior to implementation. CMS responded they are finalizing that MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature and that current, widely used treatment guidelines include those used to determine appropriate levels of care.

Some commenters requested that CMS require MA plans to adhere to Traditional Medicare coding policies related to how MA organizations pay providers. Another commenter suggested CMS also require MA plans to use only CMS' software and billing processes CMS responded to commenters that MA regulations expressly prohibit CMS from interfering in price structures agreed to by an MA plan and its contracted providers. Whether or how a MAO pays its providers for furnishing covered services through use of a particular CPT code or some other mechanism can vary depending on the contract between the MA plan and the provider

Several commenters stated that plan medical directors often issue determinations without up-to-date patient data. These commenters suggested that CMS require that prior to issuing a medical necessity determination, the plan medical director must have direct access to all the relevant information available to the plan and the responsibility to review all this information. Several commenters stated that peer-to-peer reviews often include medical directors without relevant expertise. CMS responded that MA organizations must make medical necessity determinations based on, among other things, the enrollee's medical history, physician recommendations, and clinical notes. This regulation requirement means that the MA organization, and its staff that review requests for an organization determination related to medical necessity, must review these materials that are specific to the enrollee and the contemplated services.

Some commenters requested that CMS require that a treating clinician's medical determination be the primary factor in any determination related to admission or transfer to another level of care when no NCD or LCD is present. CMS responded that under the revisions finalized in this rule, physician recommendations are required to be considered when making medical necessity determinations about the specific enrollee and requested services.

CMS received some comments requesting that CMS delay the implementation date of the utilization management related provisions in this rule, including the medical necessity proposals. Other commenters stated that providing a publicly accessible summary of evidence would require significant administrative efforts. CMS believes MA organizations already have robust processes and systems in place for making medical necessity determinations, as these decisions are inherent in and fundamental to any care coordination plan. Further, CMS believes that many MA organizations are already following Traditional Medicare coverage guidelines, while others may be making greater use of other clinical decision-making tools that fall outside Traditional Medicare.

CMS is finalizing amendments largely as proposed but with modifications to clarify the scope of the requirements and to explicitly state the applicability of the inpatient-only list. Further, CMS is finalizing the regulatory language as proposed, but with modifications to state when coverage criteria are not fully established, to clarify that the obligation to make information publicly accessible applies to the internal criteria in use, to enhance transparency requirements related to the use of internal coverage criteria. Based on the scope of these modifications and clarifications, CMS addressed when Medicare coverage criteria are not fully established and the procedural and transparency requirements that apply when an MA organization adopts internal coverage criteria for basic benefits.

2. Appropriate Use of Prior Authorization (251 – 269)

Finalized Changes

CMS finalized their proposal that coordinated care plans may use prior authorization processes for basic benefits and supplemental benefits, to ensure basic benefits are medically necessary based on standards, or to ensure that the furnishing of supplemental benefits is clinically appropriate.

CMS finalized as proposed that coordinated care plans may use prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage decisions for the specific item or service, to ensure basic benefits are medically necessary based on standards, or to ensure that the furnishing of supplemental benefits is clinically appropriate.

CMS finalized at § 422.112(b)(8), that minimum continuity and coordination of care requirements for coordinated care plans include that approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, and that prior authorization be prohibited for a minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment.

Background/Rationale

Many commenters supported CMS codifying that prior authorization policies and procedures for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, and for basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1). CMS noted that ensuring access to covered benefits is one of CMS's policy goals for the MA program and regulating use of prior authorization to ensure that inappropriate barriers to services are not being established supports that policy goal.

Other commenters suggested that CMS do more to limit the use of prior authorization, in general. CMS responded that they do not believe that they have authority for a sweeping prohibition on all use of prior authorization.

Many commenters suggested CMS require MA plans to implement a number of PA standardizations including timelines, format, and content. Other commenters stated that CMS should standardize prior authorization requirements across all CMS programs. CMS noted that existing regulations governing organization determinations, which include pre-service requests and prior authorization requests, address many of the issues raised by these commenters. CMS recently released the Interoperability proposed rule, which includes proposals to expand access to health information and streamline certain procedures used for prior authorization. They believe the proposals in the Interoperability proposed rule, if finalized, may address these commenters' recommendations.

Some commenters recommended that CMS clarify how they intend to enforce these new utilization management rules and the prior authorization requirements at new section § 422.138. CMS currently monitors MA organization compliance with this existing policy through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations alert CMS to any issues with access to care, and CMS may require MA plans to address these matters if they arise. CMS intends to continue these oversight operations to ensure MA organizations' compliance with the final rule.

CMS received some comments requesting that CMS delay the implementation date of all the UM related provisions in this rule, including the new prior authorization requirements at § 422.138. These commenters requested that CMS delay the implementation date to 2026 to better align with the requirements in the Interoperability rule. CMS believes that many coordinated care plans are already using prior authorization to confirm diagnoses or other medical criteria, to determine medical necessity of basic benefits, and to ensure the clinical appropriateness of supplemental benefits as proposed at the new § 422.138(b)(1) through (3). Therefore, they do not believe that these requirements present such burden that they should be delayed.

3. Continuity of Care (269 – 289)

Finalized Changes

CMS finalized their proposal, with revisions, to require approval of a prior authorization request for a course of treatment be valid for as long as medically necessary to avoid disruptions in care, in accordance with the applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation.

CMS finalized their proposal to require plans to provide a minimum 90-day transition period when an enrollee who is currently undergoing an active course of treatment switches to a new MA plan.

Background/Rationale

The majority of commenters expressed support for the proposal to require that any plan approval of a prior authorization request from a provider on behalf of an enrollee, or from an enrollee directly, for a course of treatment be valid for the entire duration of the approved course of treatment.

Several other commenters expressed concern that requiring a prior authorization be valid for an entire duration of the approved course of treatment is overly broad and could lead to the continuation of treatments that are no longer medically necessary. Several commenters stated that the requirement conflicts with MA plans' obligations to ensure access to medically necessary care, and impedes MA plans' ability to manage care through strategies that ensure quality and control unnecessary cost.

CMS noted they understand the concerns that the proposal could result in the continuation of medically unnecessary care, which in turn could result in waste and increased costs. However, as highlighted in the preamble, over the past several years, they have received feedback from many stakeholders, including enrollees and providers, that MA plans often require repetitive prior approvals for needed services, even when enrollees have a previously approved course of treatment, plan of care, or are receiving ongoing treatments for a chronic condition. The feedback they have received consistently outlines how this practice delays medically necessary care and can cause gaps in care delivery that threaten an enrollee's health, sometimes leading to negative outcomes. For that reason, they believe this proposal is essential to minimize such delays and disruptions to care for MA enrollees.

A few commenters stated that care should not be based solely on a physician's order, but include other provider types when appropriate. CMS stated that the term "provider" is defined in § 422.2 to mean an individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State and an entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation. This definition is not limited to physicians. Therefore, the definition of course of treatment they proposed and are finalizing at § 422.112(b)(8)(ii)(A) includes courses of treatment ordered by non-physician health care providers.

Several commenters requested clarification regarding whether and how the continuity of care provisions apply specifically to Part B drugs, and how the "entire prescribed or ordered course of treatment" would be determined where a drug may be used indefinitely. CMS noted that these provisions apply two new requirements for the use of prior authorization by MA coordinated care plans for covered Part A and B services (that is, basic benefits as defined in § 422.100(c)). This includes relevant Part B drugs.

A majority of commenters expressed support for requiring a 90-day transition period when an enrollee is new to an MA plan. Other commenters expressed concern that this transition period restricts plans' ability to conduct concurrent reviews, which are necessary for quality control and to prevent waste, fraud, and abuse. Other commenters expressed concern that this transition period restricts plans' ability to conduct concurrent reviews, which are necessary for quality control and to prevent waste, fraud, and abuse.

CMS responded that the 90-day transition period only applies to active courses of treatment when an enrollee has enrolled in the MA plan after starting a course of treatment. This does not mean that the active course of treatment must last for the full 90-days, rather this means that the new plan may not subject an active course of treatment to an additional prior authorization for a period of 90 days, beginning the day enrollment in the new plan becomes effective. Because this new requirement is tied to an active course of treatment that began before enrollment in the new MA plan, the transition period applies for the shorter of the 90-day period (though MA plans have the discretion to extend this period) or the end of the active course of treatment.

Several commenters requested additional time to implement the requirements related to continuity of care, citing that operationalizing these new requirements will involve significant information technology and administrative resources. Commenters requested that the implementation date be moved to 2025 at the earliest. CMS noted they appreciate the intricacies involved with implementing new regulatory requirements. However, since several MA plans indicated they already have existing policies in place that are similar to what CMS proposed at § 422.112(b)(8), and they continue to receive feedback from stakeholders that medically necessary care is being disrupted by unnecessary prior authorization, they believe that it is important to implement this requirement as soon as possible.

4. **Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee (289 – 306)**

Finalized Changes

CMS finalized their proposal to require MA organizations to establish a Utilization Management (UM) committee to operate similar to a Pharmacy and Therapeutics, or P&T, committee. An MA organization that uses UM policies, such as prior authorization, must establish a UM committee that is led by an MA plan's medical director.

CMS finalized their proposal that an MA plan may not use any UM policies for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed and approved by the UM committee.

CMS finalized the committee responsibilities, which would include that the UM committee, at least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. The review must consider:

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

CMS finalized their proposal that the committee approve only utilization management policies and procedures that:

- Use or impose coverage criteria that comply with the requirements and standards
- Comply with requirements and standards
- Apply and rely on medical necessity criteria that comply

CMS finalized their proposal that the committee must revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines.

CMS finalized their proposal that the UM committee must include a majority of members who are practicing physicians; include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan; include at least one practicing physician who is an expert regarding care of elderly or disabled individuals; and include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies.

CMS finalized their proposal that the UM committee must clearly articulate and document processes to determine that the requirements have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. They also propose that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

Background/Rationale

CMS solicited comment on whether MA organizations should be permitted to use one committee to serve multiple plans. Many commenters expressed support for making this allowance. Some commenters recommended that plans maintain the flexibility to define the structure and appropriate additional responsibilities of the UM committee. CMS noted they will allow MA organizations the discretion regarding whether the UM committee is best served at the organization or plan level, and they will not prescribe whether UM committees must be formed at the plan or organization level. This flexibility does not, however, extend to the parent organization of the MA organization (that is, an UM committee cannot serve multiple MAOs). Regardless of whether the MA organization decides to organize its UM committee at the plan or organization level, the MA organization must ensure that the committee's review functions cover the needs of all plans under its organization.

A majority of comments were supportive of requiring MA organizations to establish UM committees. Several commenters pointed out that some accrediting bodies require MA plans to maintain active committees that serve a similar function to the proposed UM committee, and that many plans are already accredited and therefore already have such standing committees. For that reason, some commenters suggested that CMS permit plans to adopt existing committees to fulfil the regulatory requirements of the UM committee.

CMS responded that they appreciate that many plans already have existing committees that are similar in composition and function to the proposed UM committee, including committees required by various accrediting bodies. While they do not believe requiring MA plans to be accredited is necessary or within the scope of this rule, they do believe it is appropriate to permit MA organizations to leverage existing committees to satisfy the new regulatory requirement. Therefore, MA organizations may adapt or alter existing committees, including committees required by accrediting bodies and existing P&T committees, to conform with the regulatory requirements of § 422.137.

A few commenters requested that CMS delay the effective date to at least January 1, 2025, citing the administrative burden associated with forming and operationalizing a committee, as well as the requirement to review all UM policies and procedures. CMS declined these suggestions. They noted that because plans are permitted to leverage existing committees, and some plans indicated they already had committees in place serving a similar function to what was proposed (for example, when required by an, accrediting organization and P&T committees established to review utilization management associated with covered drugs), they believe there is sufficient time for MA organizations and MA plans to form UM committees and review UM policies within the proposed timeframe.

Many commenters stated they would be supportive of requiring an UM committee to ensure, as required by § 422.202(b)(2), that an MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees. CMS will continue to monitor compliance with the existing obligations under § 422.202(b) and with § 422.137 as finalized and consider this requirement for future rulemaking.

Some commenters requested flexibility in the requirements regarding the composition of the UM committee, specifically the requirement that the committee include various clinical specialties, because of potential operational challenges, including that the conflict of interest requirement be removed. Many

commenters requested that specific provider types be explicitly required for the committee, including but not limited to: Nurse practitioners; physical therapists; chiropractors; integrative medicine providers; pharmacists; clinicians with skilled nursing facility experience; nonphysician care team members; and case management professionals.

CMS noted they believe the proposed composition requirements are sufficient because they represent a diverse group of medical professionals, with the relevant expertise necessary to fulfill the regulatory requirements. Requiring additional specific provider types or specialties could end up limiting the committee composition, and that there is value in allowing plans the flexibility to determine which providers should be represented.

Many commenters supported having a specialist with expertise in the particular item or service that is subject of the UM policy and procedure under review by the UM committee be involved in that review. A few commenters suggested that there should be specialty-focused subcommittees or workgroups to ensure appropriate expertise is represented. CMS believes that the requirements in § 422.137(d)(1) and (2) that set the standards for the review by UM committees, including that utilization management policies comply with § 422.101(b) (which includes compliance with Traditional Medicare coverage rules and limits on MA plan internal coverage criteria) and that the committee review relevant current clinical guidelines, are sufficient to ensure that appropriate evidence is reviewed and relied upon by the committee during its annual (or more frequent) review of utilization management policies.

F. Section 1876 Cost Contract Plans and Cost-Sharing for the COVID-19 Vaccine and its Administration (section III.F, pgs 307-309)

Finalized Changes

CMS finalized as proposed to require 1876 cost plans, coordinated care plans with features like MA plans but separate statutory authority, to cover the COVID–19 vaccine and its administration without cost sharing as described in section 1861(s)(10)(A) of the Act. Specifically, CMS will replace the provision adopted at § 417.454(e)(4) in the November 2020 interim final rule (Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency) with the new requirement.

Background/Rationale

Provisions were finalized as proposed, and comments supported the proposals.

G. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (section III.G, pgs 309-332)

Finalized Changes

CMS finalized the requirement as proposed by revising §§ 422.566(d) and 422.629(k)(3) to state if the MA organization or applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision.

CMS also finalized as proposed a technical correction at § 422.590(b)(1) to include the correct cross reference regarding favorable decisions on payment requests at § 422.618(a)(2).

Background/Rationale

Most commenters expressed strong support for the proposed changes and agreed that the standard would likely enhance the overall decision-making process and quality of medical necessity reviews. Moreover, many of the commenters agreed that health care professionals making coverage decisions should have the expertise in the field of medicine or health care that is appropriate for the service at issue and were supportive of the decision not to require the case reviewer involved to be of the exact same specialty or sub-specialty as the treating physician.

Some commenters expressed concern related to the ability of MA organizations to implement this requirement in practice and questioned whether or not the proposal will solve the problem we are seeking to address, as well as the cost associated with implementing the requirement. CMS did not agree, and believed that the proposed approach strikes a balance between ensuring a robust review when the plan expects to issue a partially or fully adverse medical necessity organization determination and maintaining flexibility in how plans manage their review resources.

Numerous commenters expressed concern with the use of the term “expertise” as it relates to this proposal, suggesting it is too vague. CMS clarified that they did not propose that the plan reviewer be of the same specialty or subspecialty as the treating physician, or that the reviewer have a minimum number of years of experience in specialized training.

A few commenters expressed concern related to the time it will take an MA organization to identify the appropriate reviewer in certain cases. These commenters requested that CMS ensure that this proposal does not result in MA organizations extending the timeframe to review prior authorization requests. CMS noted that the proposal is not intended to allow plans additional time to review organization determinations where the plan expects to issue a partially of fully adverse medical necessity decision.

Other commentors asked about how this requirement will be enforced. CMS noted that it is assessing the best options for oversight.

H. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267) (III.H, pgs 332-364)

1. Standing Request for Translated Materials and Materials in Accessible Formats

Finalized Changes

CMS is finalizing as proposed to establish new paragraphs at §§ 422.2267(a)(3) and 423.2267(a)(3) describing the requirements for MA organizations and Part D plans to provide, on a standing basis, materials to enrollees in accessible formats and non-English language that make that are the primary language of at least 5 percent of the individuals in a plan benefit package service area as defined under §§ 422.2267(a)(2), 423.2267(a)(2) upon learning of the enrollee's preferred language or need for an accessible format. CMS is also finalizing as proposed the addition to §§ 422.2267(a)(3) and 423.2267(a)(3) to explicitly apply this requirement the individualized plans of care described in § 422.101(f)(1)(ii) for SNP enrollees.

Background/Rationale

CMS received widespread support for this proposal and its ability to strengthen access to care and equity.

Some commenters noted the significant costs and time associated with developing translated materials and systems for making them available on a standing basis. However, CMS does not agree with this assessment, as plans are already required to make translated and accessible materials available per other federal authorities, and CMS estimates relatively few plans serve populations that meet the 5% threshold.

Some commentors also noted that plans should be given the flexibility to work with enrollees to identify the document format(s) that would best meet their needs, for example an audio recording of a provider directory may be technically accessible, but not easily navigable. CMS concurs with these comments, and will allow plans to ask enrollees if they would like materials provided in alternative formats or translated on a standing basis or one-time only.

Finally, several commenters expressed concern about meeting translation turn-around time requirements and suggested CMS establish a stakeholder workgroup to discuss how to improve document turnaround times. While CMS acknowledged these concerns, they note that plans are already required to provide timely translations or alternative formats under 45 CFR Parts 92, 80 and 84, and CMS has provided additional guidance on how MA plans can meet these standards, including reasonable modifications. CMS will however consider establishing the stakeholder workgroup in the future.

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

Finalized Changes

CMS finalized as proposed the requirement at §§ 422.2267(a)(4) and 423.2267(a)(4) for FIDE SNPs, HIDE SNPs, and Applicable Integrated Plans to translate materials into the Medicare translation standard plus additional Medicaid language(s).

Background/Rationale

Many commenters, including MACPAC supported these proposals, noting that dually eligible beneficiaries are more likely to racial/ethnic minority groups than other Medicare beneficiaries. Some commenters expressed concern that these proposals were limited to a subset of D-SNPs, or that CMS did not establish a national, uniform translation standard. However, CMS believes that by taking this incremental approach, following state translation standards, and leveraging the state Medicaid contract will help plans meet these requirements.

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

Finalized Changes

CMS is finalizing, as proposed the changes at §§ 422.2267(e)(30)(vi) and 423.2267(e)(30)(vi) to expand the exclusion for member ID cards to include the new translation requirements at §§ 422.2267(a)(3) and (a)(4) and §§ 423.2267(a)(3) and (a)(4).

Background/Rationale

CMS received no comments on this proposal.

I. Medicare Advantage (MA) and Part D Communications and Marketing (Subpart V of Parts 422 and 423) (III.I, pgs 365-436)

1. Requirement for TPMOs to Submit Materials into the Health Plan Management System (HPMS) (367-370)

Finalized Changes

CMS initially looked to finalize a provision in accordance with §§ 422.2261(a) and 423.2261(a), requiring that MA organizations and Part D sponsors submit all marketing materials, all election forms, and certain designated communications materials for CMS review. HPMS is CMS' system of record for marketing materials.

After reviewing the comments and for the reasons outlined in the proposed and our responses to comments, CMS is finalizing the provision to require TPMOs to submit marketing materials into HPMS as proposed. The benefits of ensuring that TPMO marketing materials are submitted into HPMS and are approved by each plan to permit the TPMO to use the material far outweigh any additional effort made by TPMOs.

CMS believes these changes are beneficial to the MA and Part D programs, for CMS, and plans. By having the TPMO submit materials directly to CMS and MA organizations and Part D sponsors opting into the piece, CMS will know exactly which organizations the piece is being used to market. This will allow CMS to hold only those MA organizations and Part D sponsors accountable for inappropriate marketing. This also allows organizations to decide whether they want to be represented by the TPMO on a specific material.

Background/Rationale

CMS received substantial comments supporting the proposal. CMS received a supporting comment that expressed concerns regarding the burden if all plans did not opt into the marketing piece.

CMS also received comments that the current process is cumbersome and inefficient and that requiring a TPMO to receive approval from every plan prior to submission into HPMS. In response, CMS stated TPMOs may not use the marketing piece for any plan that does not opt into the piece. CMS highlighted that the proposal does not change the current process. Currently, marketing materials are required to be submitted to CMS, with HPMS being the method of submitting materials. CMS emphasized that the change to require TPMOs to submit the materials they develop ensures that all plans on whose behalf the TPMO is marketing know what material is being submitted and that CMS knows which materials will be used by which plans. This process also allows for MA organizations and Part D sponsors to either opt into or opt out of each material, which allows CMS to see which organizations the TPMO material is being used for.

CMS also received a comment opposing requiring TPMOs to submit materials on behalf of the employer group waiver plans (EGWPs). CMS clarified that currently, Medicare Communication and Marketing Guidelines (MCMGs) do not require EGWPs to submit communications or marketing materials in HPMS, provided the materials are specific to the EGWP(s). The HPMS material submissions requirement is waived for TPMOs and EGWPs when the materials are only applicable to and used for EGWPs.

2. **Prohibit the use of the Medicare name, CMS logo, and products or information issued by the Federal Government in a misleading way (370-374)**

Finalized Changes

Initially, CMS proposed to modify the current regulations by adding a new paragraph (xix) to § 422.2262(a)(1) and a new (xviii) to § 423.2262(a)(1), which specifically prohibits the use of the Medicare name, CMS logo, or products or information issued by the Federal Government, including the Medicare card, in a misleading manner.

After review of the comments CMS is finalizing the proposal, with a minor modification, to prohibit the use of the Medicare name, logo, or products in a misleading manner when used in marketing of MA and Part D plans. The modification is to permit use of the Medicare card image with CMS authorization.

A top CMS priority, consistent with sections 1851(h)(2) and 1860D-01(b)(1)(B)(vi) of the Act and CMS's implementing regulations at §§ 422.2262 and 423.2262, is to ensure that MA organizations and Part D sponsors, and their first tier and downstream entities, disseminate information to beneficiaries that is accurate and not misleading. While CMS already prohibits inaccurate or misleading information under §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), they believe it is important to specifically prohibit the misleading use of the Medicare name, CMS logo, and products or information issued by the Federal Government, as well as prohibiting the use of the Medicare card unless previously approved by CMS in §§ 422.2262(a)(1) and 423.2262(a)(1).

Background/Rationale

CMS received many comments supporting the proposal. Some commenters supporting the proposal requested that CMS provide additional guidance on ways the Medicare name or Medicare card image could be used. Commenters stated specific circumstances such as using the image of the Medicare card to help beneficiaries recognize their card when needed. In response, CMS recognized that there are instances where the use of the word "Medicare" or the image of the Medicare card are both necessary and not misleading. To ensure that the Medicare card image is not being used inappropriately, CMS is requiring organizations, including first tier, downstream, and related entities to receive authorization from CMS prior to the use of the image.

CMS also received one comment opposing the proposal. The commenter stated that as long as the website clearly states it is not Medicare, then the use of the word Medicare is not misleading. CMS highlighted that ensuring beneficiaries can recognize and trust that materials are from Medicare or the federal government is important. Specifically prohibiting misleading use of the Medicare name, CMS logo, and products or information issued by the Federal Government as well as prohibiting the use of the Medicare card unless previously approved by CMS in §§ 422.2262(a)(1) and 423.2262(a)(1), will protect beneficiaries. CMS stated that websites containing Medicare may easily be confused with Medicare.gov and that although sites may have a disclaimer, the disclaimer may be small and difficult for beneficiaries to notice. CMS emphasized that it is necessary to consider and evaluate the facts, when using the Medicare name, CMS logo, and products or information issued by the Federal Government to determine whether the use of them violates the provision being filed.

3. Prohibiting the use of unsubstantiated statements without supporting data (374-378)

Finalized Changes

CMS initially proposed to modify paragraphs §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) to prohibit the use of superlatives, unless sources of documentation and/or data supportive of the superlative is also referenced in the material, and to provide that such supportive documentation and/or data must reflect data, reports, studies, or other documentation that has been published in either the current contract year or the prior contract year.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to the comments, CMS is finalizing the proposal with two minor modifications. First, they are finalizing the regulatory revision using language that more clearly requires supporting documentation or data to be about, from or based on the current or prior contract year, instead of requiring the data to have been published in the current or prior year. Second, they are finalizing an additional paragraph to both §§ 422.2262(a)(1)(ii)(A) and 423.2262(a)(1)(ii)(A) to clarify that the inclusion of older data (that is data that is not about, from or based on the current or prior contract year) in the documentation and data included in the communication or marketing material to support the superlative.

CMS believes it is critical to provide current, reliable, and valid data or documentation, such as reports or studies, as the basis for a superlative statement in order for beneficiaries to review and understand the context and reference point for the superlative.

Background/Rationale

CMS received many comments supporting the proposal. CMS also received some comments with recommendations. One commenter noted that the proposed regulation text stated, "published documentation." This commenter recommended replacing "published documentation" with "documentation that is applicable," stating that published documentation could be based on significantly older data. In response, CMS agreed that more precise language was necessary. CMS stated that ensuring that superlative statements, which lack nuance, are supported by current and relevant data is at the heart of the goal for the proposed revisions. CMS then changed the proposal to include more precise language.

Another commentor partially supported the proposal, stating that their support was contingent on permitting citations to be used as documentation. CMS highlighted that they consider footnotes explaining the basis, noting the source (with enough information for a beneficiary to locate), or providing the actual comparison sufficient documentation. Therefore, a citation referring the reader to the actual documentation, with a link to the documentation, to be a "source of documentation," would be acceptable.

CMS also received a comment opposing the two-year limit on using data for the superlative. The commenter stated that plans may want to advertise a long-standing positive performance. In response, CMS clarified that they understand the concerns and agree with the commenter that advertisements describing long-standing positive performance should not be prohibited by the two-year data requirement. CMS stated that it was not their intent to prohibit advertising an organization's long-standing positive performance, but to ensure that the performance is advertised within the current or previous contract year. CMS stated they will permit the advertising of the past two years' worth of data if an organization has maintained high performance for the current and previous contract year, as well as years prior. However, if the organization received a four star rating in the previous contract year, the organization would not be able to advertise that they received five star rating since X date or Y years out of the past five years.

4. **Prohibition on advertising benefits not available in a service area (378-384)**

Finalized Changes

CMS is finalizing provisions as proposed for a new paragraph (8) at §§ 422.2263(b) and 423.2263(b) that provides that MA organizations and Part D sponsors are required to not engage in marketing that advertises benefits that are not available to beneficiaries in the service area where the marketing appears, unless unavoidable in a local market. Since the advertised benefits must be available in the area in which the marketing is occurring, the "unless unavoidable" standard in our regulation is only applicable to advertising that is occurring in a limited area. National advertisements cannot be tailored to only market benefits available to specific service areas.

Background/Rationale

CMS received many comments supporting the proposal. Additionally, CMS received comments requesting clarification on what "unavoidable" means in the context of this proposed rule. In response, CMS stated §§ 422.2263(b)(8) and 423.2263(b)(8) permits advertising benefits that are not available to all potential Medicare beneficiaries viewing the advertisement if it is unavoidable in the local market. CMS then used examples of newspaper advertisements in a metropolitan area being distributed to individuals that do not live in the region as "unavoidable" since the "normal" distributed of the local newspaper is greater than the service area of the plan. CMS also used local television ads as an example and reemphasized the exception that is being finalized for unavoidable marketing does not apply for any national marketing and that "unless unavoidable" standard in only applicable to advertising that is occurring in a limited area.

CMS also received comments requesting that CMS permit the marketing of benefits if a certain percentage of plans in the marketed area offered benefits. While CMS appreciated the suggestions, they clarified that they believe limited the scope of the regulation as suggested will result in marketing that misleads or has the potential to mislead beneficiaries or marketing that does not provide sufficient information to be useful for a beneficiary. CMS received comments opposing the proposal stating that plans would have to create multiple materials to address different benefits for each specific area. One commentor highlighted that this would be especially problematic for regional plans who have multiple products spanning across large areas. In response, CMS stated they disagree that plans will face significant issues in accurately marketing available benefits. CMS highlighted that plans will not be required to create a new material for each area, but rather will just need to change the dollar amounts reflecting the benefits offered in the specific markets.

5. **Prohibits marketing unless the names of MA organizations or Part D sponsors being advertised are clearly displayed (384-388)**

Finalized Changes

CMS proposed a new paragraph (9) at §§ 422.2263(b) and 423.2263(b) to prohibit MA organizations and Part D sponsors from marketing any products or plans, benefits, or costs, unless the MA organization's or Part D sponsor's name or marketing name(s) (as listed in HPMS of the entities offering the referenced products or plans) are identified in the marketing material. By requiring the name of the organization, CMS believes beneficiaries will have knowledge of who they are contacting.

In addition, CMS proposed requirements regarding the display and identification in marketing materials of sponsoring organizations' names. In reviewing television, print, and online marketing, CMS has noted that the disclaimers are often small, not displayed long enough, read too fast, or are difficult to find. CMS proposed including requirements in this new paragraph (9) to ensure the information is comprehensible and visible. CMS proposed adding that in print advertisements must display the MA organization, Part D sponsor, or marketing name in 12-point font and the MA organization, Part D sponsor, or marketing name may not only be displayed in the disclaimer or fine print. CMS uses the phrase "fine print" as it is generally defined to mean printed matter in small type or print displayed in an inconspicuous manner. For television, online, or social media-based advertisements, CMS proposed that these names must either be displayed during the entire advertisement in the same font size as displayed benefits and phone numbers, or be read within the advertisement at the same pace as advertised benefits or phone numbers. For radio or other advertisements that are voice-based only, CMS proposed that these names must be read at the same speed as the phone number. To implement these new requirements, CMS proposed new paragraphs (b)(9)(i), (ii), and (iii), respectively. (In the proposed rule, CMS mistakenly identified these as paragraphs (b)(9)(A), (B), and (C) but use the correct references here.)

After review of the comments received and for the reasons outlined in the proposed rule and our responses to the comments, CMS is finalizing as proposed with minor modifications to paragraphs (9)(ii) and (iii) to require the marketing names to be read or displayed at the same pace or in the same font as the phone number or contact information included in the advertisement.

Background/Rationale

CMS received many comments supporting the proposal. CMS also received comments opposing this proposal with one commenter noting that there would be too much information in the advertisement. CMS also received a comment noting that advertisements would need to be pulled if a plan did not opt into the TPMO advertisement. In response, CMS stated that they do not believe that concerns regarding the names of the plan or organization being marketed is "too much information" justifies not finalizing the proposal. CMS emphasized that beneficiaries need to have certain information to make informed decisions. CMS then stressed that the marketing material should be reviewed by the applicable MA organizations and Part D sponsors meaning all of those for whom the marketing material(s) will be used and all those named in the material(s) plans prior to submission into HPMS.

6. Prohibit the marketing of "savings" not realized (388-391)

Finalized Changes

CMS finalized as proposed to add a new paragraph (b)(10) at §§ 422.2263 and 423.2263 to prohibit MA organizations and Part D sponsors from including information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

CMS believes that commercials and other types of advertising (for example, direct mailers) using prohibited use of "savings" are used to entice a beneficiary into calling a 1-800 number to get information

about or enroll in plan X, mistakenly believing that the beneficiary will save thousands of dollars by switching plans, switching from original Medicare, or enrolling into plan X as a new Medicare beneficiary. However, as identified in the previous examples, these "savings" are not actual savings since the beneficiary would not have incurred these costs in any case.

Background/Rationale

CMS received many comments supporting the proposal. CMS also received comments stating that they should not prohibit advertising savings associated with enrolling in Part D coverage. The commentor suggested that CMS instead require appropriate disclaimers where such "savings" are discussed. In response, CMS stated that the commentor may have misunderstood CMS's proposed change. CMS highlighted that the proposal does not prohibit all advertising of savings on Part D costs that would come from an enrollment change. Similarly, the proposal would not prohibit MA plans from marketing cost savings associated with a specific plan's coverage of Part A, Part B or supplemental benefits.

7. Clarify door to door solicitation (391-392)

Finalized Changes

CMS is finalizing provisions largely as proposed to add a new (A) to §§ 422.2264(a)(2)(i) and 423.2264(a)(2)(i) which provides that contacting a beneficiary at the individual's home is unsolicited door-to-door contact unless an appointment at the beneficiary's home at the applicable date and time was previously scheduled. CMS will finalize the provision without the phrase "considered to be" which was initially intended to be in the proposed language.

CMS believes that Business Reply Cards (BRC) and other types of documents where the beneficiary requests additional information are intended to allow the agent to reach out to the beneficiary via telephone, email, or direct mail. They do not believe a beneficiary filling out a BRC indicates a beneficiary's intention to permit an agent to show up unannounced, at the individual's home. CMS considers this activity to be unsolicited door-to-door solicitation.

Background/Rationale

CMS received no comments directly opposing the proposed language. CMS stated that upon further reflection during the commenting period, they believe the regulation would be clearer without the phrase "considered to be" because of their position that BCR is not an agreement to an unscheduled, in-person meeting initiated by an agent or other individual arriving at the beneficiary's home. Therefore, such contact is unsolicited.

8. Requirement for an annual opt-out for plan business (392-394)

Finalized Changes

CMS finalized as proposed to amend §§ 422.2264(b)(2) and 423.2264(b)(2) to require each MA organization and Part D sponsor to provide the opt-out information to all its enrollees, regardless of plan intention to contact, at least annually in writing, instead of just one time.

CMS believes that over time, beneficiaries may realize that having plans to contact them regarding marketing is not necessary. By receiving only, a one-time opportunity to opt out of plan business contacts, a beneficiary may not realize that they have the option to opt out at any time. By requiring a written annual notification from plans that an enrollee may opt-out of plan business contacts, the proposed new requirement ensures beneficiaries are reminded that they may decide at any time to opt out of being contacted by their MA organization/Part D sponsor about plan business.

Background/Rationale

CMS solicited comments on whether they should expand the existing and proposed notice requirements in some way to ensure that MA organizations and Part D sponsors do not market their products in a way that could be equivalent to prohibited cold calling. CMS received comments concerning if the change in requirements would prohibit organizations from contacting beneficiaries about their existing plan coverage. CMS highlighted that this proposal does not prohibit calls and other contacts about the enrollee's current plan. Per §§ 422.2264(b) and 423.2264(b), plan business includes discussions about other Medicare products (not the enrollee's current plan) or about other types of insurance or lines of business. Plans and agents would still be permitted to call members regarding their current plan.

CMS also received a few comments opposing the provision. One commenter stated that the opt-out notice was unnecessary and unwanted by beneficiaries because of the overall number of communications they already receive regarding their plan, including the ability to opt-out of calls regarding plan business. Another commenter opposed the provision because opting out would prohibit an agent from contacting a beneficiary about another plan that may be better for the member. CMS stated that they believe opt-out communication is necessary for beneficiaries. As noted in the proposed rule, beneficiaries may decide at a later date that they do not wish to receive calls regarding plan business. This opt-out provision provides members with a yearly notice, reminding them of their ability to opt out. CMS also highlighted that requiring an opt-out on a yearly basis does not preclude an agent from contacting a beneficiary regarding plan business and emphasized that agents are still permitted to reach out through email, direct mail, events, or other general marketing. The agent is precluded from reaching out only if the beneficiary notifies the agent they no longer wish to be contacted regarding business.

9. Prohibiting the distribution of Scope of Appointment (SOA) and Business Reply Card (BRC) forms at educational events (394-399)

Finalized Changes

Initially, CMS proposed amend the regulations that list the activities that are permissible to include in educational events (§§ 422.2264(c)(1)(ii) and 423.2264(c)(1)(ii)) by removing the paragraphs that authorize obtaining beneficiary contact information, including Scope of Appointment forms.

CMS is also finalizing a proposal removing §§ 422.2264(c)(1)(ii)(C) and 423.2264(c)(1)(ii)(C), which currently permit organizations and agents to set up future marketing appointments at educational events.

After reviewing the comments and for the reasons outlined in the proposed rule and responses to comments, CMS is finalizing the proposed policies with changes that they believe are in the best interest of the program and of beneficiaries. First, they are finalizing changes to §§ 422.2264(c)(1)(ii) and 423.2264(c)(1)(ii) to prohibit the collection of SOAs and prohibit agents from setting up future marketing appointments at educational events. This is done by removing paragraph (c)(1)(ii)(C) from both regulations as proposed and redesignating current paragraph (c)(1)(ii)(D) (permitting the distribution of business cards) as paragraph (c)(1)(ii)(C). Second, they are redesignating current paragraph (c)(1)(ii)(E) as paragraph (c)(1)(ii)(D) and revising it to permit organizations (and their agents) to make available and receive beneficiary contact information, including Business Reply Cards, but not including Scope of Appointment forms. The permission for using BRCs at educational events is similar to how CMS allows plan materials to be located in common areas of a provider's office and we intend to interpret and apply the new regulation that way.

CMS believes that beneficiaries attend educational events to learn about Medicare, unlike a sales event where a beneficiary has decided that they want to look further into a particular plan (or sponsoring organization) in which to enroll. Collecting contact information at educational events may unduly pressure a beneficiary into providing their personal information. Agents passing out SOA or BRC cards, possibly watching beneficiaries until they fill these forms out, and then collecting them may put a beneficiary in an uncomfortable position of having to decide whether the individual wants to oblige the agent by completing the form, or draw attention to the individual by declining to complete them.

Background/Rationale

CMS received a substantial number of comments supporting the proposal. CMS also received a substantial number of comments opposing the proposal. Some commenters stated that not being able to collect SOAs and BRCs at education events will result in agents not holding the events at all which will act as a detriment to beneficiaries. A few other commenters stated that the proposal will place an undue burden on beneficiaries since the beneficiary will have to reach out to the agent instead of the agent contacting the beneficiary through the SOA or BRC collected at the events. In response, CMS stated that while they appreciate the comments, they disagree that the prohibition of collecting SOAs and BRCs will cause agents to no longer hold education events. CMS also disagreed that the proposal will place undue burden on the beneficiaries and stated that if the beneficiary takes the time to travel to an educational event, it should not be burdensome for the beneficiary to alter contact the agent after attending the event.

10. Prohibiting sales events to directly follow educational events (399-406)

Finalized Changes

CMS is finalizing the proposed change to paragraph (c)(2)(1)(1) of §§ 422.2264 and 423.2264 to prohibit marketing events from taking place within 12 hours of an educational event, at the same location. The same location is defined as the entire building or adjacent buildings.

CMS is concerned about marketing events directly following an educational event; by separating the events, beneficiaries are afforded the time to consider all their questions and options before making any decision about their health care and without any pressure to decide on the spot with the agency present. Notably, CMS believes a 12-hour window is important to ensure beneficiaries are not pressured into attending a marketing event. In addition, limiting the new requirement to when the marketing event is in the same location as the educational event ensures that an agent or broker can still hold both events on the same day.

Background/Rationale

CMS received many comments supporting the proposal to clearly separate educational events from marketing events, while about half of the comments opposed the provision. Some commenters stated that this proposal will lead to friction for beneficiaries, not add any additional protection, and will degrade the consumer experience. In response, CMS highlighted that with an increase of online events and tools, they believe prospective enrollees will be motivated to either leave the event or go to another one. There was concern about this provision leading to a decrease in educational events. CMS clarified that they do not prohibit educational information being presented at marketing events, and educational events must be designed to inform beneficiaries about Medicare, thus not leading to a lack of educational events.

Several commenters opposed this provision due to the potential transportation issues that beneficiaries may experience; they argued it is critical to have access to information and resources in just one event. CMS clarified they are concerned about vulnerable populations as well, and the final rule aims to protect dually eligible individuals and other vulnerable groups to ensure they are ready to make a health care decision, rather than being pressured into a decision. CMS added that if a beneficiary attends an educational event, but has no transportation to a sales event, they believe the agent will reach out to connect with the beneficiaries, either telephonically or in person.

11. Requiring 48 hours between the Scope of Appointment (SOA) and a meeting with a beneficiary (406-410)

Finalized Changes

CMS is finalizing the proposed change to add “At least 48 hours” before the word “Prior” to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to read, “At least 48 hours prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appoinment with the beneficiary(ies).”

After review of the comments and for reasons outlined in the proposed rule, CMS is revising §§ 422.2264(c)(3)(i) and n23.2264(c)(3)(i), including the addition of new paragraphs (c)(3)(i) (A), and (B), to require that a plan (or agent or broker, as applicable) agrees upon and records a Scope of Appointment with a beneficiary, at least 48 hours prior to a personal marketing appointment or meeting, except in two situations: (A) When a beneficiary requests an appointment within four days of the end of a valid election period, including the AEP, OEP, SEP, ICEP, or the month, based on eligibility; and (B) When a

beneficiary initiatives an in-person meeting. CMS clarifies that this can include walking into an agent's office, a kiosk, a plan's office, or any other unscheduled in-person meeting initiated by a beneficiary.

Background/Rationale

CMS received a substantial number of comments opposing the proposal. A significant number of comments noted that beneficiaries that contact an agent at the end of the Annual Enrollment period (AEP) may miss their opportunity to enroll because of the required 48-hour timeframe. Some commenters were concerned about the impact of the proposed policy on beneficiaries who may face transportation barriers. CMS agreed with the commenters who highlighted potential transportation issues and those that are nearing the end of a valid election period. They clarified that the proposal was intended to provide an opportunity for beneficiaries to consider their options, but not inhibit enrollment by beneficiaries who choose to enroll through a particular agent. They do not want a beneficiary to miss the opportunity to enroll in a plan because of a required 48-hour waiting period. Based on these comments, CMS is convinced that a categorial prohibition on having a personal meeting less than 48 hours after a SOA is set is too strict and that exceptions are necessary.

12. Limiting Scope of Appointments (SOAs) and Business Reply Cards (BRCs) to a six-month timeframe (410-412)

Finalized Changes

After considering the comments, CMS is modifying the proposal to extend the timeframe from six months to 12 months.

Initially, CMS proposed to modify the current regulations at t §§ 422.2264(c)(3)(iii)(A), 422.2264(c)(3)(iii)(B), 423.2264(c)(3)(iii)(A) and 423.2264(c)(3)(iii)(B) to limit the time period when the SOAs and BRCs are valid in §§ 422.2264(c)(3)(iii)(A) and 423.2264(c)(3)(iii)(A), and the SOAs in §§ 422.2264(c)(3)(iii)(B) and 423.2264(c)(3)(iii)(B) to six months from the beneficiary's signature date or the beneficiary's request for more information. A beneficiary's permission to allow contact by an MA organization/Part D sponsor or a TPMO is not, and should not be, open-ended. Beneficiaries who request information regarding MA organization/Part D sponsors are requesting information at that present time. CMS highlighted that since the purpose of the SOA or BRC is for beneficiaries to discuss plan products applicable for the present or following contract year, having the SOA or BRC expire after 6 months satisfies that purpose, and would prevent agents from using it in perpetuity and thus avoiding the statutory and regulatory prohibitions on unsolicited contact and cold calling. If a beneficiary wants the agent tied to the SOA or BRC to continue contacting them beyond 6 months, the agency may secure and document that permission through a new SOA, BRC, or similar mechanism.

Background/Rationale

CMS received comments about limiting how long a Scope of Appointment, Business Reply Cart, or other contact mechanism remains valid. Nearly all of the commenters supported limiting the duration for which

an SOA or BRC may be used to contact a beneficiary, however, many commented that the length of time should be expanded to either nine of 12 months to account for the next Annual Enrollment Period.

After review, CMS determined that a 12-month timeframe is the appropriate timeframe for the validity of these documents, and it will facilitate a beneficiary giving permission annually to be reminded about the next AEP and the opportunity to evaluate MA and Part D plan options.

13. Searchable provider directory (412-414)

Finalized Changes

CMS finalized as proposed to add a new requirement to § 422.111(b)(3)(i) to require that provider directories include providers' cultural and linguistic capabilities. The amendment to § 422.2265(b)(4) will require the organization's provider director to be searchable by this new element. By requirement website provider directories be searchable by every element, our proposal would ensure that a beneficiary would be able to locate specific provider specialties, as well as providers by names, addresses, or other elements the organization has listed in the online provider directory.

Background/Rationale

Most of the comments CMS received discussed the need for improved accuracy of provider directory information overall. CMS notes that while provider directory accuracy is outside the scope of this proposed change, they remain committed to working towards greater accuracy in provider directories.

One commenter stated that the phrase "languages spoken" would add to the burden providers already face in communicating changes in their information reflected in a provider directory; CMS responded that providers are already required to provide information to MA organizations and Part D sponsors. Given that this proposal does not require the provider to provide more information, it does not place an additional burden on providers.

14. Effect on current coverage added to the pre-enrollment checklist (PECL) and review of PECL (414-417)

Finalized Changes

CMS finalized the provisions as proposed to add the reference to "Effect on current coverage" to §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), and requiring in §§ 422.2267(e)(4) and 423.2267(e)(4), that the PECL be reviewed with the prospective enrollee during telephonic enrollments.

Background/Rationale

CMS received many comments supporting the addition of "Effect on current coverage to the PECL" and the requirement that agents/brokers discuss the effect on current coverage with the prospective enrollment telephonic enrollments. Some commenters suggested that CMS provide model language to the PECL to be used when confirming the effect on current coverage with potential enrollees. CMS responded that they will add language to the PECL that can be used as a basis for the conversation with potential enrollees regarding the effect of an enrollment choice on the potential enrollee's current coverage.

15. Summary of Benefits (SB) medical benefits (417-418)

Finalized Changes

CMS finalized the provisions as proposed to require that the Summary of Benefits (SB) list medical benefits on the top half of the first page and then in the order currently listed in §§ 422.2267(e)(5)(ii)(A)(1) through 422.2267(e)(5)(ii)(A)(10).

Background/Rationale

All but one commenter supported this proposal. CMS responded that codifying this specific requirement will provide more clarity and transparency. The ability for beneficiaries to review and compare benefits across different MA plans will assist beneficiaries in making more informed health care choices.

16. Non-renewal Notice (418-419)

Finalized Changes

CMS finalized the provisions as proposed to update §§ 422.2267(e)(10) and 423.2267(e)(13) to specify that the non-renewal notice is a "standardized communications material" so that it is clear these materials must be used without modification except where noted in the standardized materials.

Background/Rationale

CMS received general support from commenters for this provision but had no specific comments.

17. Adding "SHIP" to the Third Party Marketing Organization (TPMO) TPMO disclaimer and disclosing the names of all entities the TPMO represents (419-425)

Finalized Changes

CMS finalized the first disclaimer as proposed by adding the addition of SHIP to the disclaimer. In addition, they are modifying the current disclaimer. If a TPMO does not sell for all MA organizations

and/or Part D sponsors in the service area the disclaimer consists of the statement: "We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program (SHIP) to get information on all of your options." If the TPMO sells for all MA organizations and/or Part D sponsors in the service area the disclaimer consists of the statement: "Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact Medicare.gov, 1-800- MEDICARE, or your local State Health Insurance Program (SHIP) for help with plan choices."

Background/Rationale

CMS received a number of comments that supported the addition of SHIP to the TPMO disclaimer.

Some of the commenters opposed adding SHIPS to the TPMO disclaimer, and focused on SHIPs having limited budgets, not being trained as well as agents, and being harmful to beneficiaries. In response, CMS highlighted that adding SHIPs to the disclaimer ensure beneficiaries are notified about another neutral party to whom they can direct questions and receive guidance regarding their health care choices. Some commenters opposed the proposal to require plan names be included within the TPMO disclaimer, and stated that the disclaimer would be long, given the average number of plans offered was 39 in Contract Year 2022. CMS recognized the complaint, however, emphasized that including the plan name in the disclaimer is intended to ensure the beneficiary is aware of the individual's options and understands the scope of plans represented by a TPMO.

18. Comprehensive Medication Review and Safe Disposal (425)

Finalized Changes

CMS finalized a technical change to § 423.2267(e) to add new paragraphs (e)(43) and (e)(44), to include the comprehensive medication review (CMR) written summary which, in accordance with § 423.153(d)(1)(vii)(B) and (D), Part D sponsors must provide to all MTM program enrollees who receive a CMR, as well as the safe disposal information that, in accordance with § 423.153(d)(1)(vii)(E), Part D sponsors must provide to all plan enrollees targeted for MTM.

Background/Rationale

CMS received no comments on this proposed technical change.

19. Requiring MA organizations and Part D sponsors have a monitoring and oversight plan and report agent non-compliance to CMS (425-428)

Finalized Changes

CMS finalized the provisions as proposed to require MA organizations and Part D sponsors to oversee the agents and brokers with whom they contract (§§ 422.2274(c) and 423.2274(c)). CMS also proposed to add a new paragraph (e) to §§ 422.2272 and 423.2272 to read, "Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS."

Background/Rationale

CMS received many comments regarding the proposal to require an oversight plan that monitors agents and brokers, identifies non-compliance, and reports non-compliance to CMS. Almost all of the commenters supported this proposal, however, some commenters requested clarification on what non-compliance needs to be reported to CMS. CMS clarified that they are not expecting organizations to report minor, insignificant issues, but if an agent continually fails to address a significant number of elements, it should be reported. They also highlighted that they provide additional information in the Medicare Communications and Marketing Guidelines.

20. CMS list of required elements prior to enrollment (429-431)

Finalized Changes

CMS finalized the addition of a new paragraph (c)(12) to §§ 422.2274 and 423.2274 as proposed. The new paragraph would include additional standards for agents and brokers, which includes requiring an MA organization or Part D sponsor ensure that the agent's/broker's marketing call goes over each CMS required question or topic, including information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.

Background/Rationale

CMS received numerous comments supporting this proposal.

21. Limit TPMO call recording to sales, marketing, and enrollment (431-434)

Finalized Changes

CMS finalized the amendments to §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) as proposed. This includes modifying §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to limit the calls that must be recorded in their entirety to marketing, sales, and enrollment calls.

Background/Rationale

CMS received numerous comments supporting this proposal. A few comments opposed the requirements to record calls in any case, mentioning that beneficiaries may not want to be recorded. CMS noted that their proposal addressed limiting the recording requirements, not eliminating CMS' recording requirements. Further, beneficiaries have the right to refuse to be recorded and have alternative methods to enroll, such as in-person or online. Lastly, CMS notes that their previous review of telephone calls between agents and beneficiaries strongly indicates that call centers, independent agents, and smaller offices face similar compliance challenges.

22. Require web-based technology meetings to be recorded (434-436)

Finalized Changes

CMS finalized the changes as proposed to modify §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to read "Record all marketing, sales, and enrollment calls, including calls occurring via web-based technology, in their entirety." Notably, CMS decided to add a clarification that the requirement applies only to the audio portion of web-based calls.

Background/Rationale

Some commenters supported this proposed change, while other commenters opposed it, stating that the beneficiary should have the choice to not be recorded; another commenter shared they opposed the requirement to record calls between beneficiaries and TPMOs. In response, CMS noted that the requirement to record calls does not prevent a beneficiary from declining to have the call recorded, and if the beneficiary declines to be recorded, the call must end. CMS clarified that the TPMO may engage with the beneficiary through an in-person meeting.

III. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies (Section IV)

A. Clinical Trial-Related Provisions (§ 422.109) (section IV.K, pgs 437-446)

1. Clinical Trials Under National Coverage Determination 310.1

Finalized Changes

CMS finalized the changes as proposed with a minor modification to the heading for paragraph (e) to clarify the scope of the new paragraphs is limited to NCD 310.1. CMS had proposed to clarify the required Medicare coverage of clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD). In § 422.109(e)(1), CMS codified the longstanding policy that traditional Medicare is responsible for coverage of routine costs of qualifying clinical trials for MA enrollees for

clinical trials covered under NCD and all necessary services used to diagnose and treat complications from participating in clinical trials. In § 422.109(e)(2), CMS codified this policy that MA enrollees participating in clinical trials are not subject to Part A and B deductibles. In § 422.109(e)(3), CMS codified the requirement that MA plans pay the difference between traditional Medicare and MA plan's in-network cost sharing incurred for qualifying clinical trial items and services. In § 422.109(e)(4), CMS codified that the enrollee's in-network cost-sharing portion must be included in the plan's maximum out-of-pocket (MOOP) calculation. In § 422.109 (e)(5), CMS specified that MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create barriers to enrollee participation in a non-plan-sponsored clinical trial.

Background/Rationale

Most comments were generally positive. One commenter suggested the CMS continue to provide MA organizations with information about coverage responsibilities for Medicare-covered trials in the final decision memo for the NCD regarding significant cost, and CMS responded that it would work to include this information in future decision memos. One commenter expressed concern that the policy as proposed could undermine an MA organization's care coordination efforts. The commenter recommended that CMS reconsider its proposal to permit MA enrollees to participate in clinical trials without prior authorization from an enrollee's MA plan. CMS responded that MA organizations do not cover these trials for MA enrollees and the costs of what is covered is paid by the Traditional Medicare program; therefore, MA organizations cannot require prior authorization. MA enrollees, like Traditional Medicare enrollees, in clinical trials have informed consent requirements and participate in a discussion of the trial's features.

2. A-B Investigational Device Exemption Trials

Finalized Changes

CMS finalized as proposed adding § 422.109(f) to specify MA plan coverage of the routine items and services, including the Category B investigational device exemption (IDE) device and related items and services in the context of a Category A and B IDE studies, that are covered by Medicare under §§ 405.211(a) and (b).

Background/Rationale

Several commenters expressed support for the proposal but stated that there needs to be a mechanism to indicate an enrollees' MA status because it can lead to confusion and delays in coverage. CMS responded MA plans must issue member identification cards that indicate that an enrollee is on an MA plan and providers have access to the HIPAA Eligibility Transaction System (HETS), which enables providers to view Medicare eligibility and coverage. CMS stated that compliance with these regulations and use of the HETS website are sufficient to allow providers and plans to determine plan coverage for B-IDE.

3. National Coverage Determinations with Coverage with Evidence Development

Finalized Changes

CMS finalized the provision without modification. CMS did not make any proposed changes to this policy; this section reiterates that MA plans must cover NCDs with "coverage with evidence development" (CED).

Background/Rationale

CMS solicited comments on whether additional regulations are needed to address NCDs with CED or if § 422.101(b) makes this requirement clear. A commenter stated that it did not believe that regulations beyond those proposed were necessary. Another commenter expressed concern that the proposal would shift costs from MA to Traditional Medicare and permit obstacles to emerging care because of MA utilization management policies. CMS responded that since MA organizations already cover NCD-CEDs there will be no cost-shifting to Traditional Medicare. CMS responded that MA plans may require utilization management, including prior authorization, and directed the commenter to requirements related to utilization management.

B. Gross Covered Prescription Drug Costs (§ 423.308) (section IV.M, pgs 447-459)

Finalized Changes

CMS finalized a proposed rule to amend the regulatory definition of GCPDC at § 423.308 by removing "actually paid" from the definition. CMS originally codified the definition to provide a mechanism for calculating the total amount for reinsurance provided to Part D sponsors. CMS noted, however, the term "actually paid" may create confusion about when the direct and indirect renumerations would be netted out based on regulatory definition of the term "actually paid". The manufacturer discounts provided through the Medicare Coverage gap program, as well as the DIR fees at the point of sale will continue to be netted out within the GCPDC and CMS does not anticipate any impact on Part D program due to this change.

Background/Rationale

Many commenters supported this rule and agreed that removing "actually paid" will make the definition more unambiguous.

Most of the other comments were based on the impact of the new definition on Inflation Reduction Act (IRA)'s Drug Price Negotiation Program (DPNP). The comments asserted that 1) IRA was passed under current definition of GCPDC and therefore Congress intended for the term to include "actually paid", 2) By removing "actually paid", the DPNP will select drugs based on gross spend, not net spend. CMS disagreed with the commenters as the language in IRA references statutory language of GCPDC (1860D-15(b)), which does not include "actually paid", and that the process for DPNP's drug selection is part of a separate guidance.

IV. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (section V)

A. Contract Ratings (section V.C, pgs 462-465)

1. Contract Type

Finalized Changes

Effective coverage year 2024, CMS finalized amending §§ 422.162(b)(1) and 423.182(b)(1) to include a sentence which states that overall and summary Star Rating calculations are based on the measures collected for a specific contract type for the respective measurement year. This amendment will add clarification to the process which is already in practice (e.g., A SNP may have additional measures for a measurement year which does not apply to non-SNPs).

Background/Rationale

CMS received a single comment in support of this amendment.

2. Contract Consolidations

Finalized Changes

Effective coverage year 2024, CMS finalized amending §§ 422.162(b)(3)(iv)(A)(1) and 423.182(b)(3)(ii)(A)(1) to provide clarification that improvement measures will not be calculated for the first year after consolidation of contracts for Parts C and D plans. Calculations in the first year would only be based on surviving contracts after consolidation, not the consumed contracts, which would not result in an accurate comparison of the measures.

Background/Rationale

All comments received by CMS were in support of this rule.

B. Adding, Updating, and Removing Measures (section V.D, pgs 465-488)

1. Diabetes Care - Kidney Disease Monitoring (Part C) Measure Removal

Finalized Changes

Effective with 2024 Star Ratings, the Diabetes Care – Kidney Disease Monitoring measure is removed as it has been retired by the measure steward (NCQA) after measurement year 2021. CMS intends to replace this measure with the Kidney Health Evaluation for Patients with Diabetes measure.

Background/Rationale

All comments received were in support of removal of the measure.

2. Measure Updates

Finalized Changes

Effective measurement year 2026, Star Rating for 2028

Substantive changes
Sociodemographic status (SDS) risk adjustment will be applied to medication adherence measures for antidiabetic agents, RAS antagonists and statins. The adjustment factors will include age, gender, low-income subsidy, dual-eligibility status, and disability status. SDS adjustment to these measures has been endorsed by the measure steward (PQA) and NQF. With this adjustment in place, these measures will be removed from Star Ratings CAI determination. According to § 423.184(d)(2) adjusting these measures based on SDS is considered a substantive change, which requires display of the proposed measure changes for 2 years before implementation.

Non-substantive changes:
Use of continuous enrollment method instead of member-year adjustments, removal of adjustments in inpatient/SNF stay from the adherence measures.

Background/Rationale

CMS received several comments on proposed updates. For the SDS adjustments, there was concern expressed about adverse impact on community pharmacies as the direct and indirect renumeration fees from PBMs may not be based on SDS adjustments. CMS noted that this concern is out of scope for them. Some commenters encouraged CMS to keep relevant adherence measures within CAI. CMS responded by noting that when measures have a direct SDS adjustment applied to them, they cannot be included within CAI. Some commenters asserted that introduction of SDS adjustment is contrary to CMS's interest in simplifying Parts C and D Star Ratings. CMS stated that they will be providing technical briefs, as well as plan-wide and beneficiary-specific scorecards.

For non-substantial changes, some commenters expressed concern about removal of inpatient and SNF stay adjustment from the measures and that it will adversely impact plans with disproportionately larger proportion of patients with frequent inpatient and SNF stays. CMS responded by stating that it wants to

align the measure with PQA, which does not adjust for inpatient and SNF stays, and avoid complexity which would be introduced by applying adjustments for SDS in addition to SNF/inpatient stay adjustments. CMS also noted that their impact analysis did not reveal a major shift in ratings for a vast majority of contracts.

3. Measure Addition – Kidney Health Evaluation for Patients with Diabetes (KED) (Part C)

Finalized Changes

Effective measurement year 2024, Star Rating for 2026.

The Kidney Health Evaluation for Patients with Diabetes (KED) measure will replace the Kidney Disease Monitoring (KDM) measure. The KDM measure would assess the proportion of adults (18-85 year old) with diabetes who receive annual kidney profile evaluation, measured by the estimated glomerular filtration rate (eGFR) and a urine albumin creatinine ratio (UACR). The measure steward (NCQA) collaborated with National Kidney Foundation to create this measure based on the American Diabetes Association guidelines.

Background/Rationale

A commenter urged CMS to delay implementation of the measure until the race neutral eGFR calculation is integrated within the measure. CMS clarified that effective 2023 measurement year, only race neutral eGFR calculation is used within the measure.

4. Measure Removal

Finalized Changes

CMS finalized as proposed its ability to remove a retired measure from Star Rating calculations per according to the process described in §§ 422.164(e)(2) and 423.184(e)(2). This will allow CMS to exclude a measure from Star Rating when the measurement steward retires the measure.

Background/Rationale

While there was broad support for this rule among commenters, some encouraged CMS to continue to inform plans about removal of measures from Star Rating calculations. CMS clarified that they will continue to follow the process described in §§ 422.164(e)(2) and 423.184(e)(2), and inform plans about the measures which are no longer part of the Star Rating calculation. One commenter expressed concern about the potential gap in the 2024 measurement year of the program for influenza and pneumococcal vaccinations as measures related to these vaccinations are being retired by NCQA. CMS clarified that the Star Rating influenza and pneumococcal measures are different from the NCQA HEDIS measures and are assessed from the CAHPS survey.

C. Patient Experience/Complaints and Access Measure Weights (section V.E, pgs 488-504)

Finalized Changes

Effective coverage year 2024, Star Rating for 2026.

To align the weights of patient experience/complaints and access measures throughout various quality programs and to give more balanced weight to clinical outcomes, CMS has lowered the weight for these measures from 4 to 2.

Background/Rationale

Most commenters supported CMS's efforts and one even requested earlier implementation of the weight reduction. CMS noted that the earliest year for the implementation of these measures will be 2026.

Many commenters asked CMS to not reduce the weights, reduce them partially to 3 or reduce them more than 2 points. The rationale presented for partial, or no reduction were to sustain stability in the Star Ratings program and to retain value in patient experience. Commenters argued that the Star Ratings program needs stability so that organizations can implement long term strategies to improve quality and that high scores for patient experience are necessary to have a patient-centered approach. CMS responded by stating that reduction in the patient experience scores will not affect stability of the program, and high patient scores may incentivize plans to shift focus away from efforts to improve clinical outcomes and preventive care as they are currently weighed less than patient experience measures.

D. Health Equity Index Reward (section V.F, pgs 504-557)

CMS is finalizing the removal of the reward factor and addition of the HEI reward to the 2027 Star Ratings as proposed. The HEI assesses contract performance among beneficiaries with certain social risk factors (initially proposing dual eligibility, LIS, disability as the risk factors).

CMS will make additional revisions to §§ 422.162(a) and 423.182(a) to modify the definition of "highly-rated contract" to remove references to CAI and reward factor and to instead reference applicable adjustments in §§ 422.166(f) and 423.186(f); to §§ 422.162(b)(1) and 423.182(b)(1) to remove references to the current reward factor and to instead reference applicable adjustments in §§ 422.166(f) and 423.186(f); and to §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B) to clarify that, for purposes of calculating the HEI, measure-level scores are used for contracts that have data for only the most recent year of the 2 years, but measure-level scores are not used for contracts that have data for only the first of the 2 years.

As a reminder, CMS the following process will be used to calculate the HEI:

1. Measure-level scores for each measure included in the HEI are calculated for each contract using data from the two most recent measurement years based on enrollees with the specified SRFs using a modeling approach that accounts for year.
2. Measures that are case-mix adjusted in the Star Ratings would employ all standard case-mix adjustors except for adjusters that are the same as the SRFs included in the HEI, are strongly correlated with the included SRFs, or are conceptually similar to the included SRFs.
3. A contract would need to meet the .7 reliability and minimum denominator criteria for at least half of the measures included in the HEI based on data from the two most recent measurement years and have at least 500 enrollees at the contract level in the most recent measurement year to have the HEI calculated.
4. For each included measure, points are awarded as follows: 1 point to those contracts that score in the top third of all contracts, 0 points to those that score in the middle third of all contracts, and 1 negative point to those that score in the bottom third of all contracts.
5. Points are added together using the weighted average of Star Ratings measure weights.
6. Separate HEIs are calculated for overall and summary ratings (e.g., an MA-PD contract would have an overall, Part C, and Part D summary rating).
7. To qualify for an award, the HEI must be greater than zero. CMS proposes a "tiered" structure to determine the amount of reward, based on the percentage of enrollees in the contract with SRFs, as noted in the table below. The award itself is based on a linear scale.

Percentage of Enrollees with Specified SRFs Threshold	**Amount of Reward**
% of enrollees in a contract with the specified SRFs < 0.5 of the median for all contracts.	Zero Reward.
% of enrollees in a contract with the specified SRFs ≥ 0.5 of the median for all contracts and < the median for all contracts.	HEI reward would vary from 0 to 0.2 on a linear scale for contracts that have an HEI score > 0.
% of enrollees in a contract with the specified SRFs ≥ the median for all contracts.	HEI reward would vary from 0 to 0.4 on a linear scale for contracts that have an HEI score > 0.

8. Once each of the HEI rewards are calculated, the HEI reward is added to the respective unrounded overall and Part C and Part D summary ratings after the addition of the Categorial Adjustment Index and the application of the improvement measures.

Background/Rationale

Nearly all commenters supported advancing health equity, and most commenters supported the HEI reward as proposed, including replacing the current reward factor. Reasons provided include alignment with CMS's goal of advancing health equity, shedding light on deep-seated disparities in the health care system, driving reductions in disparities in care, and driving better health outcomes for populations with SRFs. Other commenters noted that the HEI will allow for clearer comparisons among and between plans and remove any disincentives plans may have for serving populations with SRFs, and adding the HEI to the Star Ratings will help make health equity part of the fabric of quality programs.

Some commentors opposed removing the current reward factor, even if they supported the addition of the HEI reward. These commentors reasoned that the change would penalize and lower Star Ratings for high-performing plans and adversely impact Medicare enrollees by reducing supplemental benefits or increasing cost-sharing requirements. Other commentors suggested the new reward factor applies a two-sided net zero approach. Alternative suggestions included combining the HEI reward and the current reward factor, implementing a transition period, or taking the better of either the HEI reward or the current reward factor. CMS was not receptive to these concerns, noting that contracts will still have incentives to perform well and improve, and that different incentives are needed for MA plans given that contract performance stabilized over time. The new reward factor is upside only, and CMS notes that simulations show that no contracts with lose QBPs and only 9.4% would lose rebate dollars.

Another commentor expressed only including a subset of measures initially for the HEI reward, as well as providing for a notice and public comment period on the measures that would be included in the HIE. CMS was not receptive, noting that the current proposed rulemaking process provides this opportunity.

Other commentors provided perspectives on dually eligible beneficiaries. One requested setting different cut points for contracts with a higher proportion of duals, and others recommended ensuring additional resources flow through to providers serving a higher proportion of duals.

Other commentors recommended the consideration of additional SRFs into the HEI reward, including race and ethnicity, gender, language, gender identity, sexual orientation, enrollee self-reported social needs, cultural context, social relationships, residential and community context, rurality, and enrollees with housing, food, or transportation needs identified using data from the NCQA Social Need Screening and Intervention measure. Others questioned why the Area Deprivation Index (ADI) was not included given that it is in the Medicare Shared Savings Program (MSSP). CMS appreciated the additional suggestions, and will consider factors with readily available data, such as rurality and gender, in future rulemaking. Regarding ADI, CMS reiterated that it explains little of the variation in the quality of care beyond LIS/dual status and disability information. The ADI is more useful in situations where there is a lack of beneficiary-level quality performance data, which is the case for the MSSP.

Commentors suggested the use of a number enrollment threshold, in addition to a percentage, to qualify for the HEI reward. Commentors noted that large plans serving still a significant number of individuals with SRFs could be excluded, and others noted that it would be challenging for employer group contracts to meet the percentages, given their population is less likely to be LIS/dual or disabled. CMS was not receptive to these concerns, noting that one of their goals was to avoid rewarding contracts that serve only a small number of those with SRFs relative to total enrollment. They also noted that contracts serving a low percentage of those with SRFs tend to perform well on Star Ratings, and that the HEI reward only has an upside.

Another commentor noted disproportionate impacts to rural beneficiaries, given lower Star Ratings performance for these members. However, CMS did not find significant differences in quality scores between urban versus rural beneficiaries.

Some commenters requested more information about the HEI reward methodology and that CMS share data and simulations prior to implementing the HEI reward. A handful of commenters suggested including the HEI on the Star Ratings display page with the detailed methodology. A few commenters requested that the implementation of the HEI reward methodology be delayed to allow contracts more

time to prepare. A commenter also requested that CMS provide data on D-SNPs or other SNP types with a high proportion of LIS/DE or disabled individuals to demonstrate the effect of the HEI reward among these contracts compared to contracts with lower proportions of LIS/DE or disabled members. A commenter requested the expected measure-level performance thresholds for each of the thirds. CMS noted that it will calculate the HEI reward beginning with the 2024 Star Ratings and will share the results in confidential contract-level reports in HPMS. Contracts will have these data for 3 years prior to the HEI being implemented as part of the 2027 Star Ratings. CMS also provided simulation data using 2021 Star Ratings:

- The percent of enrollees who have the specified SRFs for the HEI (that is LIS/DE/disability status) is 15 percent for MA and cost contracts and 5 percent for PDPs that do not meet the enrollment threshold to be eligible for a reward
- 28 percent for MA and cost contracts and 10 percent for PDPs that meet one-half of the contract-level median up to but not including the median
- 61 percent for MA and cost contracts and 37 percent for PDPs that meet the median enrollment threshold.
- 42 percent for MA and cost contracts and 13 percent for PDP contracts that received an HEI reward.

Another commentor suggested the HEI replace the CAI rather than the current reward factor. CMS noted that the HEI reward serves a different purpose compared to CAI; the CAI is designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts; in contrast, the HEI reward is designed to create incentives to reduce disparities in care.

One commenter stated that Star Ratings for high-performing contracts with a disproportionately high share of enrollees with SRFs could be adversely impacted with the addition of the HEI and removal of the reward factor. Another commenter stated that D-SNP-only contracts are more adversely impacted by the removal of the reward factor. Another commenter requested that CMS study the impact of removing the reward factor on contracts with high LIS/DE/disabled enrollment. CMS noted that in its simulations, they have not found that D-SNP-only contracts or contracts that include D-SNPs along with other MA plans will be more adversely impacted by the removal of the reward factor.

A few commenters suggested alternatives to using the original reason for Medicare entitlement to identify enrollees who have a disability. A commenter suggested using diagnoses in claims data. A commenter noted a need to expand the identification of enrollees with a disability beyond the original reason for entitlement and recommended CMS only allow the physician who is treating the patient to make the determination that the patient has become disabled after Medicare enrollment. A commenter recommended additional ways to identify enrollees with a disability in future years, including the HEDIS Advanced Illness and Frailty Exclusions and enrollee self-reported disability in Health Risk Assessments. The commenter also recommended CMS include additional fields to enrollment forms to collect information on disability. A commenter suggested CMS could explore using the disability definition under the Americans with Disabilities Act. CMS appreciated these suggestions.

Some commenters raised concerns about the possibility that some plans may more heavily market to dually eligible enrollees in order to have them enroll in non-D-SNP products, so that such plans may meet the threshold of having enough members to be eligible for the HEI reward, or that the HEI reward would discourage enrollment in D-SNPs and Chronic Condition SNPs. Another commenter stated the HEI reward would create an incentive for gaming contract enrollment where plans could target or avoid

cohorts of beneficiaries, particularly dually eligible beneficiaries and beneficiaries with chronic conditions, because CMS is not proposing any corrections (similar to risk adjustment) that would ensure contracts are fairly scored relative to the different populations in each contract. CMS was not receptive to these concerns and noted that any contracts enrolling more duals must also do well serving this population to receive an HEI reward.

Commentors also asked clarifying questions on certain elements of the HEI will be calculated, including the 2-year combined rate, measure reliability, HEDIS hybrid measures, measure exclusion criteria, percentage of enrollees with SRFs.

E. Extreme Uncontrollable Circumstances (section V.G, pgs 557-562)

1. 60 Percent Rule

Finalized Changes

CMS finalized as proposed the revision at §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) to remove the 60 percent rule beginning with the 2026 Star Ratings for non-CAHPS measures.

Background/Rationale

Most commenters supported the removal of the 60 percent rule. One commenter was concerned that enrollees in affected contracts could be impacted by the change. However, CMS states that removal of the 60 percent rule will only impact which contracts are included when they calculate the measure-level cut points. It will not impact which contracts receive the extreme and uncontrollable circumstances adjustment. For MA plans, § 422.100(m) addresses special requirements for when a disaster or emergency is declared as described in § 422.100(m)(2) and there is a disruption of access to health care as described in § 422.100(m)(6). The changes in the Star Ratings extreme and uncontrollable circumstances adjustment will not change application of § 422.100(m) and the beneficiary protections required under that regulation.

2. Health Outcomes Survey (HOS) Measures

Finalized Changes

CMS previously adopted regulations for how Star Ratings would be calculated in the event of extreme and uncontrollable circumstances in the April 2019 final rule. For most measures, the extreme and uncontrollable circumstance adjustment applies for disasters from 2 years prior to the Star Ratings year. For example, CMS noted at 84 FR 15772-15773 that the 2023 Star Ratings would adjust measures derived from the HOS for 2020 extreme and uncontrollable circumstances.

CMS finalized as proposed to clarify in § 422.166(i)(3)(iv) the timing for HOS measure adjustments for extreme and uncontrollable circumstances.

Background/Rationale

All commenters supported the CMS proposal to clarify the timing of HOS disaster adjustments.

F. Calculation of Star Ratings (section V.H, pgs 562-569)

Finalized Changes

Effective date: June 5, 2023

After considering the comments received and for the reasons outlined in the proposed rule and CMS's responses to comments, CMS is finalizing the technical amendment to fix the Tukey outlier deletion codification error from the May 2022 final rule and the non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), since Tukey outlier deletion is applied prior to the other steps. The Tukey outlier deletion will be applied beginning with the 2024 Star Ratings.

Background/Rationale

Some commenters were concerned that Tukey outlier deletion would result in disproportionate losses of QBPs among D-SNPs. They cited a specific ZAHealth study to support their assertion. CMS conducted their own analysis and was unable to replicate the findings that D-SNPS would be disproportionately impacted by the change.

Another commenter stated that the changes will create new hurdles for plans trying to improve their ratings. CMS responded by stating that the Tukey outlier deletion is the only methodological enhancement to the 2024 Star Ratings. CMS finalized the application of Tukey outlier deletion for non-CAHPS measures beginning with the 2024 Star Ratings in the CY 2021 final rule published in June 2020 so this is not a new enhancement and contracts have been on notice of this upcoming change. For the 2025 Star Ratings, there are no additional measures or methodological enhancements. Interested parties have requested that CMS minimize changes in cut points from year to year; the implementation of Tukey outlier deletion supports this goal, so CMS does not believe that the implementation of Tukey outlier deletion needs to be delayed.