



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

Office of the Secretary

[CMS-4201-F]

RIN 0938-AU96

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, marketing and communications, health equity, provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, and other programmatic areas. This final rule will also codify regulations implementing section 118 of Division CC of the Consolidated Appropriations Act, 2021, section 11404 of the Inflation Reduction Act, and includes provisions that will codify existing sub-regulatory guidance in the Part C, Part D, and PACE programs.

DATES: *Effective date:* These regulations are effective on June 5, 2023.

Applicability dates: The provisions in this rule are applicable to coverage beginning January 1, 2024, except as otherwise noted. The revisions to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) regarding Tukey outlier deletion are applicable on June 5, 2023. The marketing and communications provisions at §§ 422.2262 through 422.2274 and 423.2262 through 423.2274

are applicable for all contract year 2024 marketing and communications beginning September 30, 2023. The revisions to the definition of “gross covered prescription drug costs” in § 423.308 are applicable on June 5, 2023. The removal of the Part C Diabetes Care – Kidney Disease Monitoring measure as described in sections V.D.1. of the final rule is applicable on June 5, 2023. The risk adjustment to the three Part D adherence measures based on sociodemographic status characteristics as described in section V.D.2. of this final rule is applicable for 2028 Star Rates beginning January 1, 2026. The PACE provision on the contract year definition at § 460.6 and the PACE provision on service determination requests at § 460.121 are applicable on June 5, 2023.

FOR FURTHER INFORMATION CONTACT:

Lucia Patrone, (410) 786-8621 – General Questions.

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

Catherine Gardiner, (410) 786-7638– Part D Issues.

Sonia Eaddy, (410) 786-5459 – Part D Issues.

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

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

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

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

Sara Klotz, 410-786-0507 – D-SNP Issues.

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

SUPPLEMENTARY INFORMATION:

CMS intends to address all of the remaining proposals from the December 2022 proposed rule in subsequent rulemaking. Therefore, CMS plans to make provisions adopted in the subsequent, second final rule applicable to coverage beginning no earlier than January 1, 2025. Notwithstanding the foregoing, for proposals from the December 2022 proposed rule that would codify statutory requirements that are already in effect, CMS reminds organizations, plan

sponsors, and other readers that the statutory provisions apply and will continue to be enforced. CMS intends to implement the statutory requirements in section 118 of Division CC of the Consolidated Appropriations Act, 2021 (CAA) and section 11404 of the Inflation Reduction Act (IRA) consistent with their effective provisions.

We received nearly one thousand timely pieces of correspondence containing multiple comments on the CY 2024 proposed rule. We note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule, we are not addressing comments received on the provisions of the proposed rule that we are not addressing or finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

I. Executive Summary

A. Purpose

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

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

- The Inflation Reduction Act (IRA) of 2022.

- The Consolidated Appropriations Act (CAA), 2021.

B. Summary of the Major Provisions

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

(§§ 422.162, 422.164, 422.166, 423.182, 423.184, and 423.186)

We are finalizing a health equity index (HEI) reward for the 2027 Star Ratings to further incentivize Parts C and D plans to focus on improving care for enrollees with social risk factors (SRFs); as part of this change, we also are finalizing the removal of the current reward factor (a reward for consistently high performance). This policy supports CMS efforts to ensure attainment of the highest level of health for all people. We are finalizing the reduction in the weight of patient experience/complaints and access measures to further align efforts with other CMS quality programs and the current CMS Quality Strategy, as well as to better balance the contribution of the different types of measures in the Star Ratings program. We also are finalizing the removal of the Part C Diabetes Care – Kidney Disease Monitoring measure; addition of the Part C Kidney Health Evaluation for Patients with Diabetes measure; and substantive updates to the Part D Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. We are also finalizing a rule for the removal of certain types of Star Ratings measures in the future; removal of the 60 percent rule that is part of the adjustment for extreme and uncontrollable circumstances (also called the disaster adjustment); and technical clarifications and changes related to the disaster adjustment, treatment of ratings for contracts after consolidation, and the correction of an error related to codification of the use of Tukey outlier deletion. Generally, these changes will apply (that is, data will be collected and performance measured) for the 2024 measurement period and the 2026 Star Ratings, except for the removal of the Part C Diabetes Care – Kidney Disease Monitoring measure, which will apply beginning with the 2024 Star Ratings; the HEI reward, which will apply beginning with the 2024 and 2025 measurement periods and the 2027 Star Ratings; the risk adjustment based on

sociodemographic status characteristics to the three adherence measures, which will be implemented beginning with the 2026 measurement period and the 2028 Star Ratings; and addressing the codification error related to the use of Tukey outlier deletion which will be applicable upon the effective date of this final rule and apply beginning with the 2024 Star Ratings.

The remaining Star Ratings provisions of the proposed rule are not being finalized in this rule and instead will be addressed in a later final rule. Those provisions include removing the stand-alone Medication Reconciliation Post-Discharge measure; adding the updated Colorectal Cancer Screening and Care for Older Adults – Functional Status Assessment measures; adding the Part D Concurrent Use of Opioids and Benzodiazepines, Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measures; removing guardrails (that is, bi-directional caps that restrict upward and downward movement of a measure’s cut points for the current year’s measure-level Star Ratings compared to the prior year’s measure-threshold specific cut points) when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures; modifying the Improvement Measure hold harmless policy; and adding technical clarifications related to Quality Bonus Payment (QBP) appeals and weighting of measures after a substantive specification change.

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

CMS is working to achieve policy goals that advance health equity across its programs and pursue a comprehensive approach to advancing health equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty

and inequality.¹ To that end, in addition to the health equity index, we are finalizing the following regulatory updates.

First, current regulations require MA organizations to ensure that services are provided in a culturally competent manner. The regulation provides examples of populations that may require consideration specific to their needs. In this final rule, we further clarify the broad application of our policy. Specifically, we are amending the list of populations to include people: (1) with limited English proficiency or reading skills; (2) of ethnic, cultural, racial, or religious minorities; (3) with disabilities; (4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (6) who live in rural areas and other areas with high levels of deprivation; and (7) otherwise adversely affected by persistent poverty or inequality.

Next, CMS currently provides best practices for organizations to use in developing their provider directories, including incorporating non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. In this rule, we are codifying these best practices by requiring organizations to include providers' cultural and linguistic capabilities (including American Sign Language, ASL) in their provider directories. This change will improve the quality and usability of provider directories, particularly for non-English speakers, limited English proficient individuals, and enrollees who use ASL.

In addition, as the use of telehealth becomes more prevalent, there is evidence of disparities in telehealth access due in part to low digital health literacy, especially among populations who already experience health disparities. Low digital health literacy is one of the most significant obstacles in achieving telehealth equity, and many older adults with low digital health literacy experience gaps in access to the health care they need. This is concerning for the MA program because its enrollee population includes older adults who are age 65 or older,

¹<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

which is why we are finalizing policies to address the issue by requiring MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits. We solicited comments from stakeholders on various aspects of our proposal, which informed the types of MA plans we are subjecting to the finalized regulatory requirements, and how we will collect information related to compliance with these requirements.

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

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

In recent years, CMS has received numerous inquiries regarding MA organizations' use of prior authorization and its effect on beneficiary access to care. We are finalizing several regulatory changes to address these concerns regarding prior authorization. First, we are finalizing that prior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service

is medically necessary based on standards specified in this rule. Second, we are finalizing that an approval granted through prior authorization processes must be valid for as long as medically necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient's medical history, and the treating provider's recommendation, and that plans 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. Third, we are finalizing that MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare laws. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. We are finalizing that when coverage criteria are not fully established in Medicare statute, regulation, NCD, or LCD, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature. We are also clarifying that coverage criteria are not fully established when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently; NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD, or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria. When additional, unspecified criteria are needed to interpret or supplement general provisions, the MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

Finally, to ensure prior authorization and other utilization managed policies are consistent with the rules we are adopting on coverage criteria and coverage policies and relevant current clinical guidelines, we are finalizing that all MA plans establish a Utilization Management Committee to review all utilization management, including prior authorization, policies annually and ensure they are consistent with the coverage requirements, including current, traditional

Medicare's national and local coverage decisions and guidelines. These changes will help ensure MA enrollees have consistent access to medically necessary care, without unreasonable barriers or interruptions.

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

In accordance with our statutory authority to review marketing materials and application forms and to develop marketing standards under sections 1851(h), 1851(j), 1860D-1(b)(1)(vi), and 1860D-4(l) of the Act, as well as the statutory requirements in sections 1852(c) and 1860D-4(a) of the Act requiring MA organizations and Part D sponsors disclose specific types of information to enrollees, we proposed several changes to 42 CFR parts 422 and 423, subpart V, to strengthen beneficiary protections and improve MA and Part D marketing. We are finalizing the following changes: notifying enrollees annually, in writing, of the ability to opt out of phone calls regarding MA and Part D plan business; requiring agents to explain the effect of an enrollee's enrollment choice on their current coverage whenever the enrollee makes an enrollment decision; simplifying plan comparisons by requiring medical benefits be in a specific order and listed at the top of a plan's Summary of Benefits; limiting the time that a sales agent can call a potential enrollee to no more than 12 months following the date that the enrollee first asked for information; limiting the requirement to record calls between third-party marketing organizations (TPMOs) and beneficiaries to marketing (sales) and enrollment calls; prohibiting a marketing event from occurring within 12 hours of an educational event at the same location; clarifying that the prohibition on door-to-door contact without a prior appointment still applies after collection of a business reply card (BRC) or scope of appointment (SOA); prohibiting marketing of benefits in a service area where those benefits are not available, unless unavoidable because of use of local or regional media that covers the service area(s); prohibiting the marketing of information about savings available that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other

unrealized costs of a Medicare beneficiary; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they represent on marketing materials; requiring MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS; modifying the TPMO disclaimer to add SHIPs as an option for beneficiaries to obtain additional help; modifying the TPMO disclaimer to state the number of organizations represented by the TPMO as well as the number of plans; prohibiting the collection of Scope of Appointment cards at educational events; placing discrete limits around the use of the Medicare name, logo, and Medicare card; prohibiting the use of superlatives (for example, words like “best” or “most”) in marketing unless the material provides documentation to support the statement, and the documentation is based on data from the current or prior year; clarifying the requirement to record calls between TPMOs and beneficiaries, such that it is clear that the requirement includes virtual connections such as video conferencing and other virtual telepresence methods; and requiring 48 hours between a Scope of Appointment and an agent meeting with a beneficiary, with exceptions for beneficiary-initiated walk-ins and the end of a valid enrollment period. We are not addressing our proposal to prohibit TPMOs from distributing beneficiary contact information in this final rule and may address it in a future final rule.

We are finalizing and implementing the changes, as previously discussed, to Subpart V in this rule for CY 2024. As such, they will become effective on September 30, 2023 for all activity related to CY 2024.

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

Sections 422.2267(a)(2) and 423.2267(a)(2) require MA organizations, cost plans, and Part D sponsors to translate required materials into any non-English language that is the primary language of at least 5 percent of individuals in a plan benefit package service area. In addition,

45 CFR Part 92 requires plans to provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. However, CMS has learned from oversight activities, enrollee complaints, and stakeholder feedback that enrollees often must make a separate request each time they would like a material in a non-English language or accessible format.

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

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

In this rule, we are finalizing and implementing the changes as proposed for materials produced for CY 2024.

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

As part of the January 2022 proposed rule, we solicited comments from stakeholders regarding challenges in building MA behavioral health networks and opportunities for improving access to services. Stakeholders commented on the importance of ensuring adequate access to behavioral health services for enrollees and suggested expanding network adequacy requirements to include additional behavioral health specialty types.

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

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

CMS requires notification to MA enrollees when a provider network participation contract terminates. Continuity of care is essential, especially for primary care and behavioral health, and consequently, adequate communication to enrollees is vital when network changes occur so that patients of any terminating primary care or behavioral health providers can decide how to proceed with their course of treatment. CMS is finalizing amendments to § 422.111(e)

that establish specific enrollee notification requirements for no-cause and for-cause provider contract terminations and add specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also amending § 422.2267(e)(12) to specify the content and additional procedural requirements for the notification to enrollees about a provider contract termination. These requirements will generally increase enrollee protections when MA network changes occur and will raise the standards for the stability of enrollees' primary care and behavioral health treatment.

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

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

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

Section 11404 of the IRA amended section 1860D-14 of the Act to expand eligibility for the full LIS to individuals with incomes up to 150 percent of the Federal poverty level (FPL) beginning on or after January 1, 2024. In addition, the IRA allows for individuals to qualify for the full subsidy based on the higher resource requirements currently applicable to the partial LIS group. This change will provide the full LIS subsidy for those who currently qualify for the

partial subsidy. In this rule, we are finalizing implementing regulations at §§ 423.773 and 423.780 as proposed.

C. Summary of Costs and Benefits

TABLE 1

Provision	Description	Impact
<p>a. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 423.182, 423.184, and 423.186)</p>	<p>CMS is finalizing several measure changes and methodological clarifications and enhancements to the Part C and Part D Star Ratings as described in section V. In addition to finalizing the addition of an HEI reward as a replacement for the current reward factor and the reduction of the weight of patient experience/complaints and access measures, we are finalizing removal of the 60 percent rule for extreme and uncontrollable circumstances, a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, and clarifications around additional aspects of the existing Star Ratings calculations.</p>	<p>The HEI reward provision, which would replace the current reward factor, is expected to result in net savings of between \$670 million in 2028 and \$1.05 billion in 2033, resulting in a ten-year savings estimate of \$5.12 billion. The patient experience/complaints and access measure weight provision is expected to result in net savings of between \$330 million in 2027 and \$580 million in 2033, resulting in a ten-year savings estimate of \$3.28 billion. The net impact of all of the Star Ratings provisions finalized in this rule is \$6.41 billion in savings over ten years, accounting for 0.10% of the private health baseline.</p>
<p>b. Strengthening Translation Requirements for Medicare Advantage, Cost plans, Part D, and D-SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267)</p>	<p>We are finalizing requirements that: (1) MA organizations, cost plans, and Part D sponsors provide materials to enrollees on a <i>standing basis</i> in any non-English languages that is the primary language of at least 5 percent of the individuals in that service area and/or accessible formats; and (2) FIDE SNPs, HIDE SNPs and AIPs translate both Medicare and Medicaid materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.</p>	<p>(1) We estimate the requirement for MA organizations, cost plans, and Part D sponsors to establish a process to provide materials to enrollees on a standing basis will cost \$10.4 million. We expect that implementing a standing request process will reduce future costs to MA organizations, cost plans, and Part D sponsors by decreasing rework of sending two sets of information, one in the incorrect language or format and the other in the correct format. (2) We estimate it will cost \$2.1 million for FIDE SNPs, HIDE SNPs, and AIPs to translate one set of materials into one additional language. Any additional documents needing translation will be a one-time cost with a smaller cost to update the documents in future contract years.</p>

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

Provision	Description	Impact
<p>d. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Mandate Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137 and 422.138422.4)</p>	<p>In this final rule, we are finalizing: (1) the requirement that MA plans to follow Traditional Medicare coverage NCDs, LCDs, statutes and regulations when making medical necessity determinations, (2) that MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD; (3) the requirement that an approval granted through PA processes must be valid for as long as medically necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient’s medical history, and the treating provider’s recommendation and that plans are required to provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA plan, switches from Traditional Medicare to an MA plan, or is new to Medicare, and (4) the requirement that MA organizations establish a committee, led by a plan’s Medical Director, that reviews utilization management, including PA, policies annually and keeps current of LCDs, NCDs, and other Traditional Medicare coverage policies.</p>	<p>(1) Require MA plans to follow Traditional Medicare coverage guidelines when making medical necessity determinations. The impact is difficult to quantify. (2) Requires plans to post internal coverage criteria and provide public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations. (3) Requires PA approval to be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the patient’s medical history, and the treating provider’s recommendation and is not expected to have economic impact on the Medicare Trust fund. (4) Require MA organizations to establish a committee (similar to a P&T committee), led by the Medical Director, that reviews utilization management, including PA, policies annually and keeps current of LCDs, NCDs, and other Traditional Medicare coverage policies. This is qualitatively beneficial for enrollees and is not expected to have economic impact on the Medicare Trust fund.</p>

Provision	Description	Impact
<p>e. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)</p>	<p>We are finalizing several changes to strengthen beneficiary protections and improve MA and Part D marketing. These include notifying enrollees annually, in writing, of the ability to opt out of plan business contacts from their plan; requiring agents to explain the effect of an enrollee’s enrollment choice on their current coverage; clarifying that the contact is unsolicited unless an appointment at the beneficiary’s home was previously scheduled; prohibiting marketing of benefits in a service area where those benefits are not available, unless unavoidable due to use of local or regional media; prohibiting the marketing of savings available based on a comparison of typical expenses borne by uninsured individuals; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they represent in marketing materials; requiring plans and sponsors to have an oversight plan that monitors agent/broker activities and reports non-compliance to CMS; adding SHIPs to the TPMO disclaimer; adding the number of organizations and products a TPMO represents to the TPMO disclaimer; placing limits around the use of the Medicare name, logo, and Medicare card; prohibiting the use of superlatives unless the material provides documentation to support the statement; prohibiting the collection of SOA cards at educational events; prohibiting a marketing event to follow an educational event with 12 hours at the same location; clarifying the requirement to record calls between TPMOs and beneficiaries includes virtual connections such as Zoom and Facetime; limiting the time that a sales agent can call a potential enrollee to no more than 12 months following the date that the enrollee first asked for information; and requiring 48 hours between a Scope of Appointment and an agent meeting with a beneficiary, with exceptions for beneficiary-initiated walk-ins and the end of a valid enrollment period.</p>	<p>We recognize the impact of these provisions to be primarily one of changes to Plans’ policy and procedure documents. We estimate the one-time costs of these changes to be \$172,593 (\$76.20/hr * 2265 hr).</p> <p>We believe the time and cost to plans for the requirement to report non-compliant agents and brokers for substantive violations to CMS will be nominal.</p>

Provision	Description	Impact
<p>f. Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116)</p>	<p>CMS is finalizing adding Clinical Psychology and Licensed Clinical Social Work as specialty types that will be evaluated using the time, distance and minimum provider standards in our network adequacy reviews; amending our access to services standards to include behavioral health services; codifying minimum access wait time standards (from current example wait times for primary care) to apply to both primary care and behavioral health services; clarifying that behavioral health services may qualify as emergency services and therefore not be subject to prior authorization when furnished as emergency services; and requiring plans to establish behavioral health care coordination programs to ensure enrollees are offered the behavioral health services to which they are entitled to close gaps in behavioral health treatment.</p>	<p>We estimate negligible costs for these provisions.</p>
<p>g. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)</p>	<p>CMS requires notification to MA enrollees when a provider network participation contract terminates. Continuity of care is essential, especially for primary care and behavioral health, and consequently, adequate communication to enrollees is vital when network changes occur so that patients of any terminating primary care or behavioral health providers can decide how to proceed with their course of treatment. CMS is finalizing amendments to § 422.111(e) that establish specific enrollee notification requirements for no-cause and for-cause provider contract terminations and add specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also amending § 422.2267(e)(12) to specify the content and additional procedural requirements for the notification to enrollees about a provider contract termination. These requirements will generally increase enrollee protections when MA network changes occur and will raise the standards for the stability of enrollees' primary care and behavioral health treatment.</p>	<p>These provisions are not expected to have any economic impact on the Medicare Trust Fund.</p>

Provision	Description	Impact
h. Limited Income Newly Eligible Transition (LI NET) Program	We are making the long-standing demonstration program a permanent part of Medicare Part D, as directed by the CAA.	The projected costs, estimated by OACT, are the same as what the government would have incurred if the demonstration continued. Further, the costs of the payments provided for under this program will continue, as under the demonstration, to be covered through the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance (SMI) Trust Fund. The provision is estimated to cost the Medicare Trust Fund \$95 million over 10 years. There is an additional 10-year paperwork burden of \$ 4.3 million.
i. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)	We are implementing section 11404 of the IRA to expand eligibility for the full LIS subsidy group to individuals currently eligible for the partial LIS subsidy beginning on or after January 1, 2024.	We estimate that this change will increase Medicare spending by \$2.3 billion over 10 years.

D. General Comments on the Proposed Rule

Comment: A commenter suggested that CMS had not allowed for a 60-day comment period for the proposed rule because the beginning of the comment period was calculated from the date the proposed rule was made available for public inspection on the **Federal Register** website rather than the date that it appeared in an issue of the **Federal Register**. The commenter recommended that CMS provide an additional 60-day comment period on the proposed rule.

Response: Section 1871(b) of the Act requires that we provide for notice of the proposed regulation in the **Federal Register** and a period of not less than 60 days for public comment thereon. The proposed rule was available for public inspection on federalregister.gov (the website for the Office of Federal Register) on December 14, 2022. We believe that beginning the comment period for the proposed rule on the date it became available for public inspection at the Office of the Federal Register fully complied with the statute and provided the required notice to the public and a meaningful opportunity for interested parties to provide input on the provisions of the proposed rule.

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

A. Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments

(§§ 422.503(e), 422.504, 422.510 and 422.514)

In the final rule titled “Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program” which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (hereinafter referred to as the June 2020 final rule), CMS finalized the contracting limitations for D-SNP look-alikes at § 422.514(d) and the associated authority and procedures for transitioning enrollees from a D-SNP look-alike at § 422.514(e). For plan year 2022 and subsequent years, as provided in § 422.514(d)(1), CMS will not enter into a contract for a new non-SNP MA plan that projects, in its bid submitted under § 422.254, that 80 percent or more of the plan’s total enrollment are enrollees entitled to medical assistance under a State plan under Title XIX. For plan year 2023 and subsequent years, as provided in § 422.514(d)(2), CMS will not renew a contract with a non-SNP MA plan that has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a State plan under Title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

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

assessments (HRAs); and evidence-based models of care. In addition, we noted how limiting these D-SNP look-alikes would address beneficiary confusion stemming from misleading marketing practices by brokers and agents that misrepresent to dually eligible individuals the characteristics of D-SNP look-alikes. For a more detailed discussion of D-SNP look-alikes and their impact on the implementation of D-SNP Medicare and Medicaid integration, we direct readers to the June 2020 final rule (85 FR 33805 through 33820) and the Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (85 FR 9018 through 9021) (also known as the February 2020 proposed rule). We proposed amendments to close unforeseen loopholes in the scope of the regulation adopted to prohibit D-SNP look-alikes.

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

As written at § 422.514(d) and (e), the contracting limitations for D-SNP look-alikes are based on analysis at the MA *plan* level. Section 1854(h) of the Act authorizes MA organizations to segment an MA plan and apply the uniformity requirements for MA plans at the *segment* level, provided that the segments are comprised of one or more MA payment areas. As implemented in §§ 422.2 (defining “MA plan”), 422.100(d), 422.254, and 422.262, MA plans may include multiple segments in an MA plan in which different benefit designs, cost-sharing, and premiums are available; bids are submitted at the segment level if an MA plan is segmented, and evaluation of compliance with MA requirements is done at the segment level where appropriate. For more information on MA plan segments, see 87 FR 79465 of the proposed rule. Since adopting § 422.514(d), we have seen MA plans where a specific segment looks like a D-SNP look-alike and would be subject to the contracting prohibitions in § 422.514(d) if the segment were treated as an MA plan. Currently, § 422.514(d) does not clearly apply to a segment within an MA plan. However, we believe that by applying the D-SNP look-alike contracting limitations only at the MA plan level without applying it to segments of plans, our existing

regulation has an unintended and unforeseen loophole through which D-SNP look-alikes could persist, contrary to the stated objectives in our prior rulemaking.

In the proposed rule (87 FR 79465), we described examples of non-SNP MA plan segments that would be identified as D-SNP look-alikes if we were to apply the § 422.514(d)(2) criteria at the MA plan segment level. The segments in those three plans collectively have approximately 3,000 enrollees. While the number of non-SNP MA plans at the segment level is currently small, this number could grow in the future and provide an opportunity for MA organizations to circumvent the D-SNP look-alike contracting limitations at § 422.514(d).

We proposed adding a new paragraph at 42 CFR 422.514(g) to provide that § 422.514(d) through (f) apply to segments of the MA plan in the same way that those provisions apply to MA plans. Under the proposal, CMS would not contract with or renew a contract with a plan segment where the MA plan or segment is not a D-SNP and the enrollment thresholds in paragraph (d)(1) or (d)(2) are met. This proposal, to treat a segment of an MA plan as an MA plan, is consistent with CMS' annual review of MA plan bids and Medicare cost-sharing, in which each MA plan segment submits a separate bid pricing tool and plan benefit package (PBP) like an unsegmented MA plan and CMS separately evaluates these submissions for compliance with MA requirements.

As discussed in the June 2020 final rule, CMS implements the contracting prohibition in § 422.514 at the plan level. Where an MA plan is one of several offered under a single MA contract and the MA organization does not voluntarily non-renew the D-SNP look-alike, CMS will sever the D-SNP look-alike from the overall contract using its authority under § 422.503(e) to sever a specific MA plan from a contract and terminate the deemed contract for the look-alike plan (85 FR 33812). However, CMS does not currently have clear regulatory authority to sever a *segment* from an MA plan to terminate a contract that has only a segment of an MA plan. CMS adopted the severability regulation at § 422.503(e) in the Medicare Program; Establishment of the Medicare+Choice Program interim final rule (63 FR 35103, hereafter known as the June

1998 interim final rule) as part of implementing the statutory authority for MA contracts to cover more than one MA plan. Without amending § 422.503(e), CMS would need to sever the entire MA plan that has the D-SNP look-alike segment. As a result, the other segments in that MA plan would be subject to the contracting prohibition and not renewed under § 422.514(d) as proposed to be amended. Instead, we 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. We proposed to rely on our authority to adopt MA standards under section 1856(b)(1) of the Act and our authority to adopt additional contract terms when necessary and appropriate, and not inconsistent with the MA statute, under section 1857(e)(1) of the Act. Our primary impetus for this proposal relates to D-SNP look-alikes, but our proposal at § 422.503(e) is not specific to D-SNP look-alikes; because each segment of an MA plan is like a plan itself, we believe severability should apply similarly at the plan and segment level. We also 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. In conjunction with the proposed amendments to § 422.514(g) to apply the prohibitions on contracting with D-SNP look-alikes to segments of an MA plan, the amendments to § 422.503(e) would allow CMS to eliminate existing D-SNP look-alike segments and the amendments to § 422.504(a)(19) would allow CMS to prevent new D-SNP look-alikes.

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

We identified a second loophole during our analysis of contract year 2023 MA plan bids to identify any new MA plans that meet the contract limitation at § 422.514(d)(1). An existing (that is, renewing) MA plan that did not meet the criteria in § 422.514(d)(2) (using January 2022 MMR data as provided in paragraph (e)(3)) projected in its contract year 2023 bid that the MA plan would have 80 percent or higher enrollment of dually eligible individuals in 2023. Because this MA plan is not a new MA plan for contract year 2023, the contract prohibition in § 422.514(d)(1) did not apply. To prevent similar situations in the future, we 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. We proposed to revise paragraph (d)(1) to provide that CMS does not enter into or renew an MA contract for plan year 2024 and subsequent years when the criteria in paragraphs (d)(1)(i) and (ii) are met. We proposed to begin this prohibition with 2024 because we expect that 2024 will be the first plan year after the final rule adopting this proposal. Pending finalization of this proposal, § 422.514(d)(1) will continue to prohibit contracts with new MA plans that meet the criteria. We noted in the proposed rule at 87 FR 79466 that the earliest our proposed revision to expand the scope of § 422.514(d)(1) could apply is 2024.

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

Finally, we proposed an amendment to § 422.510(a)(4), which outlined the bases for termination of an MA contract. Specifically, we 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 into or renew an MA contract in certain circumstances. In our view, § 422.514(d) is sufficient authority for the non-renewal, that is termination, of MA contracts when § 422.514(d) applies. However, we believe that adopting a specific provision in § 422.510(a)(4) will avoid any inadvertent ambiguity on this topic and make it clear that the procedures outlined in § 422.510, including notices, timeframes, and appeal rights, apply when CMS does not renew an MA contract based on application of § 422.514(d).

We received the following comments, and our responses follow.

Comment: 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. A few commenters specifically noted support for applying the contracting limitations to MA plan segments. A commenter stated that, despite concerns the commenter had raised in the past, the CMS proposal was a logical extension of existing policy and would allow remaining segments of the plan and other plans under the same contract to continue. Another commenter emphasized that MA plan segments are treated comparably to separate plans in a number of ways (for example, segments can have different benefit designs and cost-sharing; bids are submitted at the segment level; and where appropriate, compliance with MA requirements is determined at the segment level). Another commenter specifically emphasized its support to apply the D-SNP contract limitations to existing MA plans and to clarify CMS' authority to terminate an MA contract based on the application of D-SNP look-alike requirements.

Some of these 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. MACPAC stated that it views D-SNP look-alikes as acting at cross purposes to State and Federal efforts to integrate care by drawing dually eligible individuals away from integrated products and avoiding the additional requirements for D-SNPs. MedPAC indicated that D-SNP look-alikes undermine efforts to develop integrated plans for dually eligible individuals by encouraging them to enroll instead in plans that provide many of the same extra benefits as D-SNPs but do nothing to integrate Medicaid coverage. A commenter stated that dually eligible individuals are better served in integrated plans, and thus, in areas with highly integrated dual eligible special needs plans (HIDE SNPs) or fully integrated dual eligible special needs plans (FIDE SNPs), they should have a choice among these available integrated modalities rather than D-SNP look-alikes. A commenter supported CMS' proposals as an important step to advance Medicare-Medicaid integration. A few commenters supported the proposals noting that D-SNP look-alikes create unnecessary competition for integrated products without meeting any requirements to work with States to integrate or coordinate Medicaid

services, have specific models of care approved by the National Committee on Quality Assurance, or incorporate additional SNP quality measures designed for complex needs populations.

Several commenters supported CMS efforts to close unforeseen loopholes that have allowed D-SNP look-alikes to persist. A commenter appreciated CMS' efforts, citing the integrity of D-SNPs is critical since their membership consists of people with disabilities of all ages.

Response: We appreciate the widespread support we received for the proposed amendments and agree with the commenters' concerns about D-SNP look-alikes. Many of these concerns mirror the discussion in the 2020 Final Call Letter,² February 2020 proposed rule (85 FR 9018 through 9021), and June 2020 final rule (85 FR 33805 through 33808). We believe the amendments that we are finalizing in this rule will enable us to more effectively implement Medicare-Medicaid integration requirements under the BBA of 2018 along with other State and Federal requirements.

Comment: Some commenters recommended that CMS take action beyond implementing the proposals to lower the threshold used to identify D-SNP look-alikes. A few of these commenters suggested CMS reduce the threshold at § 422.514(d) for declining to contract or renew contracts with D-SNP look-alikes from 80 percent dually eligible enrollment to 50 percent, helping to mitigate the targeting of dually eligible individuals by non-integrated models. A commenter suggested lowering the threshold to at least 50 percent. Another commenter noted, while the 80 percent threshold is addressing the most obvious targeting of dually eligible individuals by non-SNP plans, it has allowed some non-SNP plans with enrollment of dually eligible individuals above 50 percent to continue to operate in markets where D-SNPs are not offered. This commenter supported lowering the enrollment threshold over the coming years as

²Available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents>

long as it can be done in a way that minimizes disruption to the enrollees and based its support for a lower threshold on the success of implementing the 80 percent threshold. A commenter indicated the current 80 percent threshold can itself serve as a loophole, allowing plans to enroll high proportions of dually eligible individuals without being subject to D-SNP look-alike requirements. This commenter encouraged CMS to consider a lower threshold to further promote integrated care and minimize enrollee confusion. MACPAC did not opine on whether or not CMS should change the enrollment threshold for identifying D-SNP look-alikes but expressed concern that there could still be a real risk of growth in plans of this type falling below the 80 percent threshold and thus continuing to detract from Federal and State efforts to integrate care.

Response: We appreciate these comments. The recommendations to reduce the enrollment threshold at § 422.514(d) are outside of the scope of our proposed amendments. We continue to monitor the level of dually eligible enrollment among non-SNP MA plans and will consider these comments for future rulemaking. We note that the D-SNP look-alike contracting limitations at § 422.514(d) only apply in a State where there is a D-SNP or any other plan authorized by CMS to exclusively enroll individuals entitled to Medicaid, which includes Medicare-Medicaid Plans.

Comment: Some commenters suggested that CMS exclude or reconsider excluding partial-benefit dually eligible individuals when calculating the 80 percent threshold at §422.514(d). Several commenters recommended that we exclude partial-benefit dually eligible individuals from the 80 percent threshold calculation in States that limit D-SNP enrollment to full-benefit dually eligible individuals. A few of these commenters noted that including partial-benefit dually eligible individuals in the 80 percent threshold calculation may limit managed care options for dually eligible individuals in these States. These commenters stated that the lack of access to medical benefits through some Medicaid programs and differences in the level of premium support and cost-sharing protections available to partial-benefit dually eligible individuals warrants separate plan benefit design from plans that are offered to full-benefit dually

eligible individuals in order to optimize benefits to support functional and social needs and limit cost-sharing for partial-benefit dually eligible individuals. These commenters listed States like Massachusetts and New Jersey that limit D-SNP enrollment to full-benefit dually eligible individuals and explained that non-SNP MA plans in these States may be incentivized not to enroll partial-benefit dually eligible individuals due to the 80 percent threshold for determining D-SNP look-alikes. Another commenter noted that, in 2025, this concern would apply to all States with FIDE SNPs. Additionally, a commenter emphasized the importance of balancing the challenge many D-SNPs have with State procurements, which can result in increased numbers of dually eligible individuals enrolling in general MA plans.

A commenter expressed concern that CMS' current policy for calculating the 80 percent threshold may fail to maximize advances in health equity, as partial-benefit dually eligible individuals who are harmed are more likely than the overall Medicare population to be Black or Hispanic/Latino, under age 65, experience isolation and food insecurity, have a mental illness, and have a multiple chronic condition diagnosis. This commenter further stated that MA plans have the ability to offer unique, targeted benefits that are tailored to low-income populations (for example, groceries, health meals, transportation, and over-the-counter benefits) that directly address social determinants of health and drive higher quality and believed that, where plans are forced to offer less targeted benefits to avoid triggering the 80 percent threshold, partial-benefit dually eligible individuals are harmed. This commenter noted that at least eight States currently prohibit partial-benefit dually eligible individuals from enrolling in D-SNPs. Without a solution, according to the commenter, plans in these States will need to take benefits and resources away from this complex low-income population to instead use them to reduce Part D cost-sharing to attract enough non-dually eligible enrollees to avoid the 80 percent threshold.

A few commenters emphasized the value of allowing partial-benefit dually eligible individuals to enroll into D-SNPs. These commenters stated that D-SNPs provide supplemental benefits and care coordination provided through individualized care plans. A commenter noted

that although partial-benefit dually eligible individuals are ineligible for most Medicaid services, these individuals have similar clinical, functional, and social needs as full-benefit dually eligible individuals and can benefit from access to stronger care management models available in D-SNPs. Recognizing that States decide whether or not to allow D-SNPs to enroll partial-benefit dually eligible individuals, a commenter recommended that CMS exclude these individuals from the calculation of the 80 percent threshold.

A commenter suggested that CMS consider alternative approaches, such as working with Congress to require States that limit D-SNP enrollment to full-benefit dually eligible individuals to, in turn, require their D-SNPs to have a separate PBP for partial-benefit dually eligible individuals, as Pennsylvania and Virginia have already done.

A commenter stated that excluding partial-benefit dually eligible individuals from the 80 percent threshold calculation would allow CMS to enforce D-SNP look-alike contracting restrictions in States where dually eligible individuals have D-SNPs they can move to, while not penalizing States that have not yet adopted the D-SNP model for all partial- and full-benefit dually eligible individuals.

Response: We thank the commenters for their perspectives. The recommendations to revise the definition of the enrollment threshold at § 422.514(d) are outside of the scope of our proposed amendments; we believe that policy making on this issue would benefit from further study and engagement with interested parties. We will consider these comments for future rulemaking. For contract year 2023, D-SNPs limited to partial-benefit dually eligible individuals exist in 11 States (that is, Connecticut, Delaware, Florida, Idaho, Michigan, Mississippi, New York, Ohio, Virginia, Washington, and Wisconsin) and the District of Columbia. We continue to believe that allowing non-SNP MA plans to enroll partial-benefit dually eligible individuals with no limit would discourage States from taking this approach.

We believe the commenter noting that limitations on D-SNPs enrolling only full-benefit dually eligible individuals would apply to all States with FIDE SNPs in 2025 is referencing an

amendment we made to the FIDE SNP definition in the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, which appeared in the **Federal Register** on May 9, 2022 (85 CFR 22704). Per the amendment to the FIDE SNP definition at 422.2 paragraph (5), for plan years 2025 and subsequent years, FIDE SNPs must have exclusively aligned enrollment. Starting for plan year 2025, FIDE SNPs will no longer be permitted to enroll any partial-benefit dually eligible individuals, because the definition of aligned enrollment is limited to full-benefit dually eligible individuals. However, the new requirement for exclusively aligned enrollment does not directly affect partial-benefit dually eligible individuals because no FIDE SNPs currently enroll partial-benefit dually eligible individuals. With respect to the comment regarding the ability of MA plans to offer benefits tailored to low-income populations such as groceries, transportation, and over-the-counter benefits, we note that these benefits may be offered when consistent with §§ 422.100(c)(2) and 422.102.

Comment: A commenter suggested that CMS impose D-SNP look-alike restrictions only on MA plans and plan segments that have a minimum number of enrollees. The commenter indicated that creating an enrollment floor would prevent a small number of dually eligible enrollees from having an outsized impact on the plan's percentage of dually eligible enrollment due to low enrollment and recommended establishing this floor at 200 enrollees per plan for both new and existing plans to create a statistically significant sample size.

Response: We thank the commenter for this perspective but disagree with the recommendation. The recommendations to revise the enrollment threshold at § 422.514(d) are outside of the scope of our proposed amendments. We will consider these comments for future rulemaking. Currently, § 422.514(d)(2)(ii) already exempts from the D-SNP look-alike contracting limitations non-SNP MA plans that have been active for less than one year and have

enrollment of 200 or fewer individuals based on January enrollment of the current year. The commenter is recommending that we adopt a minimum enrollment floor alone, without the requirement that the non-SNP MA plan be a new plan. As discussed in the June 2020 final rule at 85 FR 33813, we adopted the exemption at § 422.514(d)(2)(ii) to allow for some additional flexibility for initial enrollment patterns that may not be representative of the longer term enrollment pattern for the plan. Once the initial enrollment period has passed or the number of enrollees during that first year of operation exceeds 200 enrollees, we believe the enrollment profile accurately reflects whether or not the plan was designed to exclusively enroll dually eligible individuals.

Comment: A commenter suggested that CMS couple the proposed amendments to the D-SNP look-alike policy with additional efforts to mitigate targeting of dually eligible individuals by non-integrated models, such as by considering the application of the D-SNP look-alike policy to other types of SNPs including chronic condition SNPs (C-SNPs). Another commenter noted that the proposed rule did not specify whether the proposed standards would apply to C-SNPs and requested that CMS provide more detail and transparency regarding the application of the proposal.

Response: We welcome the commenters' perspectives but clarify that the proposed amendments would not apply the D-SNP look alike contract limitations to other types of SNPs. For plan year 2022 and subsequent years, as provided in § 422.514(d)(1), CMS will not enter into a contract for a new non-SNP MA plan that projects, in its bid submitted under § 422.254, that 80 percent or more of the plan's total enrollment are enrollees who are dually eligible. For plan year 2023 and subsequent years, as provided in § 422.514(d)(2), CMS will not renew a contract with a non-SNP MA plan that has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees are dually eligible, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination. We proposed adding a new paragraph at

§ 422.514(g) to provide that § 422.514(d) through (f) apply to segments of the MA plan in the same way that those provisions apply to MA plans.

The recommendation to extend the contracting limitations at 422.514(d) to C-SNPs and I-SNPs is outside of the scope of our proposed amendments. We stated in the February 2020 proposed rule (85 FR 9021) and June 2020 final rule (85 FR 33813) that we proposed applying the requirement at § 422.514(d) only to non-SNP plans to allow for the predominant dually eligible enrollment that characterizes D-SNPs, I-SNPs, and some C-SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. At this time, we are not aware of any non-SNP MA plans with features similar to C-SNPs and I-SNPs that do not meet the C-SNP or I-SNP requirements. Nonetheless, we will monitor evolution in enrollment patterns.

Comment: Several commenters raised concerns or requested greater clarity about CMS' authority to terminate an MA contract. A commenter opposed CMS terminating an entire H contract number if CMS determined that a PBP of a health plan is a D-SNP look-alike due to having dually eligible enrollment greater than 80 percent of total enrollment and requested more detail regarding CMS' application of the proposal. Another commenter expressed concerns about CMS terminating a full MA contract when a plan segment rises above the D-SNP look-alike enrollment threshold since it would likely lead to significant disruptions in coverage and care coordination for impacted enrollees. This commenter suggested that CMS permit plans to crosswalk enrollees from MA plans that are at the 80 percent threshold or at risk of reaching the 80 percent threshold for dually eligible enrollment in a non-SNP plan, as well as add a corrective action period before the termination of an MA plan if the threshold is crossed. The commenter explained that providing such plans with the ability to crosswalk enrollees and a six-month window for corrective action may prevent CMS from needing to terminate the full MA contract and would prevent negative impacts for enrollees. Another commenter recommended that CMS provide details regarding the circumstances under which it would use the proposed authority to

terminate an MA contract instead of taking more incremental measures to achieve compliance with the proposal.

Response: We appreciate these comments and the requests for clarification. As stated in the June 2020 final rule at 85 FR 33812 and reiterated in the preamble to the proposed rule at 87 CFR 79466, we implement the contracting prohibition in § 422.514 at the *plan* level. We will similarly implement the contracting prohibition at the segment level if enrollment in the segment exceeds the D-SNP look-alike threshold.

Where an MA plan is one of several offered under a single MA contract and the MA organization does not voluntarily non-renew the D-SNP look-alike, CMS will sever the D-SNP look-alike from the overall contract using its authority under § 422.503(e) to sever a specific MA plan from a contract, and then terminate the deemed contract for the D-SNP look-alike. The other, non-D-SNP look-alike plans offered under the original contract would not be terminated. This action, in effect, allows CMS to renew only the portion of the contract that does not include the D-SNP look-alike. In this final rule, we are finalizing an amendment to § 422.503(e) to allow for CMS to sever a segment from an MA plan and allow the remaining non-D-SNP look-alike segments of that MA plan to continue along with any other non-D-SNP look-alike plans offered under the same contract.

Further, MA plans and MA plan segments that meet the criteria at § 422.514(d)(2) will have the opportunity to transition enrollees from a D-SNP look-alike per § 422.514(e). The transition authority at § 422.514(e) only permits transitioning the enrollment from the D-SNP look-alike plan or segment, that is, MA plans or segments that meet contracting limitation requirements at § 422.514(d)(2). The transition authority at § 422.514(e) does not apply to non-SNP MA plans with less than 80 percent dually eligible enrollees; a permissible crosswalk may be available depending on the circumstances. The comments about permitting transition of enrollees from plans at risk of reaching the 80 percent threshold and allowing a correction action period before termination of the MA plan meeting § 422.514(d) are out of scope for this

rulemaking; we believe that policymaking on this issue would benefit from further study and engagement with interested parties. We will consider these comments for future rulemaking.

Comment: A few commenters supported our proposal but noted that confusion can arise when crosswalk transactions are processed between segmented and non-segmented plans due to the variety of permissible scenarios. These commenters explained that in some cases CMS approved crosswalk transition plans for 2023 but MA plans later experienced incorrect denials during the plan crosswalk process despite the prior approval. These commenters believed the proposal would clarify some of this confusion but recommended that CMS work with plan sponsors to ensure approvals are clearly indicated within the Health Plan Management System (HPMS) and appropriately communicated to all parties involved in executing crosswalk transactions.

Response: We thank the commenters for their perspectives. We acknowledge that confusion can arise related to D-SNP look-alike transitions permitted under § 422.514(e) and crosswalk exceptions under § 422.530(c). We are planning enhancements to HPMS that will improve the clarity of approved and denied transactions.

Comment: A commenter requested that CMS confirm whether it is permissible to consolidate two or more existing plans into a single plan and then segment the resulting consolidated plan.

Response: We appreciate the comment. While an MA organization could consolidate two or more existing plans into one MA plan per § 422.530(b)(1)(ii) and segment the resulting consolidated plan, the resulting consolidated plan would be subject to the requirement we are finalizing at § 422.514(g).

Comment: A commenter suggested that CMS delay implementation of the contracting limitations until January 1, 2025 to align with the transition of Medicare-Medicaid Plans (MMP). The commenter added that this delay would give dually eligible individuals who are currently

enrolled in MMPs the ability to move to a D-SNP at the end of the demonstration and would give States that are currently participating in MMPs the ability to transition to D-SNPs as well.

Response: We appreciate the commenter's suggestion but do not agree. The existing D-SNP look-alike contract limitation and transition authority at § 422.514(d) through (f), and amendments finalized at § 422.514(d) and § 422.514(g) in this rule, are not necessary to facilitate MMP to D-SNP transitions. Rather, CMS will work with States participating in the Financial Alignment Initiative to transition as described in the final rule titled Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency which appeared in the **Federal Register** on May 9, 2023 (CMS-4192-F) at 87 CFR 27796 through 27798. This process is consistent with the transition of California MMPs to D-SNPs effective January 1, 2023.³ The transition of enrollees from MMPs to D-SNPs does not address our need to stem the proliferation and growth of D-SNP look-alikes now, as summarized earlier in this section and discussed in more detail in the February 2020 proposed rule (85 FR 9018 through 9021).

Comment: A commenter encouraged CMS to continue efforts to reduce incentives for non-SNP plans to focus enrollments efforts on dually eligible individuals. A commenter suggested that CMS continue to monitor and evaluate any non D-SNP plan where dually eligible individuals make up the majority of the covered lives to ensure the plan is not engaged in deceptive marketing practices. Another commenter recommended that CMS contemplate requiring Medicare to inform beneficiaries when they are enrolling in a non-integrated model where an integrated model exists.

³The California three-way contract is available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/CAContract.pdf>

Response: We appreciate the comments and agree with concerns about the potential proliferation of D-SNP look-alikes that are not required to comply with the requirements for D-SNPs and that may undermine our goals of encouraging and furthering integrated coverage options for dually eligible individuals. As described in the June 2020 final rule at 85 FR 9020, we stated that the prevalence of D-SNP look-alikes has led to instances of misleading marketing by brokers and agents that misrepresent to dually eligible individuals the characteristics of such look-alike plans, especially where the plans have marketed themselves as being special Medicaid-focused plans. We sought to reduce that prevalence through finalizing the D-SNP look-alike contracting limitations at § 422.514(d). Also in the June 2020 final rule, we codified at § 422.2262(a)(1)(xvi) a prohibition on MA organizations, with respect to their non-D-SNP plans, from marketing their plan as if it were a D-SNP, implying that their plan is designed for dually eligible individuals, targeting their marketing efforts exclusively to dually eligible individuals, or claiming a relationship with the State Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place. We will continue to monitor the level of dually eligible enrollment among non-SNP MA plans. This comment is out of scope for this rulemaking, but we will consider ways to monitor non-D-SNP plans for deceptive marketing practices and contemplate for future rulemaking a requirement to inform beneficiaries upon enrolling into a non-integrated model where an integrated model exists.

Comment: A commenter noted that the unforeseen loopholes reinforced their concerns about the overly complex nature of MA contracting and the opportunities that complexity brings for abuse, which led to the need for D-SNP look-alike regulations. This commenter emphasized that complexity hampers transparency as shown by the MA plan segment issues and recommended that CMS take a hard look at its contracting and oversight of MA plans to ensure the system is more straightforward, accountable, and transparent.

Response: We welcome this perspective. While this comment is out of scope for this rulemaking, we will consider it for future rulemaking and oversight opportunities.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to §§ 422.503(e), 422.504(a)(19), 422.510(a)(4), and 422.514(g) as proposed.

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

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

In 2020, we 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. For example, if an individual enrolls in Part B in February 2023 (during the GEP), their Part B coverage will begin on March 1st.

Based on Medicare enrollment statutory changes made by the CAA described previously, we proposed to modify § 423.38(c)(16) to provide that on or after January 1, 2023, an individual who is not entitled to premium-free Part A and who enrolls in Part B during the GEP is eligible to use the SEP for Individuals Who Enroll in Part B During the Part B GEP to request enrollment in a Part D plan, and that this SEP will begin when the individual submits the application for Part B, and will continue for the first 2 months of enrollment in Part B. Further, we proposed to modify § 438.38(c)(16) to provide that where an individual uses this Part D SEP to request enrollment in a Part D plan, the Part D plan enrollment would be effective the first of the month following the month the Part D plan sponsor receives the enrollment request.

These proposed revisions are needed to align the timeframe for use of this Part D SEP based on new Part B GEP enrollment effective date parameters.

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

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

We received a number of comments on this proposal – those comments and our responses follow.

Comment: All commenters supported our proposal to align the timeframe for use of this SEP based on the revised GEP effective date parameters established by the CAA. One commenter stated that they support beneficiaries' access to affordable, quality health coverage, and that this change would reduce potential coverage gaps. Another commenter agreed that this change would help alleviate potential coverage gaps, and added that it would simplify the process for beneficiaries and their caregivers, as it will align the effective date of Part D coverage with the effective date for other Part D SEPs. Another commenter stated that they support policies that support enrollment alignment across Medicare Parts A, B, C and D.

Response: We thank 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.

Comment: 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.

Response: CMS 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. Per current procedures outlined in the CMS Plan Communications User Guide, Part D sponsors must verify Part D eligibility/Medicare entitlement by either the Batch Eligibility Query (BEQ) process or the MARx online query (M232 screen) or its equivalent for all enrollment requests except enrollment requests from a current enrollee of a PDP who is requesting enrollment into another PDP offered by the same parent organization with no break in coverage (that is, "switching plans"). CMS systems are updated within two business days of SSA processing new or changed Part A or Part B entitlement for a Medicare beneficiary. If the

plan needs to validate the individual's Part A entitlement status, that code/information can be found in the Part A Entitlement Status column on the M257 screen in MARx.

Comment: 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. They further stated that, the window for applying for premium-Part A in the 14 group-payer states is limited to the GEP, so, group-payer states can delay the individual's ability to take advantage of the proposed Part D SEP.

Response: We thank the commenter, but the parameters for applying for premium-Part A in group-payer states are outside of the scope of this rule.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing 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) without modification.

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

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

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

with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA-PD plan under the following provisions of section 1851.”

As required by section 1851(a)(3) of the Act (for the MA program) and section 1860D-1(a)(3)(A) of the Act (for the Part D program) and described in §§ 422.50(a)(1) and 423.30(a)(1)(i), eligibility for MA or Part D plan enrollment requires that an individual first have Medicare Parts A and B for MA eligibility and either Part A or B for Part D eligibility. Division CC, title I, subtitle B, Section 120 of the CAA established section 1837(m) of the Act to authorize the Secretary to establish Part B SEPs for individuals who are eligible to enroll in Medicare and meet such exceptional conditions as the Secretary provides. Per section 1818(c) of the Act, the provisions of section 1837 of the Act, excluding subsection (f) thereof, applies to the premium Part A program. This authority to adopt exceptional conditions SEPs for premium Part A and Part B was effective January 1, 2023. CMS finalized new exceptional condition SEPs under section 1837(m) of the Act in 42 CFR 406.27 and 407.23 for Medicare parts A and B, respectively, in a final rule that was published in the **Federal Register** on November 3, 2022, titled “Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules” (87 FR 66454). These SEPs are available to individuals who have missed an enrollment period due to an exceptional condition that is specified in the final rule. Specifically, individuals who miss an IEP, GEP, or another SEP, such as the Group Health Plan SEP, due to an exceptional condition, would be eligible to enroll in Medicare premium Part A or Part B using the new SEPs.

Based on Medicare enrollment changes made by the CAA described previously, we proposed to add corresponding exceptional condition SEPs for MA and Part D enrollment, as authorized under sections 1851(e)(4)(D) and 1860D-1(b)(3)(C) of the Act, to align with the new Medicare premium-Part A and B exceptional condition SEPs that CMS has finalized in 42 CFR 406.27 and 407.23.

We proposed at § 422.62(b) to redesignate current paragraphs (26) as (27) and add a new

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

The proposed new MA SEP would begin when the individual submits the application for premium Part A and Part B, or only Part B, and would continue for the first 2 months of enrollment in Part A (premium or premium-free) and Part B. Similarly, the proposed new Part D SEP would begin when the individual submits their premium-Part A or Part B application and would continue for the first 2 months of enrollment in premium Part A or Part B. The MA or Part D plan enrollment would be effective the first of the month following the month the MA or Part D plan receives the enrollment request.

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

Consequently, finalizing these SEPs will not have added impact. All burden impacts of these provisions have already been accounted for under OMB control number 0938-1378 (CMS-10718). We do not believe finalizing these SEPs will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees. Similarly, we do not believe the finalized SEPs will have any impact to the Medicare Trust Funds.

We received a number of comments on this proposal – those comments and our responses follow.

Comment: All commenters supported our 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. A few commenters expressed that the availability of these SEPs would reduce potential coverage gaps and help prevent late enrollment penalties. Another commenter stated that they support the timely access to prescription drugs, and these new SEPs would allow vulnerable beneficiaries access to prescription drug coverage to become effective the first of the month following the month the plan sponsor receives the enrollment request. One commenter stated that they support policies that promote enrollment alignment across Medicare Parts A, B, C and D. Another commenter stated that their priority is to improve beneficiary experience by reducing confusion and to align program dates within Medicare or between Medicare and Medicaid. They further stated that this will provide Medicare beneficiaries with the opportunity to learn about and enroll in MA special needs plans (SNPs). The commenter added that an ongoing issue for beneficiaries and stakeholders is the lack of understanding of the availability of SNPs, and that this will provide another opportunity for CMS to provide beneficiaries with the very important choice of fee-for-service vs. MA, and MA vs. SNPs.

Response: We thank the commenters for their support of our 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.

Comment: 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. Accordingly, they requested CMS to clarify how the start of the SEP factors into a plan processing an enrollment request using the SEP.

Response: 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. The SSA will have to first process the individual's premium Part A and/or Part B application and submit that information into SSA systems, which, in turn, would be populated in the CMS enrollment systems, for an MA or Part D plan to have access to that enrollment information.

- For MA enrollment, the SEP begins when the individual, using an exceptional condition SEP, submits their application for--
 - ++ Premium-Part A and Part B; or
 - ++ Part B only, if the individual is already entitled to Part A, (or enrolls in premium-free Part A within the timeframe for use of this SEP).

- For Part D enrollment, the SEP begins when the individual, using an exceptional condition SEP, submits their premium-Part A or Part B application.

We note that the timeframe for use of both of these SEPs extends two months beyond the premium-Part A and/or Part B entitlement date, which will be visible to plans.

Comment: A 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. Another commenter suggested that CMS consider creating an SEP that would allow cancer patients to switch back to Original Medicare, in the case where a patient in an MA plan receives a cancer diagnosis and is unable to access needed treatment in a timely manner. The commenter also recommended that CMS create an ongoing open enrollment window for patients diagnosed with cancer, which would automatically provide the benefits of having comprehensive in-network care.

Response: We thank the commenters for their feedback; however, we proposed 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, and these comments are outside of the scope of this rulemaking.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, 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. We are finalizing the Part D enrollment SEP at 423.38(c)(34) as proposed without modification.

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

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

a. Background on the LI NET Demonstration

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

From the beginning of Part D, CMS recognized the need to provide both immediate and retroactive coverage for full-benefit dually eligible (FBDE) beneficiaries who were newly identified by either CMS or a State. Prior to 2010, CMS automatically enrolled newly identified beneficiaries eligible for the Part D low-income subsidy (LIS) into a Part D plan with a premium at or below the low-income benchmark (“benchmark” plans), which have no or reduced premiums for LIS-eligible beneficiaries. Each benchmark plan receiving these beneficiaries was required to grant retroactive coverage to the beginning of a beneficiary’s LIS-eligible status or

their last uncovered month, whichever date was later. At the time, there were around 300 Part D benchmark plans, and each needed to develop the capacity to provide transitional and retroactive coverage for these beneficiaries. Conducting retroactive claims adjudication and providing point-of-sale coverage was not efficient for Part D sponsors and accordingly, in 2010, CMS established the Medicare Part D Demonstration for Retroactive and Point of Sale Coverage for Certain Low-Income Beneficiaries, also known as Medicare's Limited Income Newly Eligible Transition (LI NET) demonstration. The LI NET demonstration consolidates administration of transitional and retroactive Part D coverage for eligible beneficiaries to a single Part D sponsor.

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

The purposes of the demonstration are to provide the following:

- More efficient prescription drug coverage and claims reimbursement for newly eligible low-income beneficiaries, including periods of retroactive eligibility;
- More efficient prescription drug coverage and claims reimbursement for individuals who are not enrolled in a PDP and whose LIS status is not yet established in CMS' systems, but who arrive at a pharmacy with an immediate need for their prescription. This may occur, for instance, when a State has determined that a beneficiary is eligible for Medicaid but that information does not yet appear in CMS' systems;
- A seamless transition for LIS-eligible beneficiaries from LI NET into a qualifying PDP with basic prescription drug coverage absent a beneficiary's choice otherwise; and

- More efficient prescription drug coverage and claims reimbursement for LIS-eligible beneficiaries who are losing existing coverage in a PDP. For example, a beneficiary could be terminated for moving out of the service area of their current PDP. The beneficiary would be automatically enrolled into LI NET for that month and the following month, with enrollment into a qualifying PDP with basic prescription drug coverage that would become effective at the end of the LI NET enrollment absent the beneficiary's choice otherwise.

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

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

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

LI NET policies, infrastructure, and operations have evolved over the past 13 years to balance providing needed coverage with responsible stewardship of taxpayer dollars and efficiency in administering the program. The LI NET demonstration has proven successful in providing low-income individuals transitional Part D coverage. Approximately 8 million low-income individuals received the benefits of the LI NET program under the demonstration, with over 100,000 beneficiaries enrolled in LI NET in any given month. It has become a program that beneficiary advocacy groups rely on when supporting low-income individuals and connecting them with services. LI NET works directly with over a dozen advocacy groups and 51 State Health Insurance Assistance Programs (SHIPs), which collectively work with LIS beneficiaries to remove access barriers and provide health insurance counseling.

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

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

Our proposals to make LI NET a permanent program started with § 423.2500. In § 423.2500(a), we proposed the LI NET program would be based on section 1860D-14 of the Act. We proposed in § 423.2500(b) the scope of the LI NET program, which would begin no later than January 1, 2024. Under this program, eligible individuals would be provided transitional coverage for Part D drugs. Section § 423.2504 sets forth the LI NET eligibility and

enrollment proposals and § 423.2508 proposed LI NET benefits and beneficiary protections. Next, we proposed in § 423.2512 the requirements to be an LI NET sponsor and § 423.2516 proposed how the Part D sponsor administering LI NET in partnership with CMS would be selected and the requirements set forth in the LI NET contract to provide services and coverage. In § 423.2518, we included a proposal for intermediate sanctions in the event of contract violations. In § 423.2520, we proposed how an LI NET contract would be non-renewed or terminated. In § 423.2524, we included our proposals for bidding and determining the LI NET payment rate. Finally, § 423.2536 enumerated the Part D requirements we proposed waiving for LI NET.

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

2. Eligibility and Enrollment

a. Eligibility

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

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

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

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

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

We refer to the individuals in the category established in proposed paragraph (a)(2) as “immediate need” because they present at a pharmacy or to the LI NET sponsor in immediate need of a prescription and have no Part D coverage. Ideally, these beneficiaries would be able to show documentation of their pending LIS status, such as a letter received from the State showing the beneficiary’s LIS status. However, we do not believe an absence of documentation in hand at the point-of-sale should be a barrier to entry to LI NET for immediate need individuals. This is because our experience in the demonstration is that 80 percent of immediate need individuals do

have their eligibility confirmed,⁴ and we would not want to turn away these individuals who imminently require access to their prescription drugs. Under the LI NET demonstration, individuals can indicate the likelihood of their low-income status by providing the evidence they have, which can include verbal explanations of why they consider themselves eligible.

We proposed in § 423.2504(a)(2) to grant immediate access to covered Part D drugs at the point-of-sale for individuals whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale. We proposed to permit immediate need individuals to provide documentation to the LI NET sponsor to confirm LIS eligibility. Documentation could include, but would not be limited to--

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

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

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

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

b. Enrollment

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

- Automatic enrollment. Individuals who are LIS-eligible but do not yet have Part D coverage, and those individuals who have selected a Part D plan but whose enrollment has not taken effect, are enrolled by CMS into the LI NET demonstration unless the beneficiary has affirmatively declined enrollment in Part D.
- Point of sale enrollment. Immediate need individuals whose claims are submitted by the pharmacy at the point-of-sale and billed to LI NET are enrolled into the LI NET demonstration by the LI NET sponsor.
- Direct reimbursement request. Individuals who are LIS-eligible and who submit receipts for reimbursement for claims paid out of pocket are retroactively enrolled into the LI NET demonstration by the LI NET sponsor, with 36-month retroactive coverage for full dually eligible individuals and those who receive supplemental security income (SSI) benefits.

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

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

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

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

A smaller number of beneficiaries, about five to ten percent of LI NET beneficiaries, enroll in the LI NET demonstration outside of the sweeps process. Some enroll at the point-of-

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

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

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

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

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

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

proposed that LI NET coverage would end with enrollment into a Part D plan or opting out of Part D coverage.

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

We provided the following two examples to further explain how LI NET enrollment and disenrollment would work under our proposals:

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

Example 2: The Social Security Administration notifies CMS in February 2024 that Beneficiary Ilan was eligible for both Medicare and SSI starting in November 2022. CMS provides Ilan retroactive Medicare drug coverage from November 2022, which is the later of 36

months prior to enrollment in a Part D plan or the date Ilan was first LIS eligible, through March 2024. After March 2024, if Ilan does not actively enroll in a plan of their choosing, CMS would randomly enroll them into a benchmark PDP with an April 1, 2024 effective date.

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

3. Benefits and Beneficiary Protections

Section 1860D-14(e)(4)(B)(i) of the Act requires the LI NET program to provide eligible beneficiaries with access to all Part D drugs under an open formulary. The statute, at clauses (ii) and (iii) of section 1860D-14(e)(4)(B) of the Act, also requires the LI NET program to permit all pharmacies that are determined by the Secretary to be in good standing to process claims under the program, and to be consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication. These requirements are consistent with how the LI NET demonstration has operated, and we proposed to codify the requirement that the LI NET program provide access to all Part D drugs under an open formulary in § 423.2508(a). We proposed in § 423.2508(b) to require the LI NET sponsor to permit all pharmacies that CMS determines to be in good standing to process claims under the program, whether or not the pharmacy is a network or out-of-network (OON) pharmacy for the LI NET sponsor. Under the demonstration, we consider a pharmacy, including retail, mail-order, and institutional pharmacies, to be “in good standing” when it is licensed and does not have a fraud, waste, or abuse determination against it. For the permanent LI NET program, we proposed that a pharmacy would be in good standing if it is licensed, has not been revoked from Medicare under § 424.535, does not appear on the Office of Inspector General’s list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act and from Medicare

under section 1156 of the Act (unless the OIG waives the exclusion, which the OIG has authority to do in certain specified circumstances), and does not appear on the preclusion list as defined in § 423.100. A pharmacy will appear on the preclusion list if it:

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

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

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

We solicited comment on whether any of these provisions would not be compatible with the LI

NET program as proposed.

Section 1860D-14(e)(4)(B)(iv) of the Act provides the Secretary the authority to establish requirements for the LI NET coverage provided to LI NET eligible individuals. As noted in the proposed rule, we drew upon our experience under the demonstration to develop our proposed cost sharing and appeals policies for LI NET, which we proposed to codify in § 423.2508(d) and (e), respectively.

We proposed in § 423.2508(d)(1) that LI NET beneficiaries under § 423.2504(a)(1) (that is, beneficiaries whose LIS-eligibility is established and who have not yet enrolled in a prescription drug plan or MA-PD plan, or who have enrolled in a prescription drug or MA-PD plan but coverage under such plan has not yet taken effect) would pay the applicable cost sharing for their low-income category as established in the yearly Announcement of Calendar Year Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Rate Announcement publication specified in § 422.312). Under the demonstration, LI NET beneficiaries pay the reduced cost-sharing aligned with the LIS categories defined in the Part D program. Because there is already the existing statutory requirement for CMS to update the parameters for the LIS benefit each year using statutory indexing methods, and because CMS and pharmacy systems are already set up to reflect the appropriate cost-sharing based on the LIS category of the individual, we believe it is reasonable to calculate and charge cost-sharing in alignment with the Part D LIS categories. For immediate need beneficiaries, we proposed in § 423.2508(d)(2) these individuals would by default pay the cost-sharing associated with the category of non-institutionalized FBDE individuals with incomes above 100 percent of the Federal poverty level and full-subsidy-non-FBDE individuals (that is, Category Code 1)⁶. Of the four LIS eligibility categories, this category has the highest level of cost-sharing. Proposed § 423.2508(d)(2) would further provide that if the beneficiary is later confirmed to belong to a

⁶Cost-sharing amounts in Part D are established each year in the Rate Announcement. Final Part D benefit parameters can be found for a plan year at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Announcements-and-Documents>.

different LIS category, the beneficiary would be refunded by the LI NET sponsor for the difference between the cost sharing they paid versus what they would have paid in their confirmed LIS category. This approach allows for the least government liability for individuals whose LIS eligibility is unable to be confirmed while still allowing prescription drug access for immediate need individuals.

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

4. LI NET Sponsor Requirements

Section 1860D-14(e)(4)(A) of the Act specifies that, as determined appropriate by the Secretary, the LI NET program is to be administered through a contract with a single administrator. Since the beginning of the demonstration, CMS has had one Part D sponsor serve as the sole contractor for administering LI NET. We have found that this approach supports our goal of administrative simplicity by making it unnecessary for each individual plan sponsor to check eligibility and conduct a retroactive enrollment/reimbursement process. In our experience, the benefits of having a single Part D sponsor administer LI NET include the following:

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

There may be circumstances in which CMS may want to consider contracting with more than one Part D sponsor to administer LI NET. Though we have had stability in LI NET in terms of only having a single LI NET sponsor for the duration of the demonstration, we recognize the need for some protections should it become necessary for another entity to take over as LI NET sponsor and assume responsibility for providing LI NET coverage. The downside of consolidating LI NET functions into a single sponsor is the potential for beneficiary impact should there be a reason that the single LI NET sponsor no longer continues its functions. We believe that this potential for beneficiary impact is mitigated by our proposals to non-renew or terminate the LI NET contract per proposed § 423.2520. Accordingly, while we proposed at new § 423.2512 that the program will be operated by “one or more” Part D sponsors, we intend to initially continue with the current practice of operating the program through a single sponsor because we determined the benefits outweigh potential beneficiary impacts, which have not come to bear since the start of the demonstration in 2010.

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

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

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

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

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

Reimbursement to beneficiaries with retroactive coverage is provided for in section 1860D-14(e)(3)(B) of the Act, as the “amounts that would have been paid under this Part had such individual been enrolled in a prescription drug plan or MA–PD plan.” Implementing this statutory provision entails establishing a process for beneficiaries to request and receive such reimbursement. In the demonstration, we provide a means for beneficiaries who receive

retroactive coverage to submit a direct member out-of-pocket reimbursement request for Part D covered drugs for any past month(s) in which they were entitled to retroactive coverage under LI NET. The LI NET sponsor provides reimbursement to eligible beneficiaries based on the submitted cost minus any applicable copayments. Once the LI NET sponsor receives a written reimbursement request, they follow timeframes that are consistent with the timeframes that apply when a Part D sponsor authorizes payment for a benefit due to a reversal in its coverage determination (see § 423.636(a)(2)). That is, under the demonstration, the LI NET sponsor has 14 calendar days to reply with whether the claim is eligible for reimbursement, including the reason for denying the request if applicable. If the request for reimbursement is granted, the LI NET sponsor issues the reimbursement no later than 30 days after it determines the claim is eligible for reimbursement. As these timeframes have proved workable under the demonstration, we proposed in § 423.2512(c)(5) that the LI NET sponsor meet these deadlines related to direct reimbursement in the permanent LI NET program.

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

5. Selection of LI NET Sponsor and Contracting Provisions

Section 1860D-14(e)(6) of the Act authorizes us to implement LI NET without regard to laws relating to the making, performance, amendment, or modification of contracts of the United

States as we may determine to be inconsistent with the furtherance of the purpose of Title XVIII. Thus, CMS is not required to follow the Federal Acquisition Regulation (FAR) or the contracting authority used under the Part D program. Neither is CMS required to contract with every qualified plan sponsor to provide LI NET Part D coverage, as we are required to do for qualified plan sponsors providing non-LI NET Part D coverage. If we followed the same approach for LI NET, we could have many points of contact for beneficiaries and pharmacies attempting to have their retroactive claims paid and multiple points of contact for State Medicaid agencies submitting Medicaid eligibility and attempting to reconcile and coordinate claims. This approach would not serve the purpose of providing smooth, transitional coverage for Part D drugs for LI NET eligible individuals through the LI NET program, which is a Part D program under Medicare in Title XVIII.

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

In § 423.2516(a), we proposed that CMS would appoint a Part D sponsor that meets the requirements at § 423.2512 to serve as the LI NET sponsor. To determine this appointment, we proposed that CMS may choose to conduct discussions with potentially eligible entities to establish mutual interest and ability to administer the program. This circumstance could arise if, for example, CMS needs additional information in any particular year to learn more about a Part D sponsor's ability to administer the LI NET program. Under the demonstration, there is a multi-year contract approved by the Office of Management and Budget, and each year CMS and the LI NET sponsor have executed an addendum to the contract that included such information as the payment rates and risk corridors as determined in the final bid. As we consider options for establishing regulations to implement the permanent LI NET program, we find it is appropriate that we bring the LI NET contractor into closer alignment with other contracts in the Part D program by executing an LI NET contract with a Part D plan sponsor each plan year that

contains, among other information, payment information for that year. Our expectation is that unless circumstances shift to prompt a change, the existing LI NET sponsor would continue in that role in the succeeding year. Therefore, in § 423.2516(b), we proposed selection criteria CMS may use in appointing an LI NET sponsor based on some features of the LI NET program that are related to a Part D sponsor's ability to successfully administer the program. These are--

- Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.34;
- Pharmacy access as outlined in § 423.120;
- Past performance consistent with § 423.503(b), including Star Ratings (as detailed in § 423.186), and previous intermediate sanctions (as detailed in § 423.750); and
- Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536.

As noted in the proposed rule and consistent with our general approach of applying Part D requirements to the LI NET program unless waived, we stated our intention for § 423.505 to apply to LI NET with the exception of § 423.505(k)(6), which we proposed to waive in § 423.2536(g). For example, the contract between the LI NET sponsor and CMS would be required to contain provisions in which the LI NET sponsor agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments (see § 423.505(a) and (b)(2)). As another example, consistent with § 423.505(b)(22), the LI NET contract would be required to include a provision in which the LI NET sponsor agrees to use the CMS complaint tracking system to address and resolve complaints received by CMS against the sponsor. Per § 423.505(k), the LI NET contract would also require the LI NET sponsor to submit certifications of data that determine payment as applicable, such as for enrollment and payment information, claims data, bid submission information, DIR data, and overpayments. The only certification the LI NET sponsor would not submit is the one pertaining to data for price comparison under § 423.505(k)(6); we believe this

certification is unnecessary given that the LI NET plan is not one for which beneficiaries shop and thus would not be comparing against other plan options based on price considerations. We intend to exclude LI NET from Medicare Plan Finder, consistent with past practice under the demonstration. Therefore, it would not make sense to require certification to data for price comparison purposes, and we proposed to waive this requirement in § 423.2536(g).

In § 423.2516(c), we proposed that the term of the LI NET sponsor's appointment would be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per proposed § 423.2524(c)) to determine payment rates for the upcoming year. As explained in the proposed rule, this approach has worked well during the demonstration, and we saw no reason to adopt a different approach for the permanent program.

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

In § 423.2520(a) we proposed that if the LI NET sponsor decides for any reason to non-renew its existing LI NET contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS would notify the LI NET sponsor by January 1 of the year before the next contract year. We proposed that CMS could non-renew for any reason, without cause, and the LI NET sponsor would not have a right to appeal the non-renewal. To provide CMS the authority to non-renew the LI NET contract with that particular sponsor for any reason with no appeal, we proposed in § 423.2536(e) waiving the appeals requirements in Subpart N except for those relevant to a contract termination. As there has only been a single LI NET sponsor for the duration of the demonstration, and we are anticipating a single LI NET sponsor for the permanent LI NET program, we do not want to assume the risk of the appeals process not providing finality by the time an LI NET sponsor would need to begin preparing the LI NET bid. Even if we required the appeals process to be

complete by the April timeframe and while the appeal was pending moved forward with selection process, we would be cutting into or needing to forgo entirely the transition time of 3 months we proposed in § 423.2520(b) to ensure seamless transition of the LI NET program. Proposing to assume these risks would not further the purpose of the LI NET program being ready and available to provide immediate, current, and retroactive coverage for LI NET enrollees. We note that non-renewal, whether at the election of CMS or the LI NET sponsor, would not have an impact on the sponsor's eligibility to be selected as the LI NET sponsor in future years. We intend to initially contract with a single Part D sponsor to administer the LI NET program. Unlike beneficiaries in traditional Part D plans, beneficiaries enrolled in LI NET would not have the option of simply choosing to enroll in LI NET under a different sponsor. For these reasons, ample notice is needed if the LI NET sponsor does not intend to continue as the LI NET sponsor in the following year. We anticipate that CMS would be able to provide the same amount of notice to the LI NET sponsor if we were contemplating changing the LI NET sponsor for the following year. A decision to non-renew the LI NET contract with a particular Part D sponsor would not bar or prohibit that sponsor from being considered to be the LI NET sponsor in a future year. Any CMS decisions regarding LI NET sponsor selection would have no bearing on a Part D sponsor proceeding with the application process for other, non-LI NET, Medicare prescription drug plans.

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

transition period, the outgoing and incoming LI NET sponsors would work together to develop a transition plan, including setting up a training schedule and a schedule of events for a smooth changeover.

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

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

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

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

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

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

6. Bidding and Payments to the LI NET Sponsor

Section 1860D-14(e) of the Act does not specify how CMS is to determine the amounts that it pays to the LI NET sponsor under the contract or how payments are to be made. We proposed to establish the methodology and formulas that we would use to determine the amounts we pay to the LI NET sponsor under the contract. As noted in the proposed rule, we use our payment policies under the demonstration, including the bidding requirements, as the basis for the proposed payment policies for the LI NET program.

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

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

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

We proposed in § 423.2524(b)(2) that the following provisions would apply in the review, negotiation, and approval of the LI NET bid: § 423.272(a), (b)(1), and (b)(4). This would

allow CMS to review the LI NET bid, conduct negotiations regarding the terms and conditions of the proposed bid, and approve it only if the bidding LI NET sponsor and the LI NET plan comply with all applicable CMS Part D requirements. As in typical Part D bid reviews, CMS would be able to decline the LI NET bid if it proposed significant increases in cost sharing (§ 423.272(b)(4)). This approach follows the bid process under the demonstration, in which the LI NET sponsor submits a bid that estimates their costs and includes assumptions for enrollment and utilization based on prior experience. Starting with plan year 2021, the LI NET sponsor began using an LI NET Bid Pricing Tool (BPT) and accompanying instructions that were adapted from the traditional Part D BPT and instructions. Once the LI NET bid is accepted, we update this information in our systems for the new payment year for the LI NET demonstration. Each year, we advance by one the number designating the current plan benefit package. For example, the contract-PBP was X0001-011 for plan year 2021 and X0001-012 for plan year 2022.

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

In § 423.2524(c) we proposed that CMS would provide advance monthly LI NET payments, on a per-member, per-month (PMPM) basis, equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid submitted annually under paragraph (b) of this proposed section. Paying on a PMPM basis would align with other Part D payments and with our operations under the LI NET demonstration in which we provide a capitated PMPM amount established by the bid for each beneficiary enrolled in the demonstration. Unlike typical Part D monthly payments, the monthly LI NET payment under the demonstration is a PMPM amount that represents the sum of Payment Rates A and B, as determined by the LI NET bid. The bid represents the LI NET sponsor's total expected cost, minus any beneficiary co-pays, and with a reasonable margin that represents the LI NET sponsor's profit. Also, unlike other Part D

payments, payments under the LI NET demonstration would not be risk adjusted. Because payments under the LI NET demonstration are cost reconciled (with the exception of risk corridors) and there is no concern about the LI NET sponsor cherry-picking beneficiaries, we use a simpler payment methodology that does not include risk adjustment.

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

In § 423.2524(c)(2), we proposed that Payment Rate B would reflect the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit. Payment Rate

B would be the estimated actual drug costs minus direct and indirect remuneration (DIR). In the demonstration, we apply risk corridors to Payment Rate B so that excess gains and losses are shared between CMS and the LI NET sponsor. These risk corridors are symmetrical in sharing upside and downside risk, but are narrower than the risk corridors provided for under section 1860D-15(e) of the Act and applicable to other Part D plans. Because the risk corridors in the demonstration are so narrow, the LI NET sponsor has not assumed as much risk for LI NET as traditional Part D plans assume. CMS has not shared risk on Payment Rate A, in keeping with typical Part D plans for which CMS does not share risk on margin or administrative costs. In 2012, CMS revised the risk corridors under the LI NET demonstration to limit payment adjustments on Payment Rate B. For the portion of a plan's cost for drugs that is between the target amount and the threshold upper limit (101 percent of the target amount), the LI NET sponsor pays 100 percent of this amount. For the portion of the plan's cost for drugs that exceeds the threshold upper limit, the government pays 99.9 percent and the plan pays 0.1 percent. Similarly, if a plan's cost for drugs is between the target amount and the threshold lower limit (99 percent of the target amount), the LI NET sponsor keeps 100 percent of the difference between the drug cost and the target amount. If a plan's cost for drugs is lower than the threshold lower limit, the government keeps 99.9 percent and the plan keeps 0.1 percent of the difference between the plan's drug cost and the threshold lower limit.

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

annual PDE data submission deadline has passed and make the resulting payment adjustment consistent with § 423.343(a).

In § 423.2524(d)(2), we proposed to establish the same risk corridors for Payment Rate B that apply under the demonstration: no risk sharing within 1 percent of the target amount and symmetrical 0.1 percent risk sharing beyond the 1 percent corridor. To carry out risk sharing as part of reconciliation, we proposed to have § 423.336(c) apply to LI NET, which requires a plan sponsor to provide necessary cost data information to CMS and authorizes CMS to make either lump-sum payments or adjustments based on the risk corridor calculations.

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

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

7. Part D Program Waivers

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

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

Section 1860D-14(e)(5)(B) of the Act contains broad waiver authority to “waive such other requirements of title XI and this title as may be necessary to carry out the purposes of the program established under this subsection”. We also proposed to waive for LI NET some of the cost control and quality improvement requirements in Part 423 Subpart D, except for the provisions we explicitly proposed to adopt in § 423.2508(d)(1) through (d)(5) that relate to appropriate dispensing, patient safety, electronic dispensing, QIO activities, compliance, and accreditation. This proposal would waive requirements that would not make sense in the context

of temporary coverage with access to an open formulary. The requirements we proposed to waive pertain to drug utilization management programs, medication therapy management programs, and consumer satisfaction surveys.

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

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

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

We proposed in § 423.2536(j) to waive the MLR requirements in subpart X of Part 423. Section 1857 of the Act as incorporated into section 1860D-14(e) does not speak to MLR requirements for LI NET. Under the LI NET demonstration, CMS does not require the LI NET sponsor to meet the minimum medical loss ratio (MLR) requirement or to report the MLR for the LI NET contract as it does for other Part D contracts. This is due to the unique payment structure for the contract. Under Part D, a sponsor submits a single bid including estimated administrative costs, returns on investment, and drug costs, which are risk-adjusted. After a payment year concludes, Part D sponsors are required under subpart X of Part 423 to report the MLR for each contract, and if the MLR for a contract is below 85 percent, the sponsor is required to remit payment to CMS. Enrollment sanctions are applied to contracts that fail to meet the minimum MLR requirement for 3 consecutive years, and contracts that fail to meet the requirement for 5 consecutive years are subject to termination. The minimum MLR requirement is intended to

create incentives for Part D sponsors to reduce administrative costs such as marketing costs, profits, and other such uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. Because of the limits we proposed to place on how much administrative costs in LI NET under Payment Rate A can increase year over year and because of the differing payment structure, we do not believe MLR reporting should be applicable to LI NET.

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

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

8. Technical Corrections

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

We also proposed to make a technical correction in the header of subpart Z of Part 423. The header in regulation text currently is “Recovery Audit Contractor Part C Appeals Process” when it should be referring to Part D. Thus, we proposed to make the technical correction so the header correctly reads, “Recovery Audit Contractor Part D Appeals Process.”

We received a number of comments on the LI NET proposals. Summaries of the comments and our responses follow.

Comment: All comments we received on the LI NET provision stated broad support of our proposals to make LI NET a permanent program. One commenter specifically noted that our proposal will simplify and expand access for the dually eligible population, in addition to the partial-benefit dually eligible population.

Response: We thank commenters for their support.

Comment: One commenter questioned whether each MA organization needs to have programs in place to track low-income beneficiaries’ eligibility for LI NET, provide LI NET benefits, and manage LI NET enrollment.

Response: Only the LI NET sponsor appointed by CMS in accordance with § 423.2516 will have responsibility for administering the LI NET program. Other Part D benchmark plans may receive beneficiary enrollments automatically from CMS, and such enrollments could include beneficiaries who were enrolled in LI NET. The process of identifying low-income beneficiaries who may be eligible for LI NET is set forth in § 423.2504.

Comment: A few commenters encouraged us to consider additional outreach to LI NET beneficiaries during their temporary enrollment in LI NET to support beneficiaries in selecting an appropriate Part D plan for themselves if they so choose.

Response: All beneficiaries who are enrolled into the LI NET demonstration receive information at the beginning of their LI NET enrollment that describes how they can choose a specific plan for their individual circumstances or allow CMS to automatically enroll them into a benchmark plan following their enrollment in LI NET. In the demonstration, the beneficiary's welcome letter states in plain language that the LI NET beneficiary has the right to choose a plan, and lists resources like 1-800-MEDICARE, a link to Plan Compare (Plan Finder), and the phone number for Eldercare Locator. Under the demonstration, CMS automatically enrolls beneficiaries into a benchmark plan. LIS-eligible beneficiaries who wish to change plans may use a special election period (SEP) to move to another plan, and instructions for how to join a different plan are also described in CMS' notices to beneficiaries. As is routine for all beneficiary communications regarding Medicare, instructions that include the phone number for LI NET beneficiaries to call for language assistance services are provided in numerous languages to broaden the reach of beneficiary communications. We are finalizing § 423.2512(c)(3), which will require the LI NET sponsor to conduct outreach in consultation with CMS, as proposed. We anticipate that outreach under the LI NET program will be substantially similar to outreach that has been conducted under the demonstration to date.

Comment: A few commenters believed 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. Two of the commenters also referenced "best available evidence" (BAE) standards in relation to LI NET. One commenter relayed a belief that the CMS contractor reviewing BAE is too strict and improperly excludes LTC residents from receiving LIS status. According to the commenter, this causes LTC pharmacies to unfairly absorb the cost

of prescription drugs and related LTC pharmacy services that they are legally obligated to provide to LTC facility residents for whom LIS status does not get established.

Response: We proposed at § 423.2504(a)(2)(i)(A) through (F) a list of documents that would be sufficient for an immediate need beneficiary to demonstrate LIS eligibility. A copy of a letter from SSA showing LIS status is item (B) on the list. The documentation listed in proposed § 423.2504(a)(2)(i)(A) through (F) would be appropriate for any individual to submit in order to enroll in LI NET in circumstances where they are not automatically enrolled. After consideration of these comments, we are modifying our proposal to clarify that these documents can be submitted by any individual to determine LIS eligibility, regardless of whether they are enrolling in LI NET at the POS, through a direct reimbursement request, or by submitting an LI NET application form. We are modifying our proposed regulations at § 423.2504(b) to make conforming changes.

We also take this opportunity to clarify that the list of documentation of LIS eligibility in proposed § 423.2504(a)(2)(i)(A) through (F) is a non-exhaustive list of types of “best available evidence” as defined in § 423.772. “Best available evidence” in § 423.772 means “evidence recognized by CMS as documentation or other information that is directly tied to State or Social Security Administration systems that confirm an individual’s low-income subsidy eligibility status, and that must be accepted and used by the Part D sponsor to change low-income subsidy status.” As applied to LI NET, when a beneficiary chooses to provide documentation at the POS, with their direct reimbursement request form, or with their LI NET application form, the documentation is reviewed by CMS and upon approval the LI NET sponsor would change the beneficiary’s LIS status appropriately.

In § 423.2504(b)(3), the proposed rule refers to individuals submitting receipts for reimbursement for claims paid out of pocket when making a direct reimbursement request. We finalize § 423.2504(b)(3) with a modification to clarify that that we are referring to “eligible claims”. This change makes explicit that eligible claims, namely those for Part D drugs from

dates when the person was retroactively LIS eligible, are needed for enrollment to successfully occur using a direct reimbursement request.

In § 423.2504(b)(4), for consistency in referring to the documentation that may be optionally submitted along with the LI NET application form, we revise the proposed language of “supporting documentation demonstrating their LIS status” to “optional documentation of LIS eligibility listed in [new] paragraph (a)(3)” and clarify that if no documentation is submitted and accepted, the LI NET sponsor will periodically check for eligibility and enroll applicants once LIS eligibility is confirmed.

In making these clarifications, we note that LI NET individuals will be enrolled via one of the four enrollment options. Though they can, for example, submit an LI NET application form and a direct reimbursement request form at the same time, the first in time to effectuate the enrollment will be the way in which the beneficiary is enrolled.

In sum, to clarify the role of documentation in LI NET, we are finalizing § 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”; and
- 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) through (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”, we also add for clarity the term “Extra Help” to § 423.2504(a)(3)(ii).

Comment: One commenter noted 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.

Response: We agree that beneficiaries who present at the point-of-sale who do not have an immediate need for medication as defined in § 423.2504(a)(2) may use the POS mechanism of enrollment if they are otherwise eligible for LI NET and have not been automatically enrolled. Thus, we finalize this provision to include these beneficiaries by striking “with an immediate need” from the description of point-of-sale enrollment in § 423.2504(b)(2). The change would

allow for individuals to use the POS enrollment mechanism if they are either an “immediate need individual” per § 423.2504(a)(2) or if they present documentation as evidence of LIS eligibility as listed in newly numbered § 423.2504(a)(3). Note that this change from the proposed regulation allows for individuals who are not in immediate need of prescriptions to take advantage of the POS enrollment mechanism when they have documentation specified in § 423.2504(a)(3). Making this change allows for those with evidence of LIS eligibility by way of presenting documentation to not be turned away from the pharmacy counter at the POS and avoid an unnecessary delay enrolling into LI NET. Under the demonstration, this subset of non-immediate need individuals, though very few in number, can enroll in LI NET at the POS with documentation, which is consistent with the way we finalize this provision. Though beneficiaries with an immediate need who state their LIS status are not required to show documentation at the POS to have their prescription filled, they must either successfully go through the BAE process or have their LIS status reflected in CMS systems in order to be included in the auto-enrollment process into a standalone Part D plan in accordance with § 423.34(d) following their LI NET coverage.

We also note the need for a technical correction in § 423.2504(b)(2), to specify that the claim submitted at the point-of-sale must be accepted by the LI NET sponsor – it must pass the edits for the LI NET sponsor to accept the claim into its system. For instance, a claim that is billed but is rejected due to a misspelling of the beneficiary’s name would not be sufficient to complete an LI NET enrollment.

We finalize § 423.2504(b)(2) to say, “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.”

Comment: One commenter suggested expanding the definition of “pharmacies that are in good standing” in LI NET 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 pursuant to § 423.504(b)(4)(vi)(G)(4) 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.

Response: We agree with the commenter that we do not want to consider pharmacies against which there are credible allegations of fraud to be "in good standing" for purposes of participating in LI NET. Currently, each Part D sponsor performs its own investigation to determine whether a credible allegation of fraud against a pharmacy exists, which may result in implementation of a payment suspension or termination. CMS encourages Part D sponsors to use the information CMS provides through Health Plan Management System's (HPMS) Program Integrity (PI) Portal for FWA Reporting module regarding other plan sponsors' payment suspensions, as well as information provided on referrals of providers and suppliers by plan sponsors, to conduct their own investigations of pharmacies. We remind sponsors that they should not take any administrative action based solely on information within CMS' HPMS PI Portal for FWA Reporting. Plan sponsors should perform their own investigations and conduct oversight efforts to substantiate information regarding potential pharmacy FWA.

It makes sense to similarly require the LI NET sponsor to make its own determination of what is credible instead of adopting a standard that *any* Part D sponsor's determination controls, as the commenter suggests. Thus, we finalize 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 make a determination about pharmacies' standings in this regard. Thus, we also strike the phrase "as determined by CMS" from § 423.2508(b).

Additionally, we 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. We omitted reference to State Health care programs in proposed § 423.2508(b), and take this opportunity to fully cite the OIG's list of excluded entities under section 1156 of the Act.

Thus, we finalize section 423.2508(b) to read, "(b) Network. The LI NET sponsor must allow its network and out-of-network pharmacies that are in good standing to process claims under the program. Licensed pharmacies are considered to be in good standing for the LI NET program so long as they: are not revoked from Medicare under § 424.535; do not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act or from Medicare and State health care programs under section 1156 of the Act (unless waived by the OIG); do not appear on the preclusion list as defined at § 423.100; and do not have a determination by the LI NET sponsor of a credible allegation of fraud as defined at § 423.4."

Comment: One commenter raised a concern about an 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. The commenter suggested modifying proposed § 423.2512(c)(6) to incorporate the good standing standard proposed in § 423.2508(b) and to state that pharmacies that submit claims to the LI NET sponsor would be subject to the LI NET sponsor's standard pharmacy audit and overpayment recovery processes.

Response: We agree with the commenter that the requirement to adjudicate out-of-network claims would apply only to pharmacies in good standing and have modified § 423.2512(c)(6) to include a cross reference to the good standing standard we are adopting in § 423.2508(b).

We note that § 423.504(b)(4)(vi)(G) is not waived for LI NET and requires the LI NET sponsor to establish and implement "procedures and a system for promptly responding to

compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.” Further, § 423.504(b)(4)(vi)(G)(2) says that the Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation, as previously referenced.

We believe the commenter is requesting that the LI NET regulations expressly state that the LI NET sponsor has the ability to audit out-of-network pharmacies and subject them to overpayment recovery processes. The commenter does not suggest what a “standard” pharmacy audit and overpayment recovery process could mean. One possibility is for it to be the same as is used for network pharmacies, similar to how we require the LI NET sponsor to adjudicate claims from out-of-network pharmacies according to the LI NET sponsor’s standard reimbursement for its network pharmacies. However, given that out-of-network pharmacies that are in good standing under §423.2508(b) must be permitted to process claims under LI NET – a distinguishing feature of LI NET – we believe that defining a “standard” pharmacy audit and overpayment recovery process would not provide the LI NET sponsor the level of flexibility that is already provided under § 423.504(b)(4)(vi)(G). Thus, we take this opportunity to state that the LI NET sponsor must meet the requirements in § 423.504(b)(4)(vi)(G), including for out-of-network pharmacies, without incorporating these concepts into § 423.2512(c)(6).

Thus, we finalize these concepts as proposed in § 423.2512(c)(6), and add the cross-reference to the good reference standard in § 423.2508(b) to say that the LI NET sponsor must “[a]djudicate 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.”

Comment: One commenter recommended that we require the LI NET sponsor to maintain telephone and fax lines 24 hours a day, 7 days a week, and every day of the year, as

well as setting customer service standards that include limits on average hold times and disconnect rates, and availability of interpreters.

Response: The LI NET sponsor will be held to the same customer service requirements as other Part D sponsors under § 423.128(d). Under § 423.128(d)(1)(i)(B), any call center serving pharmacists must be open so long as any network pharmacy in the region is open. Given that the LI NET sponsor's "region" is nationwide because of the requirement in § 423.2512(a)(1) to have a contracted pharmacy network in all geographic areas of the United States in which low-income subsidies are available, practically speaking we would expect some network pharmacies to be open 24 hours a day and therefore, by extension, the call center serving pharmacists would also need to be open 24 hours a day.

Section 423.128(d) also sets forth requirements for interactive voice response systems, timeframes for return calls, average wait times, disconnect rates, provision of interpreters (including how quickly the interpreters are made available), and provision of effective real-time communication with individuals using auxiliary aids and services like TTY.

We note that the requirement to maintain a fax line is not separately discussed in §423.128(d), but we believe as a practical matter that it will be necessary for the LI NET sponsor to maintain a fax line in order to conduct point-of-sale enrollments in accordance with § 423.2504(b)(2).

Comment: One commenter encouraged CMS and our contractors to regularly educate and communicate with pharmacists about LI NET. The same commenter called for consistent outreach to LI NET eligible beneficiaries to make them aware of the program.

Response: We agree with the importance of making stakeholders as well as beneficiaries who are likely eligible for LI NET aware of the program. In § 423.2512(c)(3), we require the LI NET sponsor to identify, develop, and conduct outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program. Under the demonstration, CMS enrolls over 90 percent of LI NET beneficiaries into the LI NET plan, and we expect CMS

would continue to be responsible for most enrollments in the permanent LI NET program. For beneficiaries who are not auto-enrolled, we agree that outreach is important so that stakeholders such as states, SHIPs, and pharmacies have awareness and knowledge about the LI NET program. Beneficiary education and outreach is also important, though it has been our experience that pharmacists and SHIP counselors are the most effective at connecting eligible beneficiaries with LI NET. We finalize § 423.2512(c)(3) as proposed, except for an editorial change to more concisely say “conduct outreach plans” instead of “carry out outreach plans.”

Comment: One commenter expressed support for our proposal to define the LI NET sponsor as a Part D sponsor selected by CMS to administer the LI NET program.

Response: We thank the commenter for the support.

Comment: One commenter noted that the LI NET demonstration is sometimes referred to by its full name of (“Limited Income Newly Eligible Transition program”), in addition to abbreviated forms, such as “LI NET” or “LINET”. The commenter encourages us to use program nomenclature consistently to avoid beneficiary confusion.

Response: We agree that using consistent nomenclature for the LI NET program can minimize confusion. We take this opportunity to state that the proper, full name of the program in this provision is the Limited Income Newly Eligible Transition program, which may also be referred to as the “LI NET program”.

Comment: One commenter expressed support for the proposed LI NET payment policies under § 423.2524 with the exception of § 423.2524(c)(1)(i), which proposed to require that the LI NET sponsor assume in its 2024 plan year bid that Payment Rate A cannot exceed a 2 percent increase from the prior year’s Payment A, which is a figure CMS would provide to the LI NET sponsor. The commenter noted that under the demonstration program, CMS instituted a per-member, per-month cap on administrative expenses for plan year 2012 that has not been updated, and recommended reestablishing a baseline for Payment Rate A beginning in plan year 2024. The commenter recommended that the LI NET sponsor and CMS engage in a collaborative rate

setting process, which the commenter suggested would contribute to the long-term stability of the LI NET program, and provide necessary flexibility to manage the program over the long term, particularly in light of factors like inflation or extreme or unpredictable circumstances like the COVID-19 Public Health Emergency (PHE).

Response: We thank the commenter for their general support of our LI NET payment provisions. As the commenter notes, under the demonstration we have long had a 2 percent cap on Payment Rate A, the portion of the LI NET payment comprised of two components: estimated administrative costs to run the LI NET program, which is inclusive of the LI NET sponsor's profit, and the LI NET sponsor's estimated costs to pay pharmacy claims for prescriptions filled by immediate need individuals, for which the LI NET sponsor might not be able to submit a prescription drug event (PDE) record to CMS due to the individual's unconfirmed LIS status. Over this time, the Part D sponsor administering the LI NET demonstration and CMS have had multiple discussions about the appropriateness of the 2 percent cap. To date, CMS has not received adequate justification to increase the cap, including for the past few years during an ongoing PHE. We note that § 423.2524(c)(1)(i) fixes the cap at 2 percent cap for the 2024 plan year only. This will maintain stability and continuity in Payment Rate A in this year of transition from LI NET as a demonstration to a permanent Part D program. The flexibility and collaboration the commenter seeks is provided from the 2025 plan year onward, in § 423.2524(c)(1)(ii).

Comment: One commenter expressed support for our proposal to enumerate those Part D requirements that will be explicitly waived under the LI NET program, concurring with the list of proposed waivers in § 423.2536. The commenter encourages CMS to partner with the LI NET sponsor as new Part D program requirements are introduced, so there is clarity about whether new requirements apply to the LI NET program.

Response: We thank the commenter for the support. With respect to new Part D program requirements that may be adopted in the future, we would consider at the time of their adoption

whether they ought to apply to the LI NET program or be added to the list of waived requirements specified in § 423.2536, as appropriate. We finalize as proposed § 423.2536, Waiver of Part D program requirements:

“CMS waives the following Part D program requirements for the LI NET program:

(a) General information. Paragraphs (1) and (3)(B) of section 1860D-4(a) of the Act (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(b) Formularies. Subparagraphs (A) and (B) of section 1860D-4(b)(3) of the Act (relating to requirements on development and application of formularies; formulary development) and formulary requirements in §§ 423.120(b) and 423.128(e)(5) and (6).

(c) Cost control and quality improvement requirements. Provisions under subpart D of this part, including requirements about medication therapy management, are waived except for the provisions in § 423.2508(d)(1) through (5).

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) Out-of-network access. Section 423.124 Special rules for out-of-network access to Part D drugs at out-of-network pharmacies, except for § 423.124(a)(2), which applies to LI NET.

(e) Medicare contract determinations and appeals. Subpart N, except for the provisions that apply to LI NET in § 423.2520(d).

(f) Risk-sharing arrangements. Section 423.336(a), (b), and (d).

(g) Certification of accuracy of data for price comparison. Section 423.505(k)(6).

(h) Part D communication requirements. Portions of subpart V of this part related to Part D communication requirements that are inapplicable to LI NET, including:

- (1) Section 423.2265(b)(4), (5), (11), and (13);
- (2) Section 423.2265(c);
- (3) Section 423.2266(a);
- (4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), and (33); and

(5) Section 423.2274.

(i) Medicare Coverage Gap Discount Program. Subpart W of this part.

(j) Requirements for a minimum medical loss ratio. Subpart X of this part.

(k) Recovery audit contractor Part C appeals process. Subpart Z of this part.”

Comment: One commenter raised concerns about CMS’ proposal to sunset the demonstration program on December 31, 2023 and start the permanent LI NET program on January 1, 2024. The commenter requested we begin the permanent program before sunsetting the demonstration program in case glitches arise in the transition, particularly recognizing that the start of a calendar year can be busy for pharmacists assisting beneficiaries with new coverage. The commenter recommended that CMS still begin the permanent program on January 1, 2024, but allow the demonstration program to continue until at least the second quarter of 2024 or until all potential unforeseen glitches are worked out, whichever is later.

Response: We share the commenter’s desire to take precautions against any risk of disruptions in care or LI NET beneficiaries’ access to Part D drugs. If the current Part D sponsor administering LI NET under demonstration authority is selected to be the LI NET sponsor for the 2024 plan year, then the change from LI NET operating as a demonstration versus a permanent program is largely a matter of the authority under which LI NET is operated rather than significant operational differences. If there is a change in the Part D sponsor administering LI NET in 2024, the new sponsor would be vetted by CMS to confirm that the sponsor has the

ability to administer the program. CMS would work closely with that sponsor during a transition period to ensure that there are no disruptions to beneficiaries who enroll in LI NET.

We appreciate the feedback we received from the commenters. After consideration of all public comments, we are finalizing the LI NET largely as proposed, with modifications to §§ 423.2504, 423.2508, and 423.2512, as previously discussed in our responses to comments. The revisions include:

- § 423.2504: 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”; and 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”; striking “with an immediate need” from the description of point-of-sale enrollment in § 423.2504(b)(2); revise § 423.2504(b)(2) to say, “(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 and 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”; and 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) through (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; add for clarity the term “Extra Help” to § 423.2504(a)(3)(ii).

- § 423.2508: removing CMS’ role in determining pharmacies’ “good standing” for LI NET and adding a reference to OIG’s authority to exclude State health care programs; and
- § 423.2512(c)(6): adding a cross reference to the good standing standard we are adopting in § 423.2508(b).

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

The Part D low income subsidy (LIS) helps people with Medicare who meet certain statutory income and resource criteria pay for prescription drugs and lowers the costs of prescription drug coverage.

Individuals who qualify for the full LIS receive assistance to pay their full premiums and deductibles (in certain Part D plans) and have reduced cost sharing. Individuals who qualify for the partial LIS pay reduced premiums (on a sliding scale based on their income) and also have reduced deductibles and cost sharing.

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.

To implement the changes to the LIS income requirements, we proposed to amend § 423.773(b)(1) to add that to be eligible for the full subsidy for plan years beginning on or after

January 1, 2024, an individual must have an income below 150 percent of the FPL. To coordinate with this change, we also proposed to amend § 423.773(d) to specify that the requirement that an individual have an income below 150 percent of the FPL to be eligible for the partial subsidy applies only to plan years beginning before January 1, 2024. This latter change is consistent with the IRA effectively sunseting the partial LIS after 2023.

To implement the changes to the resource limits, we proposed to amend § 423.773 to state that the current resource limits applicable for the full subsidy at paragraph (b)(2)(ii) apply to years 2007 through 2023. We also proposed to add a new § 423.773(b)(2)(iii) to state that for years beginning on or after January 1, 2024, the resource limits at paragraph (d)(2) of § 423.773 – the resource standards currently applicable for the partial subsidy – would apply to full subsidy eligible individuals. This result of this change is that individuals are able to have a higher value of resources and still be eligible for the full subsidy.

Lastly, we proposed to amend § 423.780(d) to specify that the sliding scale premium amounts currently applicable for individuals with the partial subsidy apply with respect to plan years beginning before January 1, 2024. These individuals who have incomes between 135 and 150 percent of the FPL and who meet the resource requirements will now qualify for the full subsidy beginning in 2024, and will be entitled to a premium subsidy of 100 percent of the premium subsidy amount, as outlined in § 423.780(a).

We received the following comments, and our responses follow.

Comment: 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. Commenters also believed that the change would simplify the LIS benefit structure, resulting in less beneficiary confusion and a reduction in administrative burden.

Response: We appreciate 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.

Comment: 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. They recommended that all Medicare outreach materials, and specifically communications with Medicare Savings Program (MSP) enrollees, include information about the Part D LIS and that CMS should consider increasing outreach and enrollment efforts for low-income beneficiaries. One commenter questioned whether CMS would be notifying beneficiaries of the change and whether plans are expected to continue to send LIS notices. Another commenter requested that we simplify existing application forms and outreach materials, as well as translate them into languages beyond English and Spanish.

Response: 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. We currently have targeted language for people with limited income and resources in the "Get Ready for Medicare" booklet individuals receive when they become eligible for Medicare and "Medicare & You" which is mailed to beneficiaries on an annual basis. We continue to explore efforts to increase awareness of these savings programs through our publications, online resources, and training materials and note that CMS is planning to conduct direct to consumer outreach to promote MSP and LIS enrollment in 2024.

We are contemplating sending notices in the Fall of 2023 to individuals who will be transitioning from the partial LIS subsidy to the full subsidy to inform them of the increased assistance they will be receiving beginning January 1, 2024. We did not propose any changes to the LIS notice requirements, therefore, plans will continue to be responsible for sending their members required information (for example, the LIS rider).

Lastly, we are always exploring avenues for improving and simplifying our communication materials to beneficiaries, including enrollment forms. We will continue to work to refine materials, but note that there can be limitations in how much we are able to simplify forms given the information we are conveying to beneficiaries and the required information we need from them to process their request. We note that beneficiaries who require materials in a language other than English and Spanish can contact 1-800-MEDICARE to request translated materials.

Comment: 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. In addition, a few commenters questioned whether CMS would be transitioning individuals eligible for the partial subsidy to the full subsidy so these individuals do not have to take any action to receive the additional benefits.

Response: 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. As a part of our implementation efforts, we will work with governmental (for example, SSA, States) and non-governmental (for example, plans) stakeholders to operationalize this transition and make it as seamless as possible for affected beneficiaries.

We would note that while a few commenters stated that individuals with incomes between 135 percent and 150 percent of the FPL are not automatically enrolled into LIS-eligible plans, this is not entirely accurate. Since the beginning of the Part D program, CMS has had a mechanism in place – referred to as facilitated enrollment – that enrolled partial benefit individuals into benchmark plans. This is essentially the same as the auto-enrollment that CMS conducts for full-benefit dually eligible beneficiaries and results in LIS-eligible individuals without prescription drug coverage being enrolled into Part D plans.

Comment: A few commenters, while supporting our proposal, noted concerns about how other changes to the Part D program will affect LIS beneficiaries. They noted how IRA-related

changes to maximum out-of-pocket costs and requirements for coverage of insulin and recommended vaccines, as well as the introduction of the new definition of negotiated price will lead to an unknown impact on the national average monthly bid amount and the LIS benchmark, which then could result in a higher number of reassignments in the Fall. Commenters stated that reassignments create disruption for beneficiaries and recommended that we consider pathways within our authority to minimize this. These commenters recommended options such as increasing the de minimis amount to \$5, allowing Part D sponsors to offer a fourth PDP in a region that is LIS-only for plan years 2024 and 2025, and launching a demonstration to narrow the risk corridors between 2024 and 2026 to account for the changes to the Part D program and unknown impact to bids. Additionally, one commenter also requested that CMS assess the potential disproportionate impact of this proposed rule and the 2022 final rule on pharmacy reimbursements.

Response: We thank 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. While the recommendations provided by commenters are outside the scope of this particular proposal, we agree that it will be important to ensure that individuals receiving the LIS do not face undue disruption as a result of broader changes in Part D.

Comment: One commenter noted that the Part D LIS is offered only to individuals residing in the 50 states and the District of Columbia and expressed disappointment that the IRA did not extend the LIS to beneficiaries in Puerto Rico.

Response: We acknowledge the commenter's disappointment and agree that this type of change would have to be established in statute and, therefore, is outside the scope of this rulemaking.

We appreciate the feedback we received from the commenters. After consideration of all public comments, we are finalizing our proposal with one minor change. We are 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.

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

A. Health Equity in Medicare Advantage (MA)

1. Introduction

On January 20, 2021, President Biden issued Executive Order (E.O.) 13985: “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” (hereinafter referred to as E.O. 13985).⁷ E.O. 13985 describes the Administration’s policy goals to advance equity across Federal programs and directs Federal agencies to pursue a comprehensive approach to advancing equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. In response, CMS announced its 2022 CMS Strategic Plan, and “Advance Equity” is the first pillar of that Strategic Plan.⁸ This pillar emphasizes the importance of advancing health equity by addressing the health disparities that impact our health system. CMS defines health equity as “the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.”⁹ This is the definition of health equity that we use for all health equity provisions in this final rule.

CMS continues to work diligently to identify regulatory actions that can help support CMS’s goal to advance health equity or that already address health equity topics but should be expanded in order to meet the increasingly diverse needs of enrollees served by MA

⁷86 FR 7009 through 7013, available at <https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf>

⁸<https://www.cms.gov/cms-strategic-plan>

⁹<https://www.cms.gov/pillar/health-equity>

organizations. In order to support the Administration’s goal of advancing equity for all, it is imperative that we ensure our regulations address topics that enable disadvantaged populations to fully access the care that the regulations already allow them to receive. Consequently, in the proposed rule, we proposed several regulatory updates in the MA program related to health equity. These proposals included requirements intended to ensure equitable access to MA services, ensure MA provider directories reflect providers’ cultural and linguistic capabilities and notate MOUD-waivered providers, ensure MA enrollees with low digital health literacy are identified and offered digital health education to assist them in accessing any medically necessary covered telehealth benefits, and ensure MA organizations incorporate one or more activities into their overall quality improvement program that reduce disparities in health and health care among their enrollees. We are finalizing these proposals, some with modification. CMS believes that the changes included in this final rule will address health disparities in the MA program and could be essential to more broadly supporting other equity-focused efforts across CMS policies and programs.

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

Currently, § 422.112(a)(8) requires MA organizations that offer coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds. We emphasized in our proposal and reiterate here that “all enrollees” indicates that all enrollees are included in this protection even if they do not identify as belonging to one of the groups specifically listed in the regulation. Additionally, all of the changes we proposed are designed to strengthen the regulation’s current application or requirements.

Our proposal was two-part. First, we proposed to change the current paragraph heading from “Cultural considerations” to “Ensuring Equitable Access to Medicare Advantage (MA) Services”; the term “equitable access” is a broader and more suitable description for the paragraph, as it does not emphasize protecting access to care for one population over another.

As we stated in our proposal, this change would more clearly reflect the inclusive nature of the protections MA organizations must guarantee for all enrollees under this provision.

The second part of our proposal was to add more populations to the existing list of groups that appear in the regulation. Specifically, at § 422.112(a)(8), CMS proposed to replace the phrase “those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds” after the word “including” and to add in its place additional paragraphs listing more examples of populations that an MA organization must ensure services are provided to in a culturally competent manner and promote equitable access to services for in order to satisfy the existing requirement: “(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.” As we noted in our proposal, MA organizations must provide all enrollees, without exception, accommodations to equitably access services according to applicable statutory, regulatory, and other guidance. In other words, the presence of this list should not be construed to mean that accommodations or steps necessary to ensure cultural competency in delivering benefits are required only for enrollees who belong to the groups listed herein. Instead, the proposed changes, with respect to a revised list of populations, are clarifying in nature, non-exhaustive, and are intended to provide additional examples of populations MA organizations should be mindful of in their plan designs. We again emphasize that the regulation already explicitly applies to all enrollees without exception; therefore, the protections of this provision, which were already in effect prior to our proposal, must continue to be part of an MA organization’s work to ensure that all Medicare-covered items and services are available and accessible to all enrollees.

Comment: Commenters generally supported the changes we proposed for this provision. We received no modification requests for the proposed heading change from “Cultural considerations” to “Ensuring Equitable Access to Medicare Advantage (MA) Services.” Some commenters suggested that CMS include additional populations in the proposed list of groups.

For example, one commenter recommended a slight change to the language “rural areas and other areas with high levels of deprivation” to include “under-resourced areas.” Another commenter suggested that CMS change the language “persistent poverty and inequality” to include “and/or lack of access to health care services.” Some commenters suggested that we address intersectional conditions affecting some enrollees.

Response: We appreciate these suggestions. We consider an enrollee in an “under-resourced area” or who experiences a “lack of access to health care services” to be among those that an MA organization must ensure are served equitably because the regulation extends this protection to all enrollees. We also note that intersectional conditions are already included, not specifically, but by virtue of the regulation applying to all enrollees, and should likewise be addressed when they could result in inequitable access to services. In order to avoid redundancy and keep our language generally consistent with E.O. 13985, we will not be adding additional groups at this time. However, we reiterate that the protections of this provision continue to apply to all enrollees, not just the populations listed in the regulation.

Comment: Some commenters recommended that CMS further define the newly listed populations (for example, under what conditions would an area qualify as having “high levels of deprivation”) to ensure it is properly understood to whom the provisions apply and when.

Response: Because this provision applies to all enrollees, it would be of limited practical value for CMS to define each group listed in the regulation in detail. Instead, MA organizations should continue to identify remedies whenever it is evident that enrollees’ equitable access to services might be challenged by conditions such as a disability, race, geographic location, or other factors.

Comment: Some commenters recommended that CMS delay the finalization of this proposal in order to allow MA organizations to prepare for the changes.

Response: As we discussed in our proposal, the obligation on MA coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees was originally finalized in June 2000 (65 FR 40170). Because this regulation has already been in effect for a significant amount of time and our proposal makes no changes to the regulation's current application or requirements, a delay in the finalization of this proposal would unlikely benefit enrollees or the MA organizations who serve them.

Finally, all public comments received on this proposal were generally supportive, including those that requested that modifications be made to the final rule. After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, including that the requested modifications would not produce substantive changes to either the application or requirements of the provisions (which were in effect prior to the proposal), we are finalizing the revision to § 422.112(a)(8) as proposed.

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

Section 1852(c)(1) of the Act requires an MA organization to disclose, among other things, the number, mix, and distribution of plan providers in a clear, accurate, and standardized form to each enrollee in an MA plan offered by the MA organization at the time of enrollment and at least annually thereafter. CMS implemented this requirement in a regulation at § 422.111(a) and (b)(3)(i), requiring that an MA organization must disclose the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services, in the manner specified by CMS, to each enrollee electing an MA plan it offers; in a clear, accurate, and standardized form; and at the time of enrollment and at least annually

thereafter, by the first day of the annual coordinated election period. In addition, under § 417.427, the MA disclosure requirements at § 422.111 also apply to section 1876 cost plans.

CMS has historically interpreted the disclosure requirement at § 422.111(b)(3)(i)—“the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services”—as referring to the provider directory. CMS developed the MA and Section 1876 Cost Plan Provider Directory Model,¹⁰ a model material created as an example of how to convey the required information to enrollees. In accordance with § 422.2267(c), when drafting their provider directories based on CMS’s model, organizations must accurately convey the required information and follow the order of content specified by CMS.

The current provider directory model contains an array of specific required information based on § 422.111(b)(3)(i); we refer to this information collectively as required provider directory data elements. For example, organizations must list only the office or practice location(s) where the provider regularly practices, must clearly identify the capacity in which the provider is serving (that is, specialty type), and must clearly identify whether or not a provider is accepting new patients or provide a notice directing beneficiaries to contact a provider to determine if he or she is accepting new patients. Several of these data elements are tied to how § 422.111(b)(3)(i) requires the organization to disclose information about providers from whom enrollees may reasonably be expected to obtain services; issues of access, including whether the provider is accepting new patients and the location, are integral to whether an enrollee may reasonably be expected to obtain covered services from that provider. In addition, some of these provider directory data elements, such as notations on restrictions in access, or indicators regarding whether a provider is accepting new patients, contain important information that organizations should consider when verifying that their networks are truly adequate. This

¹⁰The current MA and Section 1876 Cost Plan Provider Directory Model is located at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>.

consideration enables organizations to ensure that all covered services are available and accessible under the plan, as required by section 1852 of the Act and § 422.112(a).

In addition to the required provider directory data elements, the current provider directory model also addresses best practices for provider directories, including encouraging organizations to identify non-English languages spoken by each provider as well as include a specific notation on any restrictions on the accessibility of the provider and the provider's location for people with physical disabilities.¹¹ In the proposed rule, CMS proposed to codify two best practices (the latter in terms of accessibility for deaf or hard of hearing individuals) as regulatory requirements at § 422.111(b)(3)(i). First, we proposed 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). This regulatory addition would change these two best practices to required data elements that all organizations must include in their provider directories. Currently, the Medicaid managed care regulation at § 438.10(h)(1)(vii) requires that provider directories for Medicaid managed care plans include information on the provider's cultural and linguistic capabilities, including languages (including American Sign Language (ASL)) offered by the provider or a skilled medical interpreter at the provider's office, as well as other information identifying the provider's location, contact information, specialty, and other information important for beneficiaries in selecting a health care provider. By proposing to align the Part C provider directory requirements with those used in Medicaid managed care, this proposed change sought to help move the agency closer to its goal of aligning the various CMS program requirements.

¹¹The current MA and Section 1876 Cost Plan Provider Directory Model is located at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>.

We note that the phrase “cultural and linguistic capabilities” as proposed for § 422.111(b)(3)(i) refers to the capabilities of a provider or skilled medical interpreter at the provider’s office to deliver culturally and linguistically appropriate services (CLAS), which are defined by the HHS Office of Minority Health (OMH) as “services that are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs.”¹² As indicated by several research studies, language concordance between providers and limited English proficient individuals is associated with better health outcomes, and so better matching patients with providers who speak the same language is expected to improve quality of care and reduce disparities.¹³ CMS believes this important regulatory change would enhance the quality and usability of provider directories, particularly for non-English speaking enrollees searching for providers who speak their preferred language, for limited English proficient individuals, and for those enrollees seeking providers who use ASL themselves or have an ASL interpreter available in their office.

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

¹²https://www.minorityhealth.hhs.gov/Assets/PDF/TCH%20Resource%20Library_CLAS%20CLC%20CH.pdf

¹³<https://pubmed.ncbi.nlm.nih.gov/20878497/>;

<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2599011>;

<https://link.springer.com/article/10.1007/s11606-019-04847-5>

ensure that MA enrollees have the information they need in order to access covered services from an MA plan.

This proposal is also consistent with the health equity objectives of CMS’s first strategic pillar “Advance Equity” under the 2022 CMS Strategic Plan.¹⁴ It supports current CMS efforts to advance health equity by giving enrollees a fair and just opportunity to access health care services regardless of preferred language. Please refer to sections III.A.1. and III.A.2. of this final rule for more extensive discussion of health equity issues in the MA program.

To further enhance our requirements for MA provider directories in the area of behavioral health, we also proposed 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). Access to MOUD can be life-saving, but too often, patients do not know how to access this type of care. MA enrollees may have little insight as to which providers can provide MOUD. This problem is especially urgent, as overdose deaths from opioids skyrocketed during the COVID-19 pandemic.¹⁵ Therefore, we 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).¹⁶

As we stated in the proposed rule, we believe that this additional MA provider directory data element is important and necessary for ensuring access to behavioral health services for MA enrollees. We further stated that it supports both national and CMS efforts related to behavioral health priorities and strategies, as described in section III.B.1. of this final rule. We also explained our goal that the proposed change would help MA enrollees struggling with opioid use

¹⁴<https://www.cms.gov/cms-strategic-plan>

¹⁵<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

¹⁶<https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator>

disorder to find providers who could treat them by prescribing MOUD, moving these enrollees further along the path towards long-term recovery.

In summary, CMS proposed to add two new requirements to § 422.111(b)(3)(i) that organizations must include providers' cultural and linguistic capabilities and identify certain providers waived to treat patients with MOUD in their provider directories. We solicited comment on these proposed improvements to the content of MA provider directories. We also refer readers to section III.B.2. of this final rule to review our summary of comments and outcome for our proposal to add prescribers of MOUD as a new specialty type to be subject to MA network adequacy evaluation. We thank commenters for their input on CMS's proposed new MA provider directory requirements. We received the following comments on this proposal, and our response follows:

a. Comments on Identifying Providers' Cultural and Linguistic Capabilities

Comment: Comments on this proposal were largely favorable. Commenters supported allowing enrollees to make informed decisions when choosing providers, making care more accessible and equitable, and sharing information with enrollees in advance as to whether a provider can deliver care that meets their cultural and linguistic needs. Commenters stated that identifying providers' cultural and linguistic capabilities in provider directories is crucial for enrollees to ensure that providers are equipped to provide accessible, inclusive, person-centered care. Commenters appreciated the benefit this new requirement would provide for non-English speaking enrollees searching for providers who speak their preferred language, for limited English proficient individuals, and for those enrollees seeking providers who use ASL themselves or have an ASL interpreter available in their office. They believed that enrollees who are treated by providers who speak their same language tend to have better health outcomes, and this change will ensure equity by creating expanded and better-informed access by enrollees to providers who can accommodate their language needs. A commenter praised CMS's use of the HHS OMH definition of CLAS. Another commenter supported the transparency these new

elements would provide to enrollees in understanding a provider's capabilities and whether these capabilities match the enrollee's communication needs.

Response: We thank commenters for their support, and we concur that there is added value of requiring organizations to include providers' cultural and linguistic capabilities in their provider directories. We are therefore finalizing this first aspect of § 422.111(b)(3)(i) as proposed.

Comment: Many commenters stressed the importance of provider directory accuracy, but also noted the continued challenge in maintaining accurate provider directories. They stated that there is no easy or systematic way for providers to update their information with all organizations they contract with, and organizations do not have a single source of truth for provider information. Commenters were in favor of a national provider directory and referenced CMS's recent request for information (RFI) titled Request for Information; National Directory of Healthcare Providers & Services (NDH), which appeared in the **Federal Register** on October 7, 2022 (87 FR 61018). An NDH would be a centralized data hub for provider information that would allow providers to report changes to their information once instead of to each organization with which they contract. Commenters recommended CMS focus provider directory efforts on creating an NDH rather than establishing any new piecemeal requirements that would draw resources away from focusing on an NDH and would have limited value in the interim. Some commenters suggested CMS delay implementation of the proposed requirement for organizations to include providers' cultural and linguistic capabilities in their provider directories until an NDH is implemented. Other commenters believed that if CMS does finalize this requirement, CMS should exercise enforcement discretion, provide an audit safe harbor, allow for leniency, and not penalize organizations making a good faith effort to include the new required data elements in their directories, until there is a better long-term solution in place, such as an NDH.

Response: We understand commenters' concerns regarding the difficulty in maintaining accurate provider directories without a single source of truth for provider data. As stated in our

RFI, we understand that the fragmentation of current provider directories requires inefficient, redundant reporting from providers, and an NDH could serve as a “centralized data hub” for directory and digital contact information containing the most accurate, up-to-date, and validated data in a publicly accessible index. We thank commenters for referencing this RFI and expressing strong support for an NDH. However, CMS is still considering the NDH concept. Consequently, unless and until such a long-term solution to provider directories is adopted, CMS continues to make every effort to improve our policies surrounding provider directories, including this proposal for MA directories. We believe that requiring organizations to include providers’ cultural and linguistic capabilities in their provider directories is an important improvement that promotes transparency and equitable access to care. Therefore, we are finalizing this first aspect of § 422.111(b)(3)(i) as proposed. Regarding comments requesting CMS exercise enforcement discretion, we note that CMS considers a variety of factors when operationalizing policy and taking enforcement action, including an organization’s ability to implement policy changes as they establish the processes needed to evaluate effectiveness.

Comment: Several commenters indicated that the new proposed provider directory requirements would raise significant issues related to providers. For example, commenters believed provider burden would increase, there would likely be provider abrasion with all organizations separately seeking the same data from providers, and in general there would be a low response rate from providers. A commenter stated that the bottleneck in achieving accurate directories lies with providers who do not provide updated information to organizations, and the proposed additional information may be yet another piece of information organizations and providers are not willing to try hard enough to extract or supply. Another commenter was concerned that compliance would be difficult for organizations without additional requirements to incentivize providers to submit timely and accurate information. Several commenters also recommended that CMS require providers to maintain this data, notify providers of the new requirement, and educate or raise awareness with providers on the importance of keeping this

data updated for the organizations with whom they contract. A commenter recommended a robust campaign to educate providers and seek their commitment before implementing this requirement. Another commenter stated that maintaining up-to-date provider directories should be a shared responsibility of providers and health plans. In general, commenters suggested that CMS support providers if this proposal is finalized.

Response: We acknowledge that the adoption of this new requirement may result in increased provider burden and abrasion, that providers may have low response rates to organizations, and compliance may be difficult for some organizations. However, organizations must still meet this requirement. We encourage organizations to consider using their contracts with providers to require them to provide this information and keep it updated. The contract between the provider and the organization is a useful tool that organizations have at their disposal to help them meet CMS's new provider directory requirement. At this time, CMS does not have plans to require providers to maintain this specific data, nor to conduct provider education campaigns. It is the responsibility of organizations to do all that they can in their relationships with contracted providers in order to meet § 422.111(b)(3)(i) as finalized.

Comment: A few commenters suggested that providers may have reservations regarding sharing their cultural and linguistic capabilities, some stating that providers either do not or rarely share this information today. A commenter believed that this data element should be optional for providers to disclose to organizations, acknowledging and respecting concerns with the possible unintended consequences of publicizing this demographic information.

Response: We are finalizing this first proposed change to § 422.111(b)(3)(i) without modification; therefore, it will not be optional for organizations to include this information in their provider directories. We reiterate that organizations should use their contracts with providers as leverage to require this information be provided to organizations to populate their provider directory. Information on providers' cultural and linguistic capabilities in provider directories is critical for enrollees to have when making both provider choices and MA plan

choices. Therefore, if a provider refuses to provide their cultural and linguistic capabilities, organizations should document the provider's response. CMS will take such responses into consideration when reviewing findings associated with future provider directory reviews.

Comment: Some commenters requested additional clarity, examples, and more guidance on how CMS expects organizations to implement this new requirement if finalized. Commenters sought guidance on various topics, such as how to determine a provider's cultural and linguistic capabilities, what level of language fluency is sufficient, whether a provider must be a certified translator prior to having a particular language listed, what constitutes a "skilled medical interpreter," and what exactly is meant by "cultural capabilities." A commenter stated that multiple issues remain to be addressed, including development of objective criteria for certain categories, such as language capability within a provider's office. Another commenter questioned whether organizations must identify whether linguistic assistance is available in-person or via telehealth.

Response: We appreciate these questions and requests for clarification regarding how to implement this new provider directory requirement and plan to provide additional information through future sub-regulatory guidance. As stated in the proposed rule, "cultural and linguistic capabilities" refers to the capabilities of a provider (or skilled medical interpreter at the provider's office) to deliver CLAS, which are defined by the HHS OMH as "services that are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs."¹⁷ For purposes of § 422.111(b)(3)(i) as finalized, this definition "cultural and linguistic capabilities" applies; therefore, organizations should take this under consideration when determining a provider's cultural and linguistic capabilities. The manner in which organizations do so is at their discretion, so long as the requirement at § 422.111(b)(3)(i) is met. We are not being prescriptive in exactly how this information must be displayed in provider directories. The provider directory

¹⁷https://www.minorityhealth.hhs.gov/Assets/PDF/TCH%20Resource%20Library_CLAS%20CLC%20CH.pdf

is a model communications material which, per § 422.2267(c), is created by CMS as an example of how to convey enrollee information. When drafting this required communications material, organizations must: (1) accurately convey the vital information in the required material to the enrollee, although the organization is not required to use the CMS model material verbatim; and (2) follow CMS's order of content, when specified (see § 422.2267(c)(1) and (2)). We will be updating the MA and Section 1876 Cost Plan Provider Directory Model upon finalization of this rule to incorporate the new requirement in § 422.111(b)(3)(i), and we anticipate providing additional guidance and examples to organizations within that model to explain how organizations might display providers' cultural and linguistic capabilities in their directories. Organizations should reference the forthcoming contract year 2024 model document.¹⁸ Also, for purposes of meeting the requirement in § 422.111(b)(3)(i) to identify languages offered by the provider or at the provider's location, a provider does not need to be a certified translator prior to having a particular language listed because we expect that enrollees choosing that provider because they speak their native language will not need translation services if the enrollee and provider speak the same language. Regarding what constitutes a skilled medical interpreter, the interpreter must be trained and certified in medical interpreting, especially when working in a clinical setting. As to the question about whether organizations must identify whether linguistic assistance is available in-person or via telecommunications, the current provider directory model requires organizations to notate providers who offer services exclusively via telehealth, so if a provider is identified as such and the organization also identifies the provider's linguistic capabilities, then it would be clear to the enrollee that that provider offers linguistic assistance exclusively via telecommunications technology and not in-person.¹⁹ Section 422.111(b)(3)(i) does not currently require organizations to identify all providers who offer services via

¹⁸The contact year 2024 MA and Section 1876 Cost Plan Provider Directory Model will be available at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>.

¹⁹The current MA and Section 1876 Cost Plan Provider Directory Model is located at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>.

telehealth, but if an organization chooses to identify providers who offer telehealth services, then the provider notation must also identify the provider's linguistic capabilities, per the new requirement at § 422.111(b)(3)(i) which we are finalizing here. It is the organization's choice as to whether to distinguish if that linguistic assistance is available in-person, via telecommunications, or both.

Comment: Several commenters stated concern that this requirement would increase burden on both organizations and providers. A commenter stated that it may require upgrades and investments in existing systems that could potentially require organizations to terminate contracts and change vendors, and also would require significant data pulls from network providers to populate the additional required elements in directories.

Response: We reiterate that per control number 0938-0753 (CMS-R-267) currently approved by OMB, the update and maintenance of the provider directory is part of the usual and customary normal business activities of organizations and as such is exempt from PRA by 5 CFR 1320.3(b)(2). Organizations that do not currently collect data on their contracted providers' cultural and linguistic capabilities may do so by using the same means and methods by which they already collect other information from contracted providers for inclusion in provider directories. We expect that organizations should only have to make minimal updates to their existing processes related to provider directories, such as a template, related software, and the added data points for providers.

Comment: A few commenters suggested that CMS require additional data elements in provider directories through regulatory codifications at § 422.111(b)(3)(i). Some suggestions included: whether a provider is accepting new patients, provider specialty granularity, provider sub-specialty, provider telehealth capabilities, average wait time to secure a new patient appointment, hospital affiliation, and accessibility of provider offices and medical diagnostic equipment (for example, availability of ramps, elevators, and accessible medical equipment).

Response: We thank commenters for their suggestions to amend § 422.111(b)(3)(i) to also require organizations to include these various additional data elements in provider directories. We re-emphasize that some of these data elements are already required, as stated in the proposed rule and in the MA and Section 1876 Cost Plan Provider Directory Model.²⁰ As for the data elements that are not currently required, we will carefully consider these additions as we update the MA and Section 1876 Cost Plan Provider Directory Model for contract year 2024 and as we contemplate future rulemaking on provider directory requirements.²¹

Comment: Commenters requested greater specificity regarding CMS’s oversight and compliance monitoring, stating that the language proposed (“periodic online provider directory reviews, as CMS deems necessary”) is ambiguous and does not provide transparency into the regularity in which CMS will be monitoring organizations. They suggested that CMS provide specific timelines regarding the monitoring of these new requirements, the process by which directory information will be verified, and the frequency of CMS follow-up with organizations to monitor directory accuracy. A commenter stated that CMS may wish to consider using its contracts with organizations and Medicare’s conditions of participation to reduce the cost of providing information, such that organizations and providers might be more amenable to following the requirements as proposed. Another commenter stressed that CMS oversight, including secret shopper surveys, is necessary to monitor the accuracy of provider directories. They stated that the track record of provider directories in giving accurate and current information has been dismal and unlikely to improve significantly without strong monitoring by CMS.

Response: Nothing in the proposed rule changed our compliance authority, therefore, we are not making any changes to our provider directory compliance oversight at this time.

²⁰The current MA and Section 1876 Cost Plan Provider Directory Model is located at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>.

²¹The contact year 2024 MA and Section 1876 Cost Plan Provider Directory Model will be available at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>.

Regarding the suggestion that CMS make use of its contracts with organizations and provider conditions of participation, we are not making any changes to these regulations at this time, but may consider changes in the future. We note that § 422.504(a)(4) already requires that in the contract between the MA organization and CMS, the MA organization agrees to disclose information to beneficiaries in the manner and the form prescribed by CMS as required under § 422.111. This longstanding contract provision is binding on the organization and requires all organizations to comply with § 422.111, inclusive of § 422.111(b)(3)(i) as finalized in this rule. We agree with commenters about the importance of oversight and strong monitoring of provider directory accuracy, and we intend to continue these activities to ensure organizations are complying with § 422.111(b)(3)(i).

b. Comments on Identifying MOUD-Waivered Providers

Comment: Regarding our proposal for § 422.111(b)(3)(i)—requiring organizations to identify certain providers waived to treat patients with MOUD in their provider directories—a majority of commenters pointed to recently enacted legislation that has made our proposal moot. 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. Since the waiver has been eliminated, now any licensed provider can treat patients with MOUD without a waiver. Therefore, commenters explained, identifying providers with the waiver in provider directories is not necessary, as providers no longer need to possess the special waiver in order to prescribe MOUD. Accordingly, most commenters recommended CMS not finalize this aspect of the proposal, a few commenters requested CMS clarify in the final rule how the proposal aligns with the legislation, and some commenters presented alternatives. Alternative approaches offered by commenters included requiring organizations to still identify providers from whom enrollees can

receive MOUD treatment, identify addiction specialists, or identify Opioid Treatment Programs (OTPs).

Response: We are aware that the CAA of 2023 was enacted after the proposed rule was published, and we thank commenters for alerting us of this important legislative change that has a significant impact on how we finalize the second aspect of our provider directory proposal. After careful consideration of all comments received, we have decided to not finalize our proposal to require organizations to include in their provider directories notations for MOUD-waivered providers who are listed on SAMHSA's Buprenorphine Practitioner Locator. Of those who commented on the elimination of the "X-waiver," the majority suggested we withdraw this aspect of our proposal, therefore, that is the approach we are taking. We appreciate the alternatives presented by some commenters, and we will consider including in our guidance on best practices for provider directories that organizations identify providers who have expertise in treating patients with OUD. This guidance would cover a wide variety of providers and facilities, including MOUD-prescribers, addiction specialists, and OTPs. If we choose to pursue such guidance, it would appear in the MA and Section 1876 Cost Plan Provider Directory Model, which CMS updates and releases annually.²²

Comment: Several commenters opposed our proposal to require organizations to identify MOUD-waivered providers in their provider directories. A commenter stated that there is currently no industry standard for organizations to collect and document information on the status of provider MOUD waivers. They also expressed concerns that including this information in provider directories would cause enrollee confusion, as most enrollees would not understand this designation nor how to factor it into their provider selection. Another commenter believed that it would be challenging for organizations to identify and confirm that providers have the waiver.

²²The current MA and Section 1876 Cost Plan Provider Directory Model is located at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>.

Response: We agree with commenters concerns surrounding potential implementation of this requirement. As noted previously, we are not finalizing this second aspect of our proposal for § 422.111(b)(3)(i) based on the majority of comments recommending such course of action in alignment with the CAA of 2023 provision.

c. Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulation. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed change to § 422.111(b)(3)(i) to require organizations to include in their provider directories 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.

We are not finalizing our proposal to require organizations to include in their provider directories notations for MOUD-waivered providers.

4. Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth (§ 422.100)

Telehealth has become an increasingly popular and important tool in providing access to health care, especially during the COVID-19 Public Health Emergency (PHE). For the purposes of this section of this final rule, we are using the term “telehealth benefits” very broadly to encompass covered services that are furnished to the enrollee (that is, the patient) in a different location than where the provider is located. There are multiple categories of covered benefits where this circumstance is present, with additional criteria or requirements applying to different categories of covered benefits when the enrollee and provider are not in the same place at the time the service is furnished.

Under the MA program, there are various requirements and options for coverage of telehealth benefits. When original Medicare covers telehealth benefits, such as services

described in section 1834(m) of the Act and § 411.78, MA organizations must cover those telehealth benefits as basic benefits, as defined in § 422.100(c). If an MA organization wishes to offer telehealth benefits that go beyond the scope of the original Medicare telehealth benefits that must be covered by every MA plan, MA organizations have the option to offer “Additional Telehealth Benefits” (ATBs) and/or supplemental telehealth benefits. Section 1852(m) of the Act and § 422.135 outline the requirements for ATBs, which are generally services for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act, and the services are furnished when the patient and the physician or practitioner are not in the same location. ATBs may be included in the bid and treated as basic benefits when the requirements of § 422.135 are met.

If an MA organization wishes to offer telehealth benefits that are not covered by original Medicare and are not within the scope of § 422.135, then the MA organization may choose to offer them as supplemental benefits. The requirements for MA supplemental benefits are set forth at section 1852(a)(3) of the Act and §§ 422.100(c) and 422.102. An MA organization’s bid must accurately reflect the covered telehealth service, whether it is covered as an ATB or a supplemental benefit. In addition, during the COVID-19 PHE, MA organizations have been required to account for the various waivers, amendments to regulations, and other guidance published by CMS, with regard to telehealth benefits. In using the term “telehealth benefits” here, we mean to include all of these various categories of covered benefits. In the regulation text we are finalizing in this rule, we use the phrase “covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135” as a means to encompass all of the potential covered benefits included in our broad use of the term “telehealth benefits.” As defined in § 422.135, electronic exchange means electronic information and telecommunications technology, which we believe is broad enough to include telecommunications and technologies permitted for covered Part B services under

section 1834(m) of the Act and implementing regulations as well as MA ATBs and other supplemental benefits.

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

While the supply and demand of telehealth has clearly grown in recent years, there is evidence that barriers to accessing telehealth leave room to improve health equity in telehealth. The regulatory changes we are finalizing here, taken together, are an attempt to improve health equity in telehealth and are consistent with both E.O. 13985 and CMS's first strategic pillar "Advance Equity" under the 2022 CMS Strategic Plan.^{23,24} For purposes of this provision, we are using CMS's definition of health equity, which is included in section III.A.1. of this final rule.²⁵ In developing our digital health education program policy, we were guided by HHS's definition of "health equity in telehealth" as meaning the "opportunity for everyone to receive the health care they need and deserve, regardless of social or economic status. Providing health equity in telehealth means making changes in digital literacy, technology, and analytics, which will help telehealth providers reach the underserved communities that need it the most."²⁶

As we described in the proposed rule, health equity in telehealth is difficult to attain due to barriers to telehealth access, which may include: lack of video sharing technology (for

²³<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

²⁴<https://www.cms.gov/cms-strategic-plan>.

²⁵<https://www.cms.gov/pillar/health-equity>.

²⁶<https://telehealth.hhs.gov/providers/health-equity-in-telehealth/>.

example, a smartphone, tablet, or computer), spotty or no internet access, lack of housing or private space to participate in virtual visits, few local providers who offer telehealth practices, language barriers (including oral, written, and signed language), the inability to incorporate third party auxiliary aids and services such as live captioners, telehealth software, apps, and websites that are accessible and usable by people with disabilities, and lack of adaptive equipment for people with disabilities along with incompatibility with external assistive technologies used by people with disabilities.²⁷ These barriers are especially burdensome on populations that may already experience health disparities, such as those who are adversely affected by persistent poverty and inequality, those who live in rural areas, people from some racial and ethnic groups, immigrants, people who identify as LGBTQI+, people with disabilities, older people, limited English proficient individuals, people with limited digital literacy, and people who are underinsured or uninsured. Such underserved communities often lack equitable access to health care, leading to consequences such as: higher mortality and disease rates, more severe disease and illness, higher medical costs, lack of access to treatment, and lack of access to health insurance.²⁸

The existence of communities with low digital health literacy who in turn cannot access telehealth represents a significant obstacle in achieving health equity in telehealth. The World Health Organization defines digital health literacy as “the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem. Examples of digital health literacy include accessing your electronic health record, communicating electronically with your health care team, ability to discern reliable online health information, and using health and wellness apps.”²⁹ Low digital health literacy can impact an individual’s access to or quality of telehealth visits.³⁰ Evidence

²⁷<https://pubmed.ncbi.nlm.nih.gov/33325524/>; <https://pubmed.ncbi.nlm.nih.gov/32703737/>.

²⁸<https://telehealth.hhs.gov/providers/health-equity-in-telehealth/>.

²⁹<https://nmlm.gov/guides/intro-health-literacy>.

³⁰<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8464820/>.

shows that those with low digital health literacy tend to be older, lower income, less educated, and Black or Hispanic.³¹

Many older adults with low digital health literacy experience gaps in access to the health care they need, and this is concerning for the MA program, whose enrollee population includes individuals age 65 and older (as well as individuals under age 65 with disabilities). For example, the American Association of Retired Persons (AARP) annual technology survey found that more than half of older adults (age 50 and older) in 2021 indicated they need more digital education, while more than one in three indicated they lacked confidence when using technology.³² Of the 32 million Americans who cannot use a computer, approximately one-third are seniors.³³ Further, less than one-third of Medicare beneficiaries over 65 have at-home digital access, and those over age 75 and with less than high school-level education are less likely to use telehealth.³⁴ For people with disabilities, 15 percent reported not using the internet as opposed to 5 percent in the general population in a Pew Foundation Survey, while 62 percent of people with disabilities as opposed to 81 percent of the general population own their own desktop or laptop computer.³⁵ Other studies have confirmed a significant gap in digital literacy among people with disabilities.³⁶ Another survey found that Black, Latino, and Filipino seniors and those 75 years and older are significantly less likely to own devices like computers and smartphones compared to non-Hispanic whites, Chinese, and younger seniors (ages 65–69); this was also true in terms of these groups' respective use of the internet and e-mail, as well as their ability and willingness to use technology for telehealth purposes.³⁷

As outlined in this final rule, research indicates that older adults, people with disabilities, people from some racial and ethnic groups, rural communities, underserved populations, and

³¹<https://nces.ed.gov/pubs2018/2018161.pdf>.

³²<https://www.aarp.org/research/topics/technology/info-2022/2022-technology-trends-older-americans.html>.

³³ <https://www.telehealthequitycoalition.org/improving-digital-literacy-to-improve-telehealth-equity.html>.

³⁴<https://www.jmir.org/2021/7/e27682/>.

³⁵<https://www.pewresearch.org/fact-tank/2021/09/10/americans-with-disabilities-less-likely-than-those-without-to-own-some-digital-devices/>.

³⁶<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5878361/>.

³⁷<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4799429/>.

those adversely affected by persistent poverty and inequality are all disadvantaged by limited access to modern information and communications technology (sometimes referred to as a digital divide).³⁸ Individuals with a higher degree of digital health literacy receive more health care information, are better equipped to evaluate the quality of information regarding their health care, and report higher telehealth usage.³⁹ Further, individuals with chronic diseases also benefit from digital health literacy; when such individuals possess digital health literacy, they tend to monitor and manage their diseases more competently, are more satisfied with the telemedicine services, and respond faster to changes that might adversely affect their situation, thereby improving their overall health.⁴⁰ This is significant because individuals with two or more chronic diseases are more likely to be individuals 65 and over.⁴¹

As we described in the proposed rule, CMS does not currently have requirements for MA organizations in the area of digital health literacy. Given the need to increase digital health literacy in many communities with MA enrollees and the goal to achieve health equity in telehealth, we believe it is necessary to implement regulations addressing digital health literacy in the MA program. CMS expects that these digital health literacy policies, once implemented, will help underserved communities in need of assistance to improve their digital health literacy and help advance the goal of achieving health equity in telehealth.⁴²

In the proposed rule, we 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 to assist them with accessing any medically necessary covered telehealth benefits. Specifically, we 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

³⁸<https://academic.oup.com/jamia/article/27/12/1949/5899728>.

³⁹<https://jamanetwork.com/journals/jama/article-abstract/2426088>.

⁴⁰<https://www.sciencedirect.com/science/article/pii/S0738399114001876>.

⁴¹https://www.cdc.gov/pcd/issues/2020/20_0130.htm.

⁴²<https://telehealth.hhs.gov/providers/health-equity-in-telehealth/>.

adding a new paragraph (9). We indicated that the new proposed paragraph would require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange; we used the term “electronic exchange” as it is broadly defined in § 422.135.

We noted that this proposed new continuity of care requirement would apply to all MA organizations offering coordinated care plans (that is, HMOs, PPOs, HMO-POSs, and SNPs) and would be relevant for all types of covered telehealth benefits, including basic telehealth benefits, ATBs, and supplemental telehealth benefits offered by MA coordinated care plans. We solicited comment on whether to amend § 422.100 instead of § 422.112(b) in order to apply this new requirement to all MA plans and not just coordinated care plans. As we indicated in the proposed rule, this additional standard was proposed to ensure that MA enrollees would be able to access covered benefits and that MA organizations met their obligations under section 1852(d) of the Act to make covered benefits available and accessible to enrollees in the plan. Section 1856(b) of the Act authorizes the adoption of standards that are consistent with and to carry out the Part C statute. As telehealth benefits become more prevalent in the MA program, taking steps to provide enrollees with digital health education will ensure that these telehealth benefits are truly accessible and available to enrollees.

After considering the comments received, and for reasons described in this section of the rule, we are finalizing this policy, but we are amending § 422.100 rather than § 422.112(b) as we originally proposed to apply this new requirement to all MA plans and not just coordinated care plans.

This policy will be a first step for MA organizations to assess the landscape of health equity in telehealth in their plans and help enrollees navigate telehealth. We noted in the proposed rule that, under this policy CMS would provide a degree of discretion for MA

organizations in the procedures developed and used to identify enrollees with low digital health literacy and the digital health education services the MA organization provides for those enrollees. We also explained that compliance with the proposal, if finalized, would require that MA organizations introduce a digital health literacy screening program or other similar procedure to identify current enrollees with low digital health literacy; however, MA organizations would have flexibility to design their own screening program or procedure. We noted in the proposed rule that some experts recommend such an assessment should examine patient-level barriers such as telehealth readiness, broadband access, and inaccessible or unusable information and communication technologies by individuals with disabilities that limit patient use of telehealth.⁴³ Others recommend considering certain digital foundation skills based on a specific framework.⁴⁴ CMS encourages MA organizations to research current trends and successes in the field when developing their own methods to identify enrollees with low digital health literacy. CMS anticipates that some MA organizations could ask enrollees, for example, if they have internet access and reliable connectivity, if they have a device that meets appropriate telehealth system requirements, if they use e-mail, if they can download a mobile app, or if they can change applicable settings on a device (for example, browser or camera settings), as a means to identify which enrollees have low digital health literacy.⁴⁵

Once the MA organization determines which enrollees experience low digital health literacy, the MA organization will then have to implement a digital health education program to offer to these enrollees. CMS did not propose to identify explicit parameters for this digital health education requirement, and we are not finalizing any such parameters. Rather, we have chosen to keep it flexible and allow for innovation in this area by MA organizations. Depending on the specific enrollment in an MA plan, the procedures to identify enrollees and the mechanisms and content of the digital health education could vary. However, some examples of

⁴³<https://link.springer.com/content/pdf/10.1007/s00520-021-06629-4.pdf>.

⁴⁴<https://www.digitalinclusion.org/definitions/>.

⁴⁵<https://www.telehealthequitycoalition.org/improving-digital-literacy-to-improve-telehealth-equity.html>.

digital health education designs include: distributing educational materials about how to access certain telehealth technologies in multiple languages, including sign language, and in alternative formats; holding digital health literacy workshops; integrating digital health coaching; offering enrollees in-person digital health navigators; and partnering with local libraries and/or community centers that offer digital health education services and supports.

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

Smartphones and tablets (or other similar equipment) must only be used for primarily health related purposes (and cellular data plans can only be provided if use of these plans is locked and limited to health-related activities), such as when the device is locked except for remote monitoring or to enable engagement with health care providers, in order for these items and services to be permissible supplemental benefits under § 422.100(c)(2)(ii). However, furnishing or covering a cellular data plan without limitations might be permissible (under section 1852(a)(3)(D) of the Act and § 422.102(f)) as a non-primarily health related special supplemental benefit for the chronically ill (SSBCI) when the benefit is limited to a chronically

ill enrollee and has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

For more information on SSBCI, please see the June 2020 final rule and the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) (hereinafter referred to as the January 2021 final rule). CMS encourages MA organizations whose plans have a high number of enrollees with low digital health literacy to consider offering the, previously discussed, supplemental benefits and pairing an appropriate digital health education program with the provision of such devices to enrollees, where permitted by applicable law.

To further emphasize the importance of health equity and health equity in telehealth specifically, CMS reminds MA organizations that § 422.112(a)(8) as it currently reads requires MA organizations offering coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including limited English proficient individuals or those with limited reading skills, and those with diverse cultural and ethnic backgrounds. CMS is finalizing changes in this rule to amend § 422.112(a)(8) to better reflect the broad scope of potentially underserved populations and to emphasize how MA plans must ensure equitable access to services. As adopted and with the revisions we are finalizing in this rule, § 422.112(a)(8) requires MA organizations offering coordinated care plans to ensure that services are provided in an equitable manner to all enrollees. MA organizations offering coordinated care plans must consider these additional obligations, as applicable, when developing and maintaining the digital health education programs they are required to implement under this final rule.

Furthermore, the HHS Office for Civil Rights and the U.S. Department of Justice (DOJ) Civil Rights Division recently published new guidance providing clarity on how Federal

nondiscrimination laws require accessibility for people with disabilities and limited English proficient individuals in health care provided via telehealth.⁴⁶ These Federal civil rights laws—including the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, title VI of the Civil Rights Act of 1964, and section 1557 of the ACA—require that telehealth be accessible to people with disabilities and limited English proficient individuals. CMS strongly encourages MA organizations and their contracted providers to review this new guidance issued by HHS and DOJ to ensure compliance with Federal civil rights laws pertaining to telehealth.

We also proposed to require 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)). We indicated that this would allow CMS to monitor the impact of the new requirement for these programs on MA organizations, providers, enrollees, and the MA program as a whole. In addition, we 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, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of proposed § 422.112(b)(9) (finalized at § 422.100(n)).

We indicated that the purposes of requiring MA organizations to make such information available to CMS upon request would be to identify best practices for improving digital health literacy amongst MA enrollees and to determine whether CMS should make improvements to the regulation and/or guidance regarding this requirement. We noted that the regulation text, now at § 422.100(n)(1), would include the language “upon request,” which would serve to communicate that while CMS does not intend to establish uniform data collection from all MA organizations at

⁴⁶<https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in-telehealth.pdf>.

this time, CMS reserves the right to ask for this information from individual MA organizations. However, we noted that this provision would not limit CMS's audit access when program audits review the performance of MA organizations. We solicited comment on this aspect of our proposal and whether we should require regular reporting of data of this type from all MA organizations alongside other Part C reporting requirements.

We are also finalizing the proposed requirement that the MA organization must make information about its digital health literacy screening and digital health education programs available to CMS upon request. We are further finalizing language providing a non-exhaustive list of the information CMS may request from MA organizations under this policy. Finally, we are not finalizing regular reporting of the data alongside other Part C reporting requirements.

In the proposed rule, we provided that our proposal to amend § 422.112(b) (finalized at § 422.100(n)) would impact MA organizations in terms of the burden required to both identify enrollees with low digital health literacy and to develop digital health education programs for these enrollees. We also described how our estimated analysis of these impacts was qualitative in nature as we were proposing to provide MA organizations flexibility in determining how they wish to implement these proposed CMS requirements. We indicated that CMS does not currently collect data regarding digital health literacy among MA enrollees. Consequently, we would have no way of knowing or estimating the extent of low digital health literacy specifically among MA organizations' enrollees; how MA organizations would approach digital health literacy screening and digital health education; how much spending they would engage in related to these efforts; how much savings they would encounter (due to improved enrollee health outcomes because of improved digital health literacy), for example, how much time they would spend on these efforts; or how the MA program would grow as we see the effects of the proposed regulation. We estimated the direct non-quantified burden consists of MA organization staff hours spent, resources purchased, and any digital health education for enrollees performed. We further noted that MA organizations may differ in how their spending for the proposed

requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation. Thus, we concluded that the proposed provision would impose an unknown amount of information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) because burden cannot be quantified.

We solicited comment from MA organizations on how much burden they expect this proposed provision might add. Regarding the impact of the proposed requirement for the MA organization to make information about its digital health literacy screening and digital health education programs available to CMS upon request, we noted that we did not anticipate requesting this information from more than nine MA organizations in a given year. We noted, however, that we believed it important to reserve the right to ask for this information if necessary, and that we structured the proposed regulation text accordingly. We also provided that since we estimate fewer than ten respondents, the information collection requirement was exempt (5 CFR 1320.3(c)) from the requirements of the PRA of 1995 (44 U.S.C. 3501 et seq.). Consequently, we found that there would be no need for review by OMB under the authority of the PRA.

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

In summary, CMS proposed to add a new requirement at § 422.112(b) that all MA organizations offering coordinated care plans have procedures to identify enrollees with low digital health literacy and offer them digital health education to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are

not in the same location using electronic exchange, as defined in § 422.135. We solicited comments on this proposal, including whether this requirement should be expanded to all MA organizations rather than only those offering coordinated care plans. In addition, CMS proposed to include a requirement that MA organizations make information about these programs available to CMS upon request, and questioned whether we should require regular reporting of data related to these from MA organizations alongside other Part C reporting requirements. We solicited comment on these proposals. We received the following comments on these proposals, and our responses follow:

Comment: Most comments were generally supportive, especially of the proposal to allow MA organizations flexibility and discretion in implementing the proposed requirement.

Response: We thank commenters for their support.

Comment: Many commenters requested that CMS explain what MA organization compliance and effectiveness would look like under this policy.

Response: We acknowledge that many MA organizations will be building digital health education programs from scratch and may face logistical challenges unique to their population, service area and network. As such, we will consider future compliance standards carefully, but we reaffirm that MA organizations have discretion to enact practices that best suit their unique situations. CMS recognizes best efforts in this new and emerging area of need among the MA population may evolve, and we expect that MA organizations will similarly evolve their programs as they gain experience with digital health literacy screening and programming.

Comment: Many commenters requested CMS define terminology surrounding digital health literacy.

Response: We appreciate this suggestion. However, we are concerned that establishing definitions of certain terminology may detract from the flexibility we intend to provide MA organizations during their initial development and implementation of digital health education programs. As such, we will not provide standard definitions for digital health literacy terms at

this time beyond those referred to in the preamble to this final rule. In developing future policy or guidance documents, we may consider providing or compiling such a list of relevant definitions.

Comment: Many commenters suggested CMS establish standardized reporting metrics and resources for screening enrollees' digital health literacy.

Response: We thank commenters for this suggestion and will consider establishing standards and reporting metrics in future policymaking. However, as we noted in the preamble to this final rule, CMS does not anticipate requesting information from more than nine MA organizations regarding information about their digital health literacy screening tool or their digital health education programs. Establishing standardized reporting metrics would not be consistent with this intent.

Moreover, at this time we believe that establishing such standardized resources and metrics would be counter to the principles of flexibility upon which this provision was established. We are concerned that any reporting metrics would limit the flexibility we intend to provide MA organizations in initially establishing and implementing digital health education programs tailored to their respective covered populations. However, we believe that reporting metrics may be appropriate to add in the future after MA organizations and enrollees have gained experience with these programs, and we may consider adding reporting metrics in the future.

In addition, we note that both the proposed and final rules reference several sources of information on digital health literacy, the kinds of challenges that lack of digital health literacy pose to enrollees, especially those in vulnerable populations, and a range of additional information on this topic. While these references are not meant to serve as guidance, they may prove useful as a starting point for MA organizations beginning to build a digital health education program which is compliant with the new final rule. We further note that MA organizations are afforded the flexibility in this final rule to determine the most appropriate tools and methods for the populations they serve. As such, we encourage plans to engage with

enrollees, providers, and other MA organization affiliated entities to determine the best methods for implementing this provision. Therefore, CMS is not finalizing any standard set of resources or reporting metrics at this time.

Comment: Many commenters suggested that CMS convene an industry workgroup to study research-driven standards and effective methods for improving digital health literacy. One such commenter opposed finalizing these provisions until the workgroup could make recommendations regarding definitions and standards. This commenter recommended that CMS, in the interim, work with MA organizations to improve language used to describe telehealth services in EOCs.

Response: We will take the suggestion to convene an industry workgroup into consideration; however, we will not finalize plans to convene such a workgroup in this final rule. We note that the provision regarding digital health education is sufficiently broad and flexible to allow for MA organizations to establish a range of methods and practices as they deem appropriate.

Also, CMS will not be providing standard definitions or language for describing telehealth at this time due to concerns of limiting MA organization discretion. We encourage MA organizations to use resources referenced throughout the preamble to this final rule as well as other sources as deemed appropriate.

We thank commenters for their suggestion to improve language used to describe telehealth services in EOCs and will consider adding language updates regarding telehealth to the EOC in the future.

Comment: Several commenters recommended that this proposal be expanded to require all MA organizations, and not just coordinated care plans, to implement a digital health education program. No commenters expressed opposition to this policy change.

Response: We appreciate feedback from commenters. Given the recommendations from commenters and the absence of any commenters opposed to expanding this requirement to all

MA organizations, we are finalizing our proposal with modifications to expand the requirement to encompass all MA organizations, not just MA organizations that offer coordinated care plans. We are therefore finalizing the proposed regulation text at § 422.100(n) instead of § 422.112(b)(9). Section 422.112(b) applies to only MA organizations offering coordinated care plans while § 422.100 sets forth general requirements related to benefits and coverage by MA plans.

Comment: Some commenters requested that CMS delay the effective date or any data collection until contract year 2025 and use lessons learned to build a framework for measurement. Other commenters requested that CMS not include a digital health literacy or education section in the annual Part C reporting requirements.

Response: We appreciate these comments and note these concerns. We appreciate that MA organizations may be establishing digital health education programs which are new to enrollees as well as MA organizations. However, with the flexibility and discretion afforded in this provision, we believe that MA organizations possess the capacity to develop and implement compliant programs by January 1, 2024, the effective date of these policies. We also note that this final rule does not establish a standard data collection effort or standard framework for measuring programs (aside from the broad statistics set forth in the regulation text and noted in this section of this final rule), and, as such, we do not believe that delaying the effective date of this provision would be reasonable.

We note that the proposed rule reiterates the authority of CMS to collect information upon request, including but not limited to statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of § 422.100(n). However, MA organizations may record and keep this and any other information related to their digital health

education programs in the manner they deem most appropriate, and CMS is not pursuing any uniform data collection effort (such as Part C reporting requirements) at this time.

Comment: Some commenters expressed concern that this requirement may backfire and cause enrollees to believe that they are being targeted and/or forced to participate, even though it would be voluntary.

Response: While we appreciate the commenters' concerns, we disagree. We note that while our proposed provision acknowledges the necessity of assessing enrollees' digital health literacy, CMS discourages use of screening tools which ask specific questions related to age, income, educational attainment, or race and ethnicity toward assessing an enrollee's digital health literacy. We note that such questions may make enrollees believe they are being targeted.

Comment: Other opposing comments noted that there is insufficient evidence that these programs are beneficial, that these requirements will impose new burdens or costs on MA organization, and that digital health literacy and education should be dependent on and under the purview of providers, not MA organizations.

Response: As we noted in the proposed rule, research indicates that, "Individuals with a higher degree of digital health literacy receive more health care information, are better equipped to evaluate the quality of information regarding their health care, and report higher telehealth usage."⁴⁷ We further explained that a large body of research indicates that a lack of digital health literacy has an impact on overall health. To this end, we believe that MA organizations have an opportunity to meaningfully impact the health of their enrollees by implementing robust digital health education programs.

We acknowledge the commenter's concerns that these programs may increase MA organization burden or costs, and we agree that these requirements will impose some level of burden and cost on MA organizations. However, commenters did not provide specific feedback

⁴⁷<https://jamanetwork.com/journals/jama/article-abstract/2426088>.

or data regarding the anticipated increased costs and/or burdens imposed on MA organizations, and as a result, CMS is unable to make broadly applicable estimates regarding either. Additionally, for reasons set forth in this final rule, CMS is not able to provide quantitative estimates regarding probable MA organization burden for implementing this provision.

CMS does not agree that digital health literacy and education should be exclusively dependent on, nor under the exclusive purview of, individual providers. MA organizations are often better positioned than individual providers to coordinate the care of their enrollees, and this digital health education programming is part of such care coordination. Further, we note that providing support for digital health education programs falls outside the scope of daily work assignments for most MA network providers and medical staff. Placing such a burden on providers to educate all patients who are MA enrollees in the context of hospital, clinic, or other health-related visits would therefore be counter to the principles of this provision. While providers may be well suited to give occasional guidance and support to enrollees regarding digital health literacy, CMS notes that many individuals with lower digital health literacy may attend fewer provider appointments. The potential lack of or limited access for these vulnerable enrollees means that providers may not be providing support to those who have the greatest need. In addition, we note that hospital, clinical, and other health-related visits are often brief and focused on specific medical issues, and that digital health education would not fit well into enrollees' medical visits.

We believe MA organizations are better positioned than providers and suppliers to evaluate their enrollee population's digital health literacy and provide meaningful digital health education to enrollees. MA organizations are well situated to leverage data they have that providers may not, and to promulgate surveys and other relevant materials in an efficient manner. Moreover, in efforts to comply with the provision of this final rule, MA organizations may be able to collaborate with providers and suppliers to provide digital health education in a manner that is efficient and effective for a large group of enrollees.

Comment: A few commenters expressed concern about implementation of the digital health education programs, specifically relating to lack of access to broadband or devices for low-income or rural enrollees. In addition, one commenter noted that because this population tends to be older, sicker, and often less mobile, an effective program might require in-home one-on-one training, which can be time-consuming and costly to MA organizations without additional funding. Moreover, if MA organizations were to provide equipment to enrollees, it would be challenging to limit use to only health services and would likely confuse enrollees.

Response: CMS appreciates this feedback and acknowledges that challenges faced by enrollees regarding access to technology or broadband services are likely to persist. However, as noted in both the proposed and final rules, MA organizations have the option to provide certain enrollees with supplemental benefits (including SSBCI) which address some of these challenges when enrollees meet the eligibility requirements to receive such supplemental benefits. We acknowledge that not all enrollees may be able to take advantage of these services due to access or eligibility; however, we believe that this number of enrollees would likely be small given the research and statistics⁴⁸ showing that enrollees with low digital health literacy are likely to correlate highly with enrollees who are eligible for relevant supplemental benefits. Therefore, at this time, CMS is not finalizing any requirements or provisions related to implementing digital health literacy screenings or the digital health education program specific to low-income or rural enrollees. As previously noted, MA organizations are encouraged to innovate and improve their digital health education programs as they gain experience in this field, as such CMS may consider additional flexibilities or policies in the future to address this specific challenge.

We note the commenter's concerns about providing in-home training and agree that, in some cases, such a digital health education program would be beneficial to enrollees. However, we also note that this is a broad generalization, and that MA organizations are best suited to make this determination based on the mobility, health status, and other factors unique to each

⁴⁸<https://telehealth.hhs.gov/providers/health-equity-in-telehealth>.

enrollee. Additionally, as noted previously, CMS agrees that there may be some cost involved in implementing a digital health literacy screening and a digital health education program. However, we are unable at this time to provide specific cost estimates.

We also note commenter's concerns about their ability to limit use of digital equipment to health services. However, we disagree. Current digital capability allows for a variety of controls, firewalls, and other programs that are designed to limit or otherwise curate the functions available to individuals utilizing digital equipment. Moreover, CMS has established standards in regulation relating to allowable supplemental benefits, and we believe that these regulations effectively clarify when MA organizations may offer specific supplement benefits and to whom MA organizations may offer them. We encourage MA organizations that provide digital equipment to their enrollees to take advantage of controls, firewalls, and other capabilities that would safeguard against enrollees using such equipment in an unintended or otherwise noncompliant manner.

Comment: One commenter suggested CMS work with community-based advocacy and research groups to ensure concerns of vulnerable communities are addressed in the planning and implementation of this regulation.

Response: We thank commenters for this recommendation and encourage MA organizations as a part of any care coordination activities to connect with and create links for enrollees with local advocates and groups with expertise in the area of digital health literacy and education. We encourage MA organizations to engage these groups where appropriate when creating plans for implementing digital health education programs.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, with modification, the requirement that MA organizations must establish procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same

location using electronic exchange, as defined in § 422.135. We are finalizing the proposal with modifications to apply the new requirement to all MA organizations, rather than only to MA organizations offering coordinated care plans by finalizing the revision at § 422.100(n) instead of § 422.112(b)(9). In addition, we are finalizing without modification the proposed policy that the MA organization must make information about its digital health literacy screening and digital health education programs available to CMS upon request. We are further finalizing our proposed language providing a non-exhaustive list of the information CMS may request from MA organizations under this policy.

5. Quality Improvement Program (§ 422.152)

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

Section 422.152(c) provides that CCIPs must include methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a CCIP; mechanisms for monitoring MA enrollees that are participating in the CCIP and evaluating participant outcomes, such as changes in health status; performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research, and systematic and ongoing follow-up on the effect of the CCIP. Organizations must report the status and results of each program to CMS as requested. The intent of the CCIPs is to promote effective chronic disease management and improve care and health outcomes for enrollees with chronic conditions. Furthermore, CCIPs should support the CMS Quality Strategy; include interventions that surpass MA organizations'

inherent care coordination role and overall management of enrollees; engage enrollees as partners in their care; promote utilization of preventive services; facilitate development of targeted goals, specific interventions, and quantifiable, measurable outcomes; guard against potential health disparities; and produce best practices.⁴⁹

In accordance with 1852(e) of the Act, MA organizations are required to report quality performance data to CMS. MA organizations generally report such data through the Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), Consumer Assessment of Healthcare Providers and Systems (CAHPS), and other related data collection tools. As codified at § 422.152(b)(3) and (5), MA coordinated care plans are required to report on quality performance data which CMS can use to help beneficiaries compare plans; MA local and regional PPO plans must similarly report under § 422.152(e)(2)(i). The areas of measurement include outcomes, patient experience, access, and process measures. In addition, CMS uses this information to develop and publicly post a 5-star rating system for MA plans based on its authority to disseminate comparative information, including about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act.

To meet the needs of their enrolled special needs populations, MA special needs plans (SNPs) have additional QI program requirements, including the implementation of an approved model of care (MOC), which serves as the framework for meeting the individual needs of SNP enrollees, and the infrastructure to promote care management and care coordination (see § 422.152(g)). As part of the initial MA SNP application and renewal requirements and through MOC submissions, SNPs provide to CMS a detailed profile of the medical, social, cognitive, and environmental aspects, the living conditions, and the co-morbidities associated with the SNP population, including information about health conditions impacting SNP enrollees along with other characteristics that affect health, such as population demographics (for example, average

⁴⁹<https://www.cms.gov/Medicare/Health-Plans/Medicare-Advantage-Quality-Improvement-Program/5CCIP>

age, sex, gender, ethnicity), and potential health disparities associated with specific groups (for example, language barriers, deficits in health literacy, poor socioeconomic status, cultural beliefs/barriers, caregiver considerations, or other). SNPs must also capture limitations and barriers that pose potential challenges for accessing care and/or maintaining and improving SNP enrollee health status.

Additionally, through health risk assessments (HRAs), SNPs identify the medical, functional, cognitive, psychosocial, and mental health needs of their enrollees, who are all special needs individuals, and address those needs in an individualized care plan for each enrollee. In the final rule titled “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” which appeared in the Federal Register May 9, 2022 (87 FR 27704), CMS finalized a new requirement for SNPs at § 422.101(f)(1)(i), requiring the HRA tool to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on the domains of housing stability, food security, and access to transportation beginning in 2024. We expect that this data collection would also provide information to MA organizations about potential health disparities among their enrollees.

Persistent inequities in health care outcomes exist in the United States, including among populations enrolled in MA organizations.⁵⁰ Belonging to a racial or ethnic minority group, living with a disability, being a member of the LGBTQI+ community, having limited English proficiency, living in a rural area, or being near or below the poverty level, is often associated

⁵⁰Disparities in Health Care in Medicare Advantage by Race, Ethnicity and Sex, April 2022

with worse health outcomes.^[51 52 53 54 55 56 57] Such disparities in health outcomes are the result of a number of factors and exist regardless of health insurance coverage type. Although not the sole determinant, poor health care access and provision of lower quality health care contribute to health disparities. Research has shown that the expansion of health insurance coverage, for example through Medicaid expansion under the ACA, and the resulting increased access to health care, is linked to reductions in disparities in health insurance coverage as well as reductions in disparities in health outcomes.^[58]

In the final rule titled “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023,” which appeared in the **Federal Register** May 6, 2022 (87 FR 27208), CMS finalized a proposal to update the quality improvement strategy (QIS) standards for qualified health plan (QHP) issuers, requiring them to address health and health care disparities as a specific topic area within their QIS beginning in 2023. Examples of QIS activities that fall under the health and health care disparities topic area for QHPs can include language services, community outreach, cultural competency trainings, social needs-sensitive self-management recommendations, and increased demographic and disparities-related data collection; see the QIS Technical Guidance and User Guide for the 2023 Plan Year for more information. CMS is committed to advancing health equity for MA enrollees. Based on CMS’

⁵¹Lindenauer, P.K., Lagu, T., Rothberg, M.B., Avrunin, J., Pekow, P.S., Wang, Y., Krumholz, H., & Hines, H. (2013). Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *British Medical Journal*.

⁵²Trivedi, A.N., Nsa, W., Hausmann, L.R.M., Lee, J., Ma, A., Bratzler, D., Mor, M., Baus, K., Larbi, F., & Fine, M. (2014). Quality and Equity of Care in U.S. Hospitals. *New England Journal of Medicine*. 371(24):2298-2308.

⁵³Polyakova, M., Udalova, V., Kocks, G., Genadek, K., Finlay, K., & Finkelstein, A.N. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. *Health Affairs (Project Hope)*, 40 (2), 307-316. <https://doi.org/10.1377/hlthaff.2020.02142>.

⁵⁴Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. (2018). Rural Health Research Gateway. <https://www.ruralhealthresearch.org/recaps/5>.

⁵⁵2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. (2020). HHS Office of Minority Health. https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.

⁵⁶Sexual Orientation Disparities in Risk Factors for Adverse COVID-19-Related Outcomes, by Race/Ethnicity. (2021, February 5). CDC. www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.

⁵⁷Poteat, T.C., Reisner, S.L., Miller, M., & Wirtz, A.L. (2020). COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv: The preprint server for health sciences, 2020.07.21.20159327. <https://doi.org/10.1101/2020.07.21.20159327>.

⁵⁸Guth, M., Garfield, R., & Rudowitz, R. (2020). The Effects of Medicaid Expansion Under the ACA: Studies from January 2014 to January 2020. Kaiser Family Foundation. <https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/>.

definition of health equity and in alignment with similar CMS programs, we believe that MA organizations' QI programs are an optimal vehicle to develop and implement strategies and policies designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved.

MA organizations have long focused on addressing health disparities through QI program requirements. By assessing cultural, language, health literacy, financial, psychosocial & family support, community networks, and transportation needs, etc., and addressing those needs through a variety of QI program activities across their enrollee populations, MA organizations gain insight into their enrollee populations. Some of the specific QI activities include addressing barriers to health care, for example assisting enrollees with transportation to follow-up primary care visits post-hospitalization, linking enrollees to community resources, and improving care coordination and case management, especially for vulnerable and/or underserved enrollees. In addition to implementing QI activities for the broader enrollee populations, we are aware that some MA organizations have focused their QI activities on underserved groups. For example, to better serve these groups, several MA organizations have made efforts to improve their communication by providing cultural trainings for their staff, tailoring enrollee materials to ensure they are linguistically and culturally appropriate, and hiring plan staff and establishing contracts with providers who are bilingual. Some MA organizations have implemented specific interventions that target blood pressure control, or improved rates for various cancer screenings in targeted groups. These types of activities can improve the health of and health care for MA enrollees.

To improve the quality of care and health outcomes for MA enrollees and support the first pillar in the 2022 CMS strategic plan for advancing health equity, CMS proposed to amend the MA QI program regulations at § 422.152(a). Specifically, we proposed to amend § 422.152 by adding a new paragraph (a)(5), to require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among

their enrollees. We believe that many MA organizations are already addressing disparities and gaps in care for underserved populations through a variety of quality initiatives. Rather than limit these activities to specific QI program requirements such as the CCIPs, we proposed that MA organizations would be required to incorporate one or more activities that reduce disparities in health and health care across the broad spectrum of QI program requirements. MA organizations may implement activities such as improving communication, developing and using culturally appropriate materials (to distribute to enrollees or use in communicating with enrollees, community outreach, or similar activities. MA organizations should design activities so that they meet the needs of their particular enrollees, and therefore CMS is not prescriptive in the types of activities MA organizations must implement to meet this proposed new requirement. However, MA organizations must ensure that all their designed activities are broadly accessible irrespective of race, ethnicity, national origin, religion, sex, disability, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparity in health or health care. Furthermore, adopting this requirement for MA organizations as part of their required QI programs aligns with health equity efforts across CMS policies and programs.

We summarize the comments received on the proposal at § 422.152(a)(5) and provide our responses to those comments in this section of this rule.

Comment: 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. Many of the commenters believed that MA plans' QI programs are an important vehicle to develop and execute activities designed to reduce disparities, and advance equity in the health and health care of MA enrollees. Commenters commended CMS for its continued efforts to advance health equity for those who have been historically underserved, marginalized, and adversely affected by persistent poverty and

inequality. Commenters also believed that closing health care gaps will enable every individual to achieve optimal health through the delivery of equitable health services. Additionally, each of the commenters conveyed a strong commitment to promote health equity and quality of care in the MA program.

Response: CMS thanks the commenters and agrees that MA organizations are uniquely positioned to address disparities in health and health care, and that QI programs are an important vehicle for improving quality and health outcomes for MA enrollees. CMS appreciates MA organizations commitment to promote health equity and quality of care in the MA program.

Comment: Some of the commenters conveyed that they were already addressing disparities in care for underserved populations through a variety of quality initiatives. Another commenter conveyed that the examples provided in the proposed rule, that is, improving communication, developing, and using linguistically and culturally appropriate materials, hiring bilingual staff, and engaging in community outreach, were good examples of actions that have helped reduce disparities in communities across the country.

Response: CMS thanks the commenters and appreciates the initiatives that organizations have already undertaken to reduce barriers to care, improve care coordination and access to preventive services and community resources. CMS believes these initiatives will help to promote health equity among all MA enrollees.

Comment: 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. Furthermore, they noted this will allow plans to respond to the needs of the communities they serve, define appropriate QI activities and promote meaningful efforts to address disparities. A commenter also requested that CMS not limit MA organizations to those QI activities currently being implemented by QHPs.

Response: We appreciate the comments and reiterate that the requirement we proposed and are finalizing is not prescriptive in the types of activities MA organizations must or can implement to meet this new requirement. CMS also points out that the QHP activities described in the preamble were meant to serve as examples, not required activities. CMS firmly believed that plans should tailor QI program activities to meet the needs of their enrollees. However, CMS reminds MA plans that they must ensure these activities are broadly accessible irrespective of race, ethnicity, national origin, religion, disability, sex, or gender.

Comment: A commenter requested that CMS explicitly state that QI program activities can include, as an element of the QI program (that is, CCIP, QI Initiative, etc.), nutrition services such as food, prepared meals, and groceries.

Response: CMS appreciates the comment and again notes that we are generally not being prescriptive in the types of QI program activities MA organizations must or can implement to meet this new requirement. However, CMS believes that nutrition services are one of many activities that could help to advance health outcomes in MA enrollees, and as such has included meals (on a limited basis) as an allowable supplemental benefit for which all enrollees may be eligible, provided they meet the criteria set forth in Chapter 4 of the Medicare Managed Care Manual.⁵⁹ Additionally, CMS has included meals beyond a limited basis as an allowable benefit under Special Supplemental Benefits for the Chronically Ill (SSBCI), provided that the requirements in § 422.102(f) are met regarding the chronically ill enrollees that are eligible for the benefits and that the item or service covered as an SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. We note that any benefits (including meals) provided to enrollees must be included in their bids and be offered in a manner consistent with applicable regulations and

⁵⁹<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

criteria for providing such benefits. Furthermore, we note that plans may not offer meals through a QI program instead of through regular supplemental benefits or SSBCI.

Comment: A few commenters encouraged CMS to exercise appropriate oversight to ensure that MA organizations are implementing activities that are reducing disparities, clearly and measurably. A few commenters also recommended that MA organizations seek to identify disparities through data collection and stratification of enrollees by various subpopulations. Similarly, other commenters conveyed that they already had mechanisms in place to identify disparities in health and health care access among their members, investigate root causes, and develop reduction strategies.

Response: CMS appreciates the comments and recognizes that some MA organizations already have mechanisms in place to identify disparities and address gaps in care. CMS notes that MA organizations have tools to assist them in gaining insight into their enrollee populations, such as CCIP initiatives, claims data, HRAs, detailed profiles of SNP enrollees and identification of barriers to accessing care, as required by the MOC, etc., and can use this data to identify gaps in care and tailor QI program activities accordingly.

Lastly, we note 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, we do not believe it is necessary to impose additional means of oversight.

Comment: Another commenter supported the increased focus on health equity and requested that CMS provide guidance regarding measuring disparity reduction, such as the use of the Health Equity Summary Score (HESS) Dashboard for targeted sub-groups. The commenter suggested that CMS publish the HESS and its research and findings to date so that stakeholders can review and comment. They also requested the results from CMS' recent survey about the HESS and its utility, feasibility, ease-of-use, be published. And, that CMS

stipulate a score or targeted proportional improvement which, if met, would signal that health equity results have been achieved, allowing for targeted improvement by each plan, rather than compared to a group average.

Response: CMS thanks for commenter for their feedback and appreciates the interest regarding HESS research. Though outside of the scope of this rule, CMS points out that related information has already been published about the HESS.^{60,61,62} More information can be found in The Office of the Assistant Secretary for Planning and Evaluation (ASPE) May 2021 report on health equity measures.⁶³ Finally, an article on the development of the Medicare Advantage Health Equity Summary Score Dashboard is slated to be published in the March 2023 issue of *American Journal of Managed Care*. CMS believes the references included in the footnotes will provide the commenter with additional insight on the HESS.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed change to 422.152(a)(5) without modification.

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

1. Introduction

On March 1, 2022, President Biden announced a national strategy regarding behavioral health to strengthen system capacity and connect more individuals to care by ensuring that the nation's health and social services infrastructure addresses mental health holistically and equitably.⁶⁴ Further, the 2022 CMS Strategic Framework describes CMS' broad goals to expand coverage and enhance access to equitable health care services for those covered under CMS programs.⁶⁵ CMS is also prioritizing, as part of the agency's many cross-cutting initiatives, to

⁶⁰<https://pubmed.ncbi.nlm.nih.gov/31713030/>

⁶¹https://journals.lww.com/lww-medicalcare/Fulltext/2022/06000/Measuring_Inconsistency_in_Quality_Across_Patient.9.aspx

⁶²<https://pubmed.ncbi.nlm.nih.gov/36038518/>

⁶³<https://aspe.hhs.gov/sites/default/files/private/pdf/265566/developing-health-equity-measures.pdf>

⁶⁴<https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/>

⁶⁵<https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf>

improve access to behavioral health services and outcomes for people with behavioral health care needs.⁶⁶

According to the Health Resources and Services Administration (HRSA), more than one-third of Americans live in designated Mental Health Professional Shortage Areas,⁶⁷ meaning these communities do not have enough providers to meet the needs of their population. Furthermore, according to the results from the 2020 National Survey on Drug Use and Health, published by SAMHSA, while overall 65 percent of people with serious mental illnesses (SMI) receive treatment,⁶⁸ people of color with SMI receive care at significantly lower rates. More specifically, while approximately 69 percent of white people with SMI received mental health care, for Black, Hispanic, and Asian people with SMI the rates were 55 percent, 56 percent, and 44 percent respectively.⁶⁹ The 2020 National Survey results also indicate that common reasons for not receiving treatment for SMI include: inability to afford the cost of treatment, not knowing where to go to receive services, and health insurance not covering services.⁷⁰ CMS included a request for information (RFI) in the proposed rule titled “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs” published in the Federal Register January 12, 2022 (87 FR 1842) (hereinafter referred to as the January 2022 proposed rule), to solicit public comment regarding the challenges that exist with accessing behavioral health providers within MA plans. We sought stakeholders’ input concerning a range of topics, including the challenges related to building behavioral health networks for MA plans, accessing behavioral health providers for MA enrollees, and requesting suggestions on how to address issues with building adequate behavioral health networks within MA plans. We received a number of comments from stakeholders and

⁶⁶<https://www.cms.gov/files/document/cms-behavioral-health-strategy.pdf>

⁶⁷<https://data.hrsa.gov/topics/health-workforce/shortage-areas>

⁶⁸<https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf>

⁶⁹<https://www.samhsa.gov/data/sites/default/files/reports/rpt35324/2021NSDUHMHChartbook102221B.pdf>

⁷⁰<https://www.apa.org/monitor/2020/07/datapoint-care>

explained in the December 2022 proposed rule how we used those comments in shaping our proposals.

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

We solicited comment on our proposals.

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

Section 1852(d)(1) of the Act permits an MA organization to select the providers from which an enrollee may receive covered benefits, provided that the MA organization, in addition to meeting other requirements, makes such benefits available and accessible in the service area with promptness and in a manner that assures continuity in the provision of benefits. To implement and adopt related standards for this, CMS codified, with some modifications, network adequacy criteria and access standards that were previously outlined in sub-regulatory guidance in the “Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program” final rule, which appeared in the Federal Register on June 2, 2020 (85 FR 33796), hereinafter referred to as the June 2020 final rule. In that final rule, we codified, at § 422.116(b), the list of 27 provider specialty types and 13 facility specialty types subject to CMS network adequacy standards. Although § 422.116(b)(3) authorizes removal of a specialty or facility type from the network evaluation criteria for a specific year without rulemaking, CMS did not adopt in § 422.116 a mechanism to add new provider types without rulemaking. We proposed to add to the list of provider specialties here to address access to behavioral health services more broadly than the current regulation.

Currently, MA organizations are required to demonstrate that they meet network adequacy for two behavioral health specialty types, psychiatry and inpatient psychiatric facility

services, under § 422.116(b). Further, the regulation at § 422.112 includes a number of requirements to ensure that MA enrollees have adequate access to covered services. Of note, § 422.112(a)(1) requires MA organizations to maintain and monitor a network of appropriate providers that provides access to typically used services including, primary care providers, specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics and other providers.

In response to the RFI in the January 2022 proposed rule, we received comments emphasizing the importance of network adequacy and ensuring adequate access to behavioral health providers in MA plans. Stakeholders responses to the RFI suggested that CMS expand the network adequacy time and distance standards for MA plans beyond those that we currently review through our network adequacy evaluations. Commenters suggested that we expand the standards to include other outpatient behavioral health physicians and health professionals, including those that treat substance use disorders (SUDs), as part of our evaluation of MA plan networks in order to better meet MA enrollees needs in accessing behavioral health care.

Even though over one million Medicare beneficiaries had a diagnosis of Opioid Use Disorder (OUD) and more than fifty thousand experienced an overdose in 2021, fewer than 1 in 5 of these Medicare beneficiaries with a diagnosis of OUD receive treatment for their OUD.⁷¹ Current standards of care for OUD include treatment through three Food and Drug Administration (FDA) approved medications (buprenorphine, naltrexone and methadone), along with other services to provide the best approach to treating SUD. Enrollees can access Medications for Opioid Use Disorder (MOUD) in various settings including in Opioid Treatment Programs (OTPs) and, at the time of the December 2022 proposed rule proposal, through qualified practitioners (physicians, nurse practitioners, physician assistants, etc.) who have obtained a waiver through SAMHSA to dispense these medications in office settings.

⁷¹<https://oig.hhs.gov/oei/reports/OEI-02-22-00390.pdf>

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

First, we proposed to add three new provider specialty types to the list at § 422.116(b)(1) to make them subject to the time, distance and minimum number requirements in our network adequacy evaluation: (1) clinical psychology, (2) clinical social work, and (3) one category called Prescribers of Medication for Opioid Use Disorder that includes two specialty types: providers with a waiver under section 303(g)(2) of the Controlled Substances Act (CSA) and OTPs. Most of these new specialty types are defined the same way as they are used for the original Medicare program in section 1861(hh) of the Act (defining “clinical social worker”), § 410.71(d) (defining “clinical psychologist”), and section 1861(jjj)(2) of the Act (defining “Opioid Treatment Program”). Section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)(G)(ii)) establishes which providers have a waiver and we do not believe a definition in the MA regulations at 42 CFR part 422 is necessary.

Our current regulations, at § 422.116(a)(2), specify that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type. Therefore, as part of the proposed changes to our list of provider specialty types under § 422.116(b)(1), we proposed base time and distance standards and minimum number of in-person providers in each county type for each new specialty type as follows:

Maximum Time and Distance Standards:

Provider/ Facility type	Large Metro		Metro		Micro		Rural		CEAC ⁷²	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
Clinical Social Work	20	10	30	20	50	35	75	60	125	110
Prescribers of Medication for Opioid Use Disorder (including MOUD Waivered Providers and/or OTPs)	20	10	30	20	50	35	75	60	110	100

Minimum Ratios:

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

In the proposed rule titled “Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” proposed rule which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (hereinafter referred to as the February 2020 proposed rule), we explained how CMS developed the base time and distance standards and the minimum provider requirements used in § 422.116 (85 FR 9094 through 9103). CMS established the current base time and distance standards for the provider and facility types listed in § 422.116 by mapping the various specialty types’ practice locations from the National Provider and Plan Enumeration System (NPPES) National Provider Identifier (NPI) file to the Medicare beneficiary locations from CMS enrollment data. We further explained that we then tested different options for combinations of beneficiary coverage percentages and maximum travel distances to determine what was feasible and practical for the majority of counties given the trade-off between beneficiary coverage and travel distance. The travel time standards were calculated according to the average driving speeds in each of the ZIP code types (urban, suburban, rural) that beneficiaries would traverse between their homes and the provider locations (85 FR 9097).

⁷² Counties with extreme access considerations (CEAC)

Other than the use of the different and more recent data sources that are identified in this preamble, we followed the same analysis and steps to develop the time and distance standards that we proposed to apply to the new behavioral health specialty types.

Further, we explained in the February 2020 proposed rule how CMS determines the minimum number requirement for all provider specialty types. By multiplying the “minimum ratio” by the “number of beneficiaries required to cover,” dividing the resulting product by 1,000, and rounding up to the next whole number. This is reflected in § 422.116(e)(2)(i) and (e)(3); the current regulation text addresses how the number of beneficiaries required to cover is calculated and will apply to the proposed new provider specialty types. The minimum ratio is the number of providers required per 1,000 beneficiaries. We developed the minimum ratios that currently appear in § 422.116 using various data sources, including, Medicare fee for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, US Census population data, National Ambulatory Medical Care Survey data, and AMA data on physician productivity. In developing the proposal here to add new specialty types subject to network adequacy evaluation, we conducted additional research to inform appropriate minimum ratio requirements. We reviewed utilization data among FFS Medicare beneficiaries for the proposed specialty types for 2019 through 2021. We reviewed literature on the prevalence of behavioral health disorders among Medicare beneficiaries and existing models for projecting the needed behavioral health workforce such as the Health Resources and Services Administration’s (HRSA) Health Workforce Simulation Model,⁷³ to inform estimates of the potential demand for behavioral health services. We also reviewed data on the potential supply of behavioral health providers, that is, Medicare-enrolled providers in the Provider Enrollment, Chain, and Ownership System (PECOS),⁷⁴ the list of practitioners waived to provide buprenorphine for the treatment of OUD published by

⁷³<https://bhws.hrsa.gov/data-research/projecting-health-workforce-supply-demand/behavioral-health>

⁷⁴<https://pecos.cms.hhs.gov/pecos/login.do#headingLv1>

SAMHSA,⁷⁵ and the list of OTP providers enrolled in Medicare published by CMS.⁷⁶ We also sought clinical consultation regarding the types of behavioral health providers that treat Medicare beneficiaries, the service locations in which beneficiaries typically use behavioral health care, and typical patterns of care for accessing medication treatment for opioid use disorder, that is, the use of office-based and OTP-based care. Other than the use of different and more recent data sources as identified in this preamble, we followed the same analysis and steps to develop the proposed minimum provider ratios for these new specialty types.

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

Finally, to encourage increased access to telehealth providers in contracted MA networks, § 422.116(d)(5) provides that for certain specialties, MA plans may receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Medicare FFS claims data shows that telehealth was the second most common place of service for claims with a primary behavioral health diagnosis in 2020. As noted previously, the top provider specialty types to provide certain outpatient behavioral services to beneficiaries in that year included psychiatrists, clinical social workers, nurse practitioners, and clinical psychologists. Additionally, previous input from stakeholders discussed the importance of access to telehealth services specific to behavioral health in expanding access to care. Based on these considerations, we also proposed to add all the new behavioral health specialty types to the list at § 422.116(d)(5) of the specialty types that that will receive the credit if the MA

⁷⁵<https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator>

⁷⁶<https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers>

organization's contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, for covered services.

We solicited comment on this proposal.

Comment: We received numerous comments that were supportive of our proposal to add the three new behavioral health specialty types to the list at § 422.116(b)(1), requiring these new specialty types be subject to network adequacy evaluation. Commenters noted that expanding the MA network adequacy standards to include the new specialty types would positively impact access to behavioral health providers for enrollees.

Response: We thank commenters for their input on this proposal. CMS is committed to ensuring access to provider networks for MA enrollees is sufficient. Adding behavioral health specialty types to our network adequacy standards to supplement the current specialties (psychiatry and inpatient psychiatric facility services) will further strengthen network adequacy requirements for MA plans and enhance access for enrollees.

Comment: We also received several comments that opposed the proposal to add the new behavioral health specialty types to the network adequacy evaluation, mainly citing concerns with shortages of behavioral health providers that could hinder the ability for MA plans to meet network adequacy standards. A few commenters suggested that we set the network standards for behavioral specialty types to mirror the network standards for the primary care specialty type.

Response: We used current data and followed the established steps to develop the time and distance standards and minimum ratios included in the proposal for the new behavioral health specialty types. Consistent with our established practice, the network adequacy standards for the specialty types we are finalizing in this rule are set such that MA organizations are able to meet them based on the current supply and distribution of behavioral health providers. We also remind commenters that CMS provides annual updates (422.116(a)(4)(ii)) to the Provider Supply file, which identifies available providers and facilities with office locations and specialty types

that can be utilized as a supplemental tool for identifying appropriate providers. Further, an MA plan may request an exception to network adequacy criteria under our exceptions process (422.116(f)), when providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type, and the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

Comment: Many commenters noted that the Consolidated Appropriations Act, 2023 eliminated the SAMHSA required waiver to prescribe medication for treatment of OUD, and therefore suggested that CMS not finalize the new behavioral health “Prescribers of Medication for Opioid Use Disorder” requirement as part of our network adequacy standards. Additionally, a few commenters indicated that while the waiver requirement was no longer in effect, CMS should maintain a network adequacy standard specifically for OTPs or develop alternative standards for all prescribers of medication for opioid use disorder.

Response: We acknowledge that 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. Therefore, we will not be finalizing this portion of our proposal. Because we planned to use SAMHSA’s list of waived providers to populate the Provider Supply file, we will no longer be able to accurately track the providers that prescribe medications like buprenorphine in order to create and maintain a network adequacy standard.

In addition, we are not adding OTPs to the facility-specialty type list in § 422.116(b)(2). We proposed a combined specialty type called Prescribers of Medication for Opioid Use Disorder, which included OTPs and MOUD Waivered Providers, that allowed us to create meaningful access standards. At this time there is not enough supply of OTPs to create

meaningful access standards. As OTPs continue to expand, we will monitor the appropriateness of setting network adequacy standards in future rulemaking. We remind MA organizations that they are required to arrange for and cover the Part B OTP benefit, which may only be furnished by certified OTPs. Therefore, as a practical matter, MA organizations must include certified OTPs in their networks or arrange out-of-network care (at in-network cost sharing) for their enrollees who need OTP benefits.

Finally, we thank commenters for their suggestions on alternative standards for this important category of providers, and we will consider all comments in future rulemaking.

Comment: Several commenters requested that CMS delay the effective date of the proposal to add new behavioral health specialty types to the network adequacy standards to 2025, indicating that more time would be needed for MA organizations to contract with providers to ensure they are able to meet network adequacy standards especially in advance of applying for new or expanded service areas.

Response: We appreciate commenters suggestions regarding delaying the effective date of our proposal. However, we believe that our regulations currently provide flexibilities that will assist MA applicants in meeting network adequacy standards. These flexibilities include a 10-percentage point credit for new or expanding service area applicants towards the percentage of beneficiaries residing within time and distance standards for the contracted network in the pending service area, and the ability to utilize a Letter of Intent (LOI) which meets our regulatory requirements, to meet network standards at the time of and for the duration of the application review (§ 422.116(d)(7)). In addition, MA organizations are required to provide all medically necessary services to their enrollees; it is our expectation that these organizations already have established relationships with these providers because certain Medicare Part B services are furnished by clinical social workers, as defined in section 1861(hh) of the Act, and clinical psychologist as defined in 42 CFR § 410.71(d).

Comment: A few commenters requested clarification on the types of social workers that will be allowable to submit for network adequacy review purposes.

Response: As detailed in our proposal, commenters may refer to section 1861(hh) of the Act regarding the definition for “clinical social worker.”

Comment: Several commenters supported our proposal to amend the list of health care providers in the existing access to services standards at § 422.112(a)(1)(i) to include that the network must also include providers that specialize in behavioral health services.

Response: We thank commenters for their support of this proposal. As we previously noted, this amendment will reinforce regulatory requirements for MA plans to provide access to critical behavioral health care services.

Comment: Many commenters supported our proposal to add the new behavioral health specialty types to the list of those that receive the 10-percentage point credit (§ 422.116(d)(5)) towards the percentage of beneficiaries that reside within published time and distance standards when the plan includes one or more providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Commenters indicated that telehealth is vital in accessing behavioral health services for enrollees. Some commenters requested that CMS provide a credit higher than 10-percentage points, indicating that it would help plans meet network adequacy standards in light of the behavioral health provider shortage. A few commenters did not support the proposal to provide additional credits for these provider types to MA organizations in meeting network standards.

Response: In our proposed rule, we noted that Medicare FFS claims data from 2020 shows that telehealth was the second most common place of service for claims with a primary behavioral health diagnosis. Further, we agree with commenters that telehealth is important in continuing to expand access to behavioral health care, and that the credit may encourage MA plans to provide additional telehealth benefits to expand access.

We are extending the telehealth credit for the new specialty types consistent with other established credits afforded to MA organizations in meeting network standards. We will continue to monitor the credit and consider whether changes are appropriate in future rulemaking.

Based on our review and consideration of the comments received, and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these provisions with two modifications as follows:

- We are not finalizing the addition of Prescribers of Medication for Opioid Use Disorder as a specialty type for which we set network adequacy standards. We are finalizing the addition of clinical psychology and clinical social work to the list of provider specialty types at § 422.116(b)(1), requiring these new specialty types to be subject to network adequacy standards.

- Adding time and distance standards and minimum ratios for the two new specialty types to § 422.116 to Table 1 to Paragraph (d)(2) and Table 2 to Paragraph (e)(3)(i)(C), respectively, to indicate the standards for the two new specialty types, clinical psychology and clinical social work.

- Amending § 422.112(a)(1)(i) to include that the network must also include providers that specialize in behavioral health services.

- Adding clinical psychology and clinical social work to the list at § 422.116(d)(5) that that will receive the 10 percentage point credit if the MA organization's contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, for covered services.

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

Care Coordination for Behavioral Health Services. In addition to ensuring that there are specific types of providers in behavioral health specialties accessible in an MA organization's provider network, it is also important for individuals with behavioral health needs to have care

coordination available. Care coordination in behavioral health can be broadly described as including the process of assisting an enrollee to access a range of services that will assist in their recovery or improved functioning.

Section 1852(d)(1)(A) of the Act requires MA organizations that use a network of providers to make benefits under the plan available and accessible to each individual electing the plan within the plan service area. CMS proposed to further ensure that enrollees have access to behavioral health services by adding behavioral health services to the types of services for which MA organizations that offer MA coordinated care plans must have programs in place to ensure continuity of care and integration of services at § 422.112(b)(3). Under 422.112(b)(3), MA organizations must coordinate plan services with community and social services available through contracting or noncontracting providers in the area served by the MA plan, which must be made available for enrollees as part of overall delivery and coordination of services. CMS proposed to revise § 422.112(b)(3) to include behavioral health services by adding the phrase “, and behavioral health services” after the words “community-based services” at the end of § 422.112(b)(3). CMS believes the inclusion of behavioral health care services among the services for which MA organizations must have a care coordination program in place will better ensure enrollee access to such services.

Comment: Some commenters requested CMS delay the implementation deadline. These commenters expressed concern with MA organizations’ abilities to secure contracts with providers who will deliver the services.

Response: While CMS appreciates the challenges associated with behavioral health care access, MA organizations’ fundamental responsibility to ensure their enrollees can access Part A and Part B items and services through plan networks, as applicable, remains unchanged with the advent of this provision. We also note that § 422.112(a)(3) requires MA organizations to arrange for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee’s medical needs. MA organizations’ responsibility to cover all

medically necessary care, including behavioral health care, is further discussed in section III.C. of this final rule.

Comment: A commenter expressed support for the addition of behavioral health to care coordination services provision, but also requested a list of specific services that should be added in order to comply with the new provision.

Response: CMS appreciates the request to specify services applicable to care coordination in behavioral health, and the commenter's desire to be thorough, however the codification of a list of specific behavioral health services that require care coordination could inadvertently limit the services offered to an enrollee. Further, the availability of certain types of services could vary based on an enrollee's geographic location. Thus, CMS declines to create a list of this nature at this time in order to promote MA organizations' flexibility to meet their enrollees' needs. We intend this amendment to ensure that MA coordinated care plans consider and address behavioral health conditions and needs of an enrollee when developing and facilitating community and social services for enrollees.

Emergency Medical Condition. In addition to proposing care coordination for behavioral health services, CMS proposed to fully codify the agency's interpretation of section 1852(d)(3)(B) of the Act which is used to determine a condition that qualifies as an "emergency medical condition" for purposes of carrying out the requirements of section 1852(d)(1)(E) of the Act. Section 1852(d)(1)(E) of the Act requires MA organizations to cover, and reimburse a provider for, emergency services without regard to prior authorization or the emergency care provider's contractual relationship with the MA organization.

An "emergency medical condition" under § 422.113(b)(1)(i) is defined as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in serious jeopardy to the health of the individual or their unborn child, serious impairment to bodily function, or serious

dysfunction of any bodily organ or part; this regulatory definition generally mirrors the statutory definition in section 1852(d)(3)(B) of the Act. However, the definition does not explicitly address that its criteria extends to conditions both physical and mental, that is, behavioral, health. CMS interprets the scope of the definition to pertain to both physical and behavioral health conditions when those conditions meet the prudent layperson standard discussed in § 422.113(b)(1)(i), consistent with the statute.

Accordingly, CMS proposed to amend the regulation by inserting “, mental or physical,” after the word “condition” and before the word “manifesting.” We explained that we intended the proposed revision to ensure that emergency medical conditions are easily interpreted as including both physical and mental health conditions, thereby prohibiting the use of prior authorization as required by the statute and guaranteeing that coverage is provided by the MA organization, consistent with the statute. This ensures that enrollees have access to emergency behavioral health services in parity with access to other medical emergency services.

Comment: A commenter requested that CMS specify that the rules pertaining to emergency care in this rule are applicable only to hospital emergency department or free-standing emergency departments.

Response: CMS does not dictate the site at which emergency services must be provided. Section 1852(d)(3)(A) of the Act specifies that emergency services are covered inpatient and outpatient services that are furnished by a provider qualified to furnish the inpatient or outpatient services, and are needed to evaluate or stabilize an emergency medical condition. CMS will continue to use this definition in order to determine when services are emergency services. Additionally, CMS notes that urgently needed services, as defined at § 422.113(b)(1)(iii), must also be covered by MA plans under § 422.113. Urgently needed services are not limited to services from an Emergency Room or Emergency Department and, per § 422.112(b)(1)(iii), are covered services provided when an enrollee is temporarily absent from the MA plan’s service (or, if applicable, continuation) area (or provided when the enrollee is in the service or

continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required as a result of an unforeseen illness, injury, or condition and it was not reasonable given the circumstances to obtain the services through the organization offering the MA plan.

Comment: A commenter requested that CMS consider a specific set of behavioral health services that meet the prudent layperson standard to further clarify the variations of behavioral health symptoms that necessitate emergency care.

Response: We respectfully disagree with this comment. Identifying a specific set of behavioral health services that can or must be used to treat an emergency medical condition in order for the condition (and the corresponding emergency services and post-stabilization services) to be subject to the protections in § 422.113 would undermine and inappropriately limit the regulation.

Comment: Some commenters suggested that CMS clarify that when an enrollee has an emergency medical condition, MA organizations may not issue denials based on medical necessity. The commenters also pointed out that some MA organizations frequently deny payment for emergency services (for example, those services rendered prior to stabilization) based on opinions that such services were not medically necessary, and this practice is variably referred to by MA organizations using terms such as prior authorization, retrospective authorization, retrospective prior authorization, or medical necessity review. Similarly, another commenter offered a scenario when payment for services is denied by an MA organization because the individual, who is stabilized and awaiting evaluation or placement, is provided care that is no longer medically necessary in the opinion of the MA organization.

Response: CMS emphasizes here that section 1852(d)(1)(E) of the Act and § 422.113(b)(2) require coverage—which means payment—of emergency services defined under § 422.113(b)(1)(ii). Emergency services, under the statute and regulation, are covered inpatient and outpatient services that are furnished by a provider qualified to furnish the services and

needed to evaluate or stabilize an emergency medical condition (determined using the prudent layperson standard). Further, emergency services must be covered regardless of the final diagnosis, consistent with § 422.113(b)(2)(iii), so the services needed to treat the emergency medical condition as presented therefore may not be retrospectively denied payment by the MA plan. As CMS has explained in Ch 4, § 20.3, of the Medicare Managed Care Manual interpreting § 422.113, an MA organization is not responsible for the care provided for an unrelated non-emergency problem during treatment for an emergency situation. For example, if the attending physician is treating a fracture, the plan is not responsible for any costs connected with a biopsy of skin lesions performed while treating the fracture.

Under § 422.113(b)(3), the physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the MA organization. The MA organization is financially responsible (consistent with § 422.100(b) and 422.214 regarding payment) for post-stabilization services as specified in § 422.113(c)(2) and (c)(3).

Comment: Some commenters cautioned CMS against defining ‘emergency medical condition’ with reference to ‘conditions for which an enrollee may receive behavioral health crisis services’ because emergencies vary from “crisis” in behavioral health treatment, and referred CMS to the work being done to define behavioral health crisis services by an interagency workgroup organized by the Substance Abuse and Mental Health Services Administration (SAMHSA).

Response: CMS believes that the commenter has misinterpreted the goal of this clarification to 422.113(b)(1)(i), which is simply to add “mental” (behavioral health) to the definition of emergencies to capture mental and physical health emergencies. There is no mention of “crisis” services in this change, and the scope of “behavioral health crisis services” is beyond the scope of this regulation. CMS notes that an emergency medical condition is not defined by the types of services used to treat the condition, as the commenters suggested. CMS

acknowledges the suggestion of collaboration with SAMHSA as that agency does important work to improve behavioral health crisis care, but notes that it is not related to the content of this regulation.

All public comments received on these proposals were generally supportive, including those that requested modifications be made to the final rule. For reasons presented in the proposed rule and our discussion of the public comments, we are finalizing changes to § 422.113 as proposed.

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

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

Section 1852(d) of the Act requires MA plans that limit coverage using provider networks to make covered benefits available and accessible to enrollees in the plan service area with reasonable promptness and in a manner that assures continuity in the provision of benefits, and that medically necessary care must be available and accessible 24 hours a day and 7 days a week. The MA regulation at § 422.112 includes requirements and standards to ensure that MA organizations that offer coordinated care plans, which generally use networks of providers, meet the statutory requirements. Under these rules, MA organizations must ensure that all covered services are made available and accessible to enrollees by the plan's designated provider network. Furthermore, MA organizations are required under § 422.112(a)(6)(i) to maintain

written standards that require timely access to care for enrollees which meet or exceed those established by CMS. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the MA organization must take corrective action as necessary. CMS has provided guidelines for MA organizations in the Medicare Managed Care Manual, Chapter 4, “Benefits and Beneficiary Protections,” section 110.1.1,⁷⁷ regarding provider network standards. That guidance includes directions that MA organizations make their timeliness standards known to network providers (which is necessary in order to ensure that providers in the network comply with MA plan’s written standards) and that the MA organization should consider an enrollee’s need for the services and common waiting times in the community. In particular, the Manual provides examples of appointment wait times for certain primary care services, based on the type of services and level of need: (1) urgently needed services or emergency—immediately; (2) services that are not emergency or urgently needed, but requires medical attention—within 1 week; and (3) routine and preventive care—within 30 days.

The 2022 CMS Behavioral Health Strategy⁷⁸ describes CMS’ goals to increase and enhance access to equitable behavioral health care services for people with behavioral health care needs. To support these goals, CMS is committed to strengthening our requirements for MA organizations to ensure beneficiaries can access needed behavioral health care services similar to how they access needed physical health services. Therefore, we proposed to codify appointment wait times as standards for primary care services that are the same as the appointment wait times described in the Manual and to extend those standards to behavioral health services. These new standards for minimum appointment wait times would be added to the existing requirement that MA organizations offering coordinated care plans establish written

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

⁷⁸<https://www.cms.gov/cms-behavioral-health-strategy>

policies for the timeliness of access to care and member services so that MA organizations must have appointment wait times that meet or exceed the minimum standards we proposed here.

We proposed that the wait time standards for behavioral health services would apply to both mental health services and substance use disorder services. We remind MA organizations that substance use disorder services include medications for opioid use disorder (MOUD), which is particularly important as opioid-related overdose deaths have spiked during the pandemic,⁷⁹ and we have heard from commenters that beneficiaries have experienced barriers to behavioral health treatment. Proposing to codify these wait time standards as discussed by commenters through our RFI, should reduce access barriers to behavioral health treatment for those who need it; and help ensure access to a robust array of practitioners furnishing behavioral health services, including Opioid Treatment Providers who prescribe medications for opioid use disorder.

In addition, the proposal to codify wait time standards for primary care is consistent with the goal to increase access to primary care articulated in HHS' Initiative to Strengthen Primary Care.⁸⁰ The National Academies for Science, Engineering, and Medicine (NASEM) Report outlined the importance of ensuring that high-quality primary care is available to every individual and family in every community, particularly those that are underserved. After all, access to primary care practitioners, as opposed to any other practitioner type, is associated with decreased mortality.⁸¹

We also sought comment on alternative specific appointment wait times standards to apply to MA organizations. For example, we considered, as suggested by a commenter on our RFI, establishing appointment wait time standards that align with those established for qualified health plans, (QHPs) as outlined by CMS in the "2023 Final Letter to Issuers in the Federally-facilitated Exchanges."⁸² The appointment wait time standards for QHPs include: Behavioral

⁷⁹<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁸⁰<https://www.hhs.gov/about/news/2022/06/27/fact-sheet-hhs-initiative-to-strengthen-primary-health-care-seeking-public-comment.html>

⁸¹<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724393>

⁸²<https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2023-Letter-to-Issuers.pdf>

health appointments must be available within 10 business days, Primary care (routine) must be available within 15 business days; and Specialty care (non-urgent) must be available within 30 business days. We explained that under this alternative, the wait time requirements would be applicable to primary care and behavioral health specialty types. We solicited comment on whether a more flexible approach would be appropriate, such as requiring MA organizations have specific standards for appointment wait time in their written internal policies, but that CMS require MA plans to meet the specific standards for appointment wait time limits for routine or non-emergency services for only a significant portion (for example, 95 percent) of appointments.

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

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

We solicited comment on our proposal, including whether one or more of the previously described sets of standards for wait time would more effectively address our goals of ensuring that MA organizations are meeting timely access standards for primary care and behavioral

health services for enrollees, supporting parity between behavioral health and physical health services, and strengthening our requirements for MA organizations to ensure beneficiary protections in access to care. In addition, we solicited comment on whether a specific standard limit for appointment wait times for emergency or urgently needed services is duplicative of the mandatory coverage and access requirements in § 422.113.

Comment: We received many comments in support of our proposal to codify, as requirements, the example standards for appointment wait times for primary care and extend them to behavioral health.

Response: We thank commenters for their support regarding this proposal. Codifying the standards for appointment wait times and extending them to behavioral health will support our goals of reducing barriers to behavioral health treatment and to supporting parity with physical health. It also underscores the importance of access to timely primary care. As adopted, these new wait time standards for behavioral health services apply to both behavioral health services and substance use disorder services.

Comment: We received several comments that did not support our proposal to codify standards for appointment wait times and apply them to both primary care and behavioral health. Commenters cited challenges with behavioral health provider shortages and associated burden with implementing specific wait times with providers in MA networks that may dissuade providers from contracting with MA plans. Further, some commenters indicated that maintaining strict wait times could also discourage MA plans from expanding their service areas, impacting enrollee access. In addition, commenters expressed interest in allowing MA plans to maintain the flexibility in establishing wait times afforded in Chapter 4 of the Medicare Managed Care Manual, and delaying implementation of this proposal.

Response: As indicated in our proposed rule, codifying the standards for appointment wait times for primary care and extending them to behavioral health will support our goals for parity, and will help strengthen beneficiary protections in access to care. We are committed to

ensuring that MA enrollees are able to access covered services and that MA organizations meet their obligations under section 1852(d) of the Act to make covered benefits available and accessible to enrollees in the plan.

Comment: Some commenters requested clarity on evaluation criteria and mechanisms for monitoring MA organizations' compliance standards of appointment wait times. Additionally, some requested that CMS provide opportunities for stakeholders to comment on such mechanisms.

Response: CMS will use existing mechanisms to monitor and investigate complaints related to access concerns. This includes monitoring the Complaint Tracking Module (CTM) and working with regional office account managers to resolve issues with the MA organizations. In addition, § 422.504(m) sets forth CMS' approach to issuing compliance actions for failure of an MA organization to comply with the terms of its contract (which incorporates a requirement for MA organizations to comply with regulations in 42 CFR Part 422). CMS may issue compliance actions when it determines that an MA organization is out of compliance by applying the performance standards in the applicable statute or regulation or, if there is not already a specific statutory or regulatory standard, CMS may determine that an MA organization is out of compliance when its performance represents an outlier relative to the performance of other MA organizations.

Comment: One commenter indicated that establishing standards for appointment wait times could impact implementation of certain integrated care models, such as Collaborative Care, indicating that these models would not consider wait times.

Response: While we believe the commenter may be referring to the Psychiatric Collaborative Care Model, CMS lacks sufficient information from this comment to explain what the impact of this policy is on such initiatives. The regulatory change to § 422.112 applies to MA coordinated care plans.

Comment: In response to our proposal, several commenters requested that CMS align our standards for appointment wait time consistent with those standards established for the Qualified Health Plans or by the National Committee for Quality Assurance (NCQA). For example, commenters stated that aligning our standards with recognized NCQA standards would provide consistency for stakeholders; commenters also requested that CMS consider a standard for behavioral health services of 10 business days in alignment with Qualified Health Plans.

Response: We thank commenters for their input regarding alternative standards for appointment wait times. While we have decided to finalize the specific wait time standards as proposed, we have decided to clarify that our appointment wait time standards will be based on business days which is the approach adopted for the Qualified Health Plans that aligns with NCQA in basing the standards for appointment wait times on business days. The final regulation text refers to business days.

Comment: A few commenters requested that CMS consider different approaches to finalizing appointment wait time standards. For example, establishing separate standards for appointment wait times for mental health and substance use disorder, implementing a pilot program and conducting additional analysis or studies related to appropriate appointment wait times.

Response: We appreciate the commenters' suggestions regarding the standards for appointment wait times. The standards that we are finalizing in this final rule were previously established through our sub regulatory guidance in section 110.1.1, Chapter 4 of the Medicare Managed Care Manual. Our approach, supports parity between behavioral health and physical health services for enrollees and strengthens our requirements to ensure that MA organizations are meeting timely access standards for these covered services.

Comment: We received a few mixed comments regarding our comment solicitation and considerations on implementing the requirement that MA organizations meet the final wait time standard for at least 95 percent of appointments, and on implementing an attestation within the

MA application for applicants to attest to meeting the final standards. For example, some commenters agreed that a 95% threshold for compliance would be an appropriate standard for MA organizations to meet regarding wait times. Conversely, one commenter did not agree to the 95% threshold indicating that any failure to meet wait time standards would fail to ensure access to care.

Response: We thank commenters for their input and we will monitor and reevaluate these standards if necessary, for future rulemaking.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the proposed revisions to § 422.112(a)(6)(i) substantially as proposed but with a modification to clarify that the standards are based on business days.

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

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

More specifically, section 1852(d)(1)(D) of the Act requires an MA organization to provide access to appropriate providers, including credentialed specialists, for medically necessary treatment and services, as a condition of the MA organization limiting coverage to a

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

Historically, CMS has interpreted these statutory and regulatory requirements to mean that in the event an in-network provider or service is unavailable or inadequate to meet an enrollee's medical needs, the MA organization must arrange for any medically necessary covered benefit outside of the plan provider network at in-network cost sharing for the enrollee. For example, if an enrollee needs OTP services but there is no in-network OTP available, then the MA organization must arrange for the enrollee to go to an out-of-network OTP at in-network cost sharing. In our view, furnishing access out of network with higher cost sharing when the MA plan's network is inadequate or otherwise does not address the medically necessary benefit required by an enrollee is not consistent with section 1852(d)(1) of the Act. Enrollees should not bear a financial burden because of the inadequacy of the MA plan's network. This interpretation is reflected in CMS guidance in section 110.1.1 of Chapter 4 of the MMCM,⁸³ and CMS has routinely emphasized this interpretation to MA organizations about their obligations whenever the need arises, for example, when an MA organization is undergoing a network change due to a provider termination. Therefore, MA organizations are familiar with the policy and should be applying it in the routine course of operations within their MA plans. It is important that MA organizations ensure adequate access to medically necessary covered benefits for enrollees when the plan network is not sufficient by both arranging or covering the out-of-network benefits and

⁸³<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

only charging in-network cost sharing for those out-of-network benefits. To reflect this important and well-established enrollee protection in the MA program, we proposed to amend § 422.112(a)(1) and (a)(3) to more clearly state the scope of the MA organization's obligation to ensure adequate access to medically necessary covered benefits.

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

CMS proposed to codify this policy by revising § 422.112(a)(3) and adding new regulatory text to § 422.112(a)(1) to reflect the longstanding policy. Specifically, we proposed to move the sentence requiring the MA organization to arrange for out-of-network care currently in paragraph (a)(3) to a new paragraph (a)(1)(iii) and revise and supplement it with additional text to better state the full scope of the current policy. We proposed that new paragraph (a)(1)(iii) would require MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

CMS currently monitors MA organization compliance with this existing policy through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations alert CMS to any issues with access to care, and CMS may require MA

organizations to address these matters if they arise. We stated in the proposed rule that, if finalized, CMS intends to continue these oversight operations to ensure MA organizations' compliance with the proposed regulation.

This proposal to amend § 422.112 codifies the agency's existing interpretation of applicable law and longstanding guidance. CMS has not been made aware of any issues of MA organization non-compliance with this policy and, as such, believes that MA organizations have been complying with this longstanding guidance. Therefore, we stated in the proposed rule that 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 we did not provide 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.

We solicited comment on this proposal, including on the accuracy of our assumptions regarding information collection requirements and regulatory impact. We did not receive comment on our information collection requirements nor regulatory impact. We thank commenters for their input on CMS's proposed amendment to § 422.112. We received the following comments on this proposal, and our response follows:

Comment: The majority of comments were supportive of this proposal. Commenters agreed with codifying at § 422.112(a)(1)(iii) CMS's existing interpretation of the statute and longstanding guidance that MA organizations offering coordinated care plans must arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. They believed that MA organizations are obligated to ensure adequate access to medically necessary covered benefits by maintaining a strong network, and when it fails, the enrollee should be entitled to in-network cost sharing.

Response: We thank commenters for their support, and we agree that this codification at § 422.112(a)(1)(iii) is a necessary and important enrollee protection.

Comment: Some comments requested that CMS develop more guidance surrounding this policy. For example, a commenter suggested that CMS apply a definition of “unavailable” that accounts for the specific patient, their medical condition, and the urgency of their medical need. Another commenter believed CMS should specify what “arranges for” means and also define what constitutes “necessary specialty care,” suggesting that this is a determination that should be made by an enrollee and their provider, not the MA organization. This commenter also recommended that CMS clarify that an enrollee can maintain continuity of care and complete their treatment plan with an out-of-network provider who has specialized expertise that cannot be found in-network, once it has been determined that such care is medically necessary. Other commenters requested that CMS further clarify that it is the MA organization’s responsibility to ensure medically necessary care is provided in a timely manner, even when care must be accessed out of network. A commenter believed CMS could further enhance enrollee protections and access to care by establishing timelines such as a requirement to ensure services are available within one business day of an approved authorization. Another commenter sought specific CMS guidance regarding the MA organization’s obligation around arranging timely out-of-network care for cancer diagnoses.

Response: Regarding the definition of “unavailable,” we clarify here that an in-network provider or benefit being “unavailable” means that there is no provider or benefit in the current plan provider network to meet the enrollee’s medical needs, as we noted in the proposed rule. In other words, the MA plan’s network is inadequate or otherwise does not address the medically necessary benefit required by an enrollee. For instance, if an enrollee requires the services of a particular specialty or subspecialty that is not in the plan network, then we would view this as fitting the description of “unavailable.” We believe that this is inclusive of the specific patient, their medical condition, and the urgency of their medical need, and thus MA organizations must

take these factors into consideration when determining unavailability and complying with this requirement.

The term “arranges for” means that the MA organization may need to enter into case-by-case agreements with non-contracted, out-of-network providers to ensure enrollees’ access to services. In the example previously discussed, if an enrollee needs to see a particular out-of-network specialist or subspecialist, the MA organization may need to enter into a limited contract with the closest available qualified specialist to ensure its enrollee has access to the medically necessary specialist services. (We note that except for emergency services, non-contracted providers are generally not legally required to treat MA enrollees.) Or the MA organization may authorize and cover services furnished by a non-contracted provider selected by the enrollee without the MA organization engaging in a short-term agreement with the provider. Regarding what constitutes “necessary specialty care,” the MA organization must make medical necessity determinations as discussed in section III.E.2. of this final rule. In addition, we agree with the commenter that an enrollee should be able to maintain continuity of care and complete their treatment plan with an out-of-network provider who has specialized expertise that cannot be found in-network, once it has been determined that such care is medically necessary. We believe that this policy is embodied in current regulatory guidance in § 422.206(a)(1), which prohibits or otherwise restricts MA organizations from interfering with a health care professional, acting within the lawful scope of practice, from advising, or advocating on behalf of, an individual who is a patient and enrolled under an MA plan.

We understand commenters’ concerns around timeliness of access to care. Per current CMS regulations at § 422.112(a)(6)(i), MA organizations must establish written access standards for timeliness of access to care that meet or exceed standards established by CMS, timely access to care within a plan’s provider network must be continuously monitored to ensure compliance with these standards, and the MA organization must take corrective action as necessary. CMS does not (and will not under the revisions to § 422.112(a)(6)(i) adopted elsewhere in this final

rule) apply the same wait time standards for out-of-network care because MA organizations do not have contracts with out-of-network providers to require timely access to care; we appreciate that MA organizations have no contractual mechanism to hold out-of-network providers accountable and ensure out-of-network care is provided timely to their enrollees. While these requirements for timeliness of access to care apply to in-network care only, per § 422.568, MA organizations must notify the enrollee of its determination to in or out-of-network care as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the MA organization receives the request for a standard request, and no later than 72 hours for an expedited request, with the exception that the MA organization may extend the timeframe by up to 14 calendar days if the extension is justified and in the enrollee's interest. If an MA organization chose to enter into a case-by-case agreement or limited contract with a non-contracted provider, as described in the preceding paragraph, then they may be able to include a clause about timely access to care in their agreement or contract with an expedited review time no greater than the requirement established in § 422.568(b)(1)(i)(B), but CMS does not require this.

In general, while MA organizations may not have the same level of control when it comes to care provided outside of their plan provider network, we still expect MA organizations to make their best effort to ensure that the out-of-network care they arrange for is provided timely, including for cancer diagnoses. The manner in which they do so is at the MA organization's discretion, however, enrollees' best interests should always be prioritized.

We note that the inability to offer in-network care may be evidence that an MA organization is failing to meet CMS's required network adequacy standards. Arranging for care outside of the network, while a responsibility of MA organizations, should not be the norm. Any out-of-network alternative arrangements should only be made in the rare circumstance that an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. We also note that MA organizations are required to arrange for medically necessary covered out-

of-network care at in-network cost sharing if in-network care is unavailable or inadequate to meet the enrollee's medical needs, despite the type of care (cancer or otherwise).

We are finalizing § 422.112(a)(1)(iii) as proposed and not adding any definitions to the regulatory text, however, we hope our response provides some helpful clarification and guidance to commenters on how we interpret and will implement these changes.

Comment: Other comments discussed the benefits of this requirement for ensuring adequate access to medically necessary covered care particularly for more vulnerable enrollees with cancer, enrollees with rare conditions, and dually eligible enrollees. Commenters stressed that these types of enrollees often face higher cost sharing (especially out-of-network), higher out-of-pocket expenses, risk of exhaustion of savings or personal bankruptcy, challenges in accessing the care they need in a timely manner and in their geographic area, and, for individuals with rare conditions, pools of experienced providers that are relatively small. Further, they expressed that some of these implications have a disproportionate effect on those with lower incomes, for example, dually eligible enrollees. As such, commenters believed that enrollees should not be penalized when an MA network is not adequate to provide necessary and life-saving care and treatment.

Response: We agree that this requirement, which seeks to guarantee access when in-network providers or services are unavailable or inadequate to meet an enrollee's medical needs, is particularly beneficial for protecting more vulnerable enrollees, such as those with cancer or rare conditions, and dually eligible enrollees. We thank the commenters for expressing these sentiments and for their support.

Comment: A few commenters recommended that, in addition to CMS's existing oversight processes, CMS establish a provider complaint mechanism that would allow providers to report MA organization behavior that potentially violates these requirements. They stated that providers are likely to recognize patterns of enrollees' inability to access care through network providers, inappropriate delays in care, and denials from MA organizations, and could therefore

raise concerns that could guide heightened enforcement of this requirement. A commenter specifically suggested CMS track MA enrollees' appeals of requests for obtaining out-of-network services in order to better identify MA organizations that are not following this rule.

Response: We operationally support the ability of providers to submit complaints to CMS regarding MA organization behavior that potentially violates these requirements. Contracted providers are instructed to resolve their complaints directly with the MA organizations since the contract is between the MA organization and the provider. In addition, the definition of organization determination in § 422.566(b) includes both an MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization and an MA organization's failure to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee. MA enrollees, and their providers on their behalf, may file an appeal of organization determinations of this type under subpart M of Part 422. We appreciate any information that providers are willing to share that may help us enforce this requirement. Regarding tracking MA enrollees' appeals of requests for obtaining out-of-network services, we currently track this information and can use it to identify MA organizations failing to comply with the requirements at § 422.112(a)(1)(iii).

Comment: A few commenters opposed this proposal. A commenter believed 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, and build higher performing networks of providers. This commenter further emphasized that out-of-network providers are not required to follow plan treatment protocols and guidelines for care and in some cases do not accept Medicare rates for services, thereby creating clinical and fiscal risk to the enrollee resulting in additional costs for the MA organizations to absorb in the absence of a contract. On the same topic, another commenter requested that CMS clarify that in these

circumstances, MA organizations must pay out-of-network providers the traditional Medicare rates for their services, not a discounted rate. Yet 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. A commenter also stated that they appreciated the intent behind this proposal but noted that it will not meaningfully improve access to medically necessary services. They noted that many MA organizations' existing processes for providing access to out-of-network care are fraught with obstacles and unnecessary hurdles, prompting many enrollees to delay or forego needed care.

Response: We acknowledge commenters' concerns that requiring MA organizations to allow out-of-network providers to be seen at in-network cost sharing limits the MA organization's oversight in the absence of a contract with the providers. Nevertheless, this has been longstanding policy, and we are finalizing § 422.112(a)(1)(iii) as proposed. We reiterate 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 such things as utilization, quality, treatment protocols, and costs.

Alternatively, if the MA organization has another means or mechanism to address the enrollee's need for care without contracting with an out-of-network provider to furnish that care, then the applicable regulations do not necessarily prohibit alternate solutions. For example, the MA organization may waive referral or "gatekeeper" requirements for an enrollee who cannot access in-network primary care providers (PCPs) in a timely manner to get a referral or gatekeeper approval for a specialist visit. In addition, if an MA organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, specialty care is medically necessary, and the enrollee has not selected a PCP, then the MA organization could assign a PCP for purposes of making the needed referral. To account for situations like these—where the enrollee finds the provider and the issue is not about the MA

organization not contracting with that provider, but rather authorizing the ability to obtain medically necessary services out-of-network—we are modifying the regulatory text at § 422.112(a)(1)(iii) to read “arrange for and cover” instead of just “arrange for.”

Regarding comments about reimbursement rates for non-contracted providers, it is true that MA organizations are required to pay non-contracted providers at least what they would have received had they furnished the services in an original Medicare setting, but providers are not obligated to participate in Medicare. This is required by section 1852(k)(1) of the Act and § 422.100(b)(2). We note that § 422.220(a) prohibits MA organization from paying, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. In addition, § 422.224(a) prohibits MA organizations from paying, directly or indirectly, on any basis, for items or services furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2. We reiterate that MA organizations must prioritize meeting CMS’s required network adequacy standards, and arranging for care outside of the network, while a responsibility of MA organizations, should not be the norm. Any out-of-network alternative arrangements should only be made in the rare circumstance that an in-network provider or benefit is unavailable or inadequate to meet an enrollee’s medical needs.

Finally, we recognize the commenter’s concern that many MA organizations’ existing processes for providing access to out-of-network care are problematic. It is our hope that this regulation will strengthen our requirement that MA organizations ensure adequate access to medically necessary covered benefits and compel MA organizations to reexamine their existing processes and make improvements to fully comply with CMS’s requirements.

Comment: Some commenters stressed that any alternative arrangements made by MA organizations for enrollees for out-of-network benefits should not substitute for compliance with network adequacy requirements. They suggested that CMS monitor the use of these alternative arrangements and continue oversight of MA organizations to ensure that they meet the network adequacy requirements, consistently provide access to in-network care, and give enrollees access to a variety of in-network and, if necessary, out-of-network, providers and facilities.

Response: We agree and again emphasize that any out-of-network alternative arrangements should only be made in the rare circumstance that an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. MA organizations are still required to comply with our network adequacy requirements at §§ 422.112(a)(1)(i) and 422.116, and we will continue our oversight of MA organizations' compliance with these requirements through routine network adequacy reviews. Also, as noted in the proposed rule, we will monitor the use of alternative arrangements through account management activities, complaint tracking and reporting, and auditing activities.

Comment: A commenter believed that CMS should amend the regulatory text to specify that when an MA organization arranges for medically necessary covered out-of-network benefits, enrollee preferences should be considered. They noted that the enrollee should have options regarding their out-of-network care, and it should be at a setting and location that best fits the enrollee's needs and is in their best interests.

Response: While we understand the commenter's desire to specifically include "enrollee preferences" in the regulatory text, we believe that the existing regulatory text "to meet an enrollee's medical needs" is sufficient. Any out-of-network care that the MA organization arranges for must meet the enrollee's medical needs because in-network providers or benefits were unavailable or inadequate to meet the enrollee's medical needs. We are therefore finalizing the regulatory text as proposed.

Comment: Another comment suggested that CMS require MA organizations to clearly and prominently highlight this requirement in plan materials, including the Explanation of Benefits (EOB).

Response: We agree and note that this requirement is already contained in the EOB. We intend to strengthen this language in the next iteration of updates to the model documents.

Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulation. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed changes to § 422.112(a)(1)(iii) and (3) with slight modification. We are modifying the regulation text as follows. In proposed regulation text § 422.112(a)(1)(iii), we are adding the phrase “and cover.” Thus, we are revising § 422.112(a)(1)(iii) to read as follows: “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.”

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

As provided in section 1852(d) of the Act and discussed in section 110.1.2.1 of Chapter 4 of the MMCM, MA organizations have considerable discretion to select the providers with whom to contract in order to build high-performing, cost effective provider networks.⁸⁴ This flexibility is also apparent in how CMS is prohibited by section 1854(a)(6)(B)(iii) of the Act from requiring MA organizations to contract with a particular provider. Under our current regulations, MA organizations are able to make changes to these networks at any time during the contract year, as long as they continue to furnish all Medicare-covered services in a non-discriminatory manner, meet established access and availability standards and timely notice

⁸⁴<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

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

First, we proposed to clarify the regulatory text at § 422.111(e) regarding whether the provider contract termination was for cause or without cause. The regulation currently requires that the MA organization must make a good faith effort to notify enrollees at least 30 calendar days before the termination effective date, irrespective of whether the termination was for cause or without cause. This last clause does not consider § 422.202(d)(4), which outlines the timeframe requirement for suspension or termination of an MA organization's contract with a

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

Next, we proposed to add new provisions to § 422.111(e) to address provider contract terminations that involve behavioral health providers. For purposes of this proposal, CMS considered various specialty types (both providers and facilities) as fitting the category of behavioral health providers so long as the treatment they furnish to enrollees is about behavioral health; these included but were not limited to psychiatrists, clinical social workers, clinical psychologists, inpatient psychiatric facilities, outpatient behavioral health clinics, and OTPs. As noted in section III.B.1. of this final rule, behavioral health is a top priority of both CMS and the broader administration. Specifically, CMS's goal is to improve access to behavioral health services and improve outcomes for people with behavioral health care needs. The CMS Behavioral Health Strategy seeks to remove barriers to care and services.⁸⁵ To support these policy goals, using a behavioral health perspective, in the proposed rule, we reexamined the MA enrollee notification requirements when a provider contract termination occurs at § 422.111(e).

According to a recent study, because of the ongoing nature of patient/provider relationships, when a provider leaves a plan's network, there is a potential disruption to the patient's treatment plan; this disruption could be especially problematic in the case of behavioral health treatment because this treatment may be longer in duration than that of physical health, and providers and patients are likely to need more time to develop mutual trust.⁸⁶ Trusting relationships and continuity in the relationship between the patient and provider have shown to be central for behavioral health recovery, therefore, breaks in these relationships tend to cause patient stress, anxiety, and generally less opportunity to contribute to their treatment plan.⁸⁷ Thus, ensuring continuity of care in these situations becomes even more critical. As a consequence, sufficient enrollee notification is needed when a behavioral health provider leaves an MA network. We believe that affected enrollees need ample time to make decisions that may determine the trajectory of their behavioral health treatment. They may wish to continue seeing

⁸⁵<https://www.cms.gov/cms-behavioral-health-strategy>

⁸⁶<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785383>

⁸⁷<https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2719-9>

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

A similar case is made for terminating primary care providers both due to the fact that behavioral health services are often offered by primary care providers and the foundational role primary care providers play in an individual's overall health. According to the American Academy of Family Physicians, up to 75 percent of primary care visits include aspects of behavioral health.⁸⁸ Primary care is foundational because it integrates services to meet the patient's health needs throughout a lifetime, including key elements such as health promotion, disease prevention, treatment, rehabilitation, palliative care, and end-of-life care.⁸⁹ Furthermore, CMS believes that the importance of a patient's relationship with their primary care provider is likely higher in managed care situations, such as MA, where referrals to specialists are often dependent on the primary care provider. Therefore, similar to behavioral health, continuity of care is essential, and sufficient enrollee notification is needed when a primary care provider leaves an MA network. For these reasons, we proposed more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. We expected positive impacts associated with improving communication about provider terminations from MA networks, including providing more time to MA enrollees with behavioral health conditions to make informed decisions about the future of their behavioral health treatment after their provider leaves their network. We stated in the proposed rule that enrollee benefits would

⁸⁸<https://www.aafp.org/pubs/fpm/issues/2021/0500/p3.html#fpm20210500p3-b1>

⁸⁹https://www.who.int/health-topics/primary-health-care#tab=tab_1

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

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

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

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

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

We proposed that MA organizations would continue to be required to provide written notice at least 30 days before the termination effective date of a termination of a contracted provider that is not a primary care or behavioral health provider to all enrollees who are patients seen on a regular basis by the terminating provider. We also proposed to codify at § 422.111(e)(2)(iii) a definition of the phrase “enrollees who are patients seen on a regular basis by the provider whose contract is terminating.” CMS currently has sub-regulatory guidance in section 110.1.2.3 of Chapter 4 of the MMCM that defines this term as enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated, also called “affected enrollees.”⁹⁰ As this guidance has been in place since 2016, and based on various MA organization inquiries we have received asking how CMS defines “regular basis,” we believed the majority of MA organizations have come to adopt this CMS standard and use it routinely as they determine which enrollees to notify when provider contract terminations occur, in order to comply with § 422.111(e). Therefore, we proposed to codify this definition at proposed § 422.111(e)(2)(iii).

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

⁹⁰<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

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

Finally, regarding the content of the provider termination notice, CMS's regulation at § 422.2267(e)(12) currently provides that the Provider Termination Notice is a required model communications material through which MA organizations must provide the information required under § 422.111(e). CMS has provided additional guidance regarding the content of the provider termination notice in section 110.1.2.3 of Chapter 4 of the MMCM.⁹¹ Similar to the definition of "affected enrollees," these best practices have been in our guidance since 2016, thus we believe the majority of MA organizations likely already follow them as they develop the content of their provider termination notices. Therefore, we proposed to codify the best practices for provider termination notices at § 422.2267(e)(12). Specifically, we proposed to make these requirements for the content of MA organizations' provider termination notices and also require MA organizations to include additional pieces of information in the notice.

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

⁹¹<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

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

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

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

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

The provider termination notice is a model communications material which, per § 422.2267(c), is created by CMS as an example of how to convey enrollee information. When drafting this required communications material, MA organizations must: (1) accurately convey the vital information in the required material to the enrollee, although the MA organization is not required to use the CMS model material verbatim; and (2) follow CMS's order of content, when specified (see § 422.2267(c)(1) and (2)). While the regulation currently identifies the provider termination notice as a model communications material, CMS has not yet developed the model document for MA organizations to use. Rather, MA organizations have been expected to follow the current guidance in section 110.1.2.3 of Chapter 4 of the MMCM.⁹² Given that we proposed new regulatory requirements for the content of these provider termination notices (including

⁹²<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

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

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

termination notice if we receive complaints or other information signifying that the notice warrants additional oversight to ensure compliance with CMS regulations for provider termination notices at §§ 422.111(e) and 422.2267(e)(12). We also stated that if CMS does exercise its authority under § 422.2261(c) to review an MA organization's provider termination notice, per § 422.2261(d)(1) and (3), CMS will review the notice to ensure compliance with the applicable regulations and, as a result, may require the MA organization to modify the notice or no longer use it.

In summary, CMS proposed to revise: (1) § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur; and (2) § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination. We solicited comment on these proposals. We thank commenters for their input on CMS's proposed new enrollee notification requirements for MA provider contract terminations. We received the following comments on this proposal, and our response follows:

Comment: Comments were mixed, with about half in support of the proposal and half opposed to it. Those in favor applauded the proposal's emphasis on network adequacy, increased communication and transparency to enrollees, and promotion of enrollee choice. A few commenters expressed support specifically for codifying the required content of provider termination notices.

Response: We appreciate commenters' support for this proposal. We are finalizing this proposal with modification, as discussed in our responses to more specific comments in this section of this rule.

Comment: Many commenters expressed support for the proposal to add specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. Some believed that CMS should apply these requirements

more broadly to all provider contract terminations regardless of specialty type. A commenter specifically requested that the 45-day enrollee notice requirement apply to all provider contract terminations. Another commenter suggested CMS include hospitals and other facilities' contract terminations along with primary care and behavioral health provider contract terminations, in relation to the requirement for the MA organization to notify all enrollees who have ever been patients of the terminating provider or facility. A few commenters expressed support for the telephonic notice to enrollees. Another commenter recommended a 60-day enrollee notice requirement for primary care and behavioral health provider contract terminations. A commenter suggested specific requirements in the case of OTP terminations.

Response: We thank commenters for their support and suggestions. We are not extending the requirements for primary care and behavioral health provider contract terminations to any other specialty types because, as discussed in detail in the proposed rule and this final rule, there are special considerations applicable to the services furnished by and relationship of an enrollee with a primary care provider and a behavioral health provider. Also, we are finalizing the 45-day enrollee notice requirement as proposed. We are modifying our proposal for the telephonic notice to enrollees in response to other comments received, as discussed in this section of this rule.

Comment: We received many comments regarding CMS's proposed lookback period for identifying impacted enrollees to notify for primary care and behavioral health provider contract terminations. Most of these commenters opposed the infinite lookback period because it would be burdensome and may cause enrollee distress or confusion if they had not seen the terminating provider in a long time. They noted that often enrollees shop around for behavioral health providers and so there may be multiple providers that they saw only once before choosing the right fit. Some commenters believed it might make the enrollee believe there was something wrong with the network status of their current provider. Instead of an infinite lookback period, they requested that CMS specify a limited lookback period. A commenter proposed that CMS

work with MA organizations to determine an appropriate lookback period. Other recommendations for a lookback period included retaining CMS's existing requirements regarding which enrollees should be notified, maintaining the existing requirements for primary care provider contract terminations and applying those same requirements to behavioral health provider contract terminations, only notifying enrollees assigned to a terminating primary care provider, performing a six-month lookback period, performing a 12-month lookback period, and only notifying enrollees who had a minimum number of visits with the terminating primary care or behavioral health provider.

Response: We appreciate commenters' recommendations. After careful consideration of these comments, we have decided to modify our proposal to require MA organizations to notify enrollees who are currently assigned to the terminating primary care provider and enrollees who have been patients of the terminating primary care or behavioral health provider in the past three years. We believe use of a three-year look back period strikes an appropriate middle ground that does not stray too far from our original intent while also taking into consideration the commenters' suggestions and reasons for recommending a shorter period.

Comment: A significant number of commenters expressed opposition to CMS's proposal to require MA organizations undergoing primary care and behavioral health provider contract terminations to notify enrollees via telephone in addition to the required written notice. Commenters characterized this telephonic notice as overly aggressive, intrusive, unhelpful, unwelcome, unnecessary, and bothersome. They also noted that the calls may potentially be perceived by enrollees as spam. A few commenters pointed out that enrollees already receive too many calls and so there may be some annoyance and complaints regarding privacy. Several commenters stated that more outreach to enrollees in instances of primary care and behavioral health provider contract terminations would be disruptive to enrollees and unnecessary if they are already receiving a written notice of the termination. A commenter recommended CMS allow MA organizations the flexibility to determine the best method of notice based on the facts

of the termination and enrollees' preferred method of communication. Relatedly, some commenters suggested that enrollees have the right to opt out of telephonic communication from their plan, so requiring this would deliberately violate their request. A few other commenters indicated that increased outreach to enrollees ignores the fact that providers will contact their own patients to let them know that they are leaving the plan's network and therefore will no longer accept their insurance, so additional telephonic notice from the plan would be excessive and unnecessary. Another commenter suggested that if this is finalized then it should only be required for terminations initiated by the MA organization, not provider-initiated terminations. Commenters responding to CMS's request for comment on how many telephonic attempts are reasonable, recommended between one and three attempts but only for enrollees who agree to receive telephonic communication.

Response: We thank commenters for offering their ideas based on experience to help inform how we finalize our proposal. We understand the concern that an additional telephonic notice with multiple attempts may potentially be problematic, and we agree with commenters that enrollees should not be contacted by telephone if they have opted out of this type of communication with their plan. This is helpful information, and we appreciate commenters bringing it to our attention. Given the extent of these comments and our concurrence, we are modifying our proposal by requiring only one telephone call to impacted enrollees who have not opted out of receiving telephonic communication with the MA organization. Specifically, we are identifying these enrollees as those who have not opted out of calls regarding plan business as described in § 422.2264(b). We believe this is another middle ground solution that is responsive to comments on this issue and still preserves the spirit of the proposal.

Comment: Several commenters remarked on the proposed timeframes for written notice of the provider contract termination. A few encouraged CMS to retain the "good faith effort" standard for provider-initiated terminations, while others requested that CMS maintain the existing 30-day standard for all specialty type terminations, except when the provider does not

notify the MA organization in time or when the two parties are in active negotiations. Some commenters opposed the 45-day standard for primary care and behavioral health provider contract terminations, stating that the change from 30 to 45 days would trigger both enrollee and provider abrasion. A commenter suggested that CMS require timeframes only when there is 60 days' notice of the termination or longer, while retaining the "good faith effort" standard for all other circumstances. Some commenters discussed the impact of contract negotiations and stated that in some cases, re-notification to enrollees may be required if the termination does not end up happening, which again raises concerns with burden and enrollee confusion or distress. Another commenter requested CMS provide flexibility in these requirements particularly for quick for-cause provider contract terminations.

Response: We appreciate commenters' input on the timeframes we proposed for notifying enrollees that a provider is leaving their network. While commenters expressed valid concerns, we are finalizing the timeframes as proposed. We believe that more notice (45 days instead of 30 days) is necessary for primary care and behavioral health specialty types, as stated in the proposed rule, because of the importance of a trusting, continuous patient-provider relationship for behavioral health and the foundational role that primary care plays in an individual's overall health. Therefore, affected enrollees need ample time to make decisions that may determine the trajectory of their treatment.

Comment: Several commenters either sought guidance on certain aspects of our proposal or posed questions. For example, a commenter requested CMS clarify whether MA organizations would only be required to notify those impacted enrollees for whom they have a record of their entire health history in order to determine previous provider relationships. Another commenter requested that CMS clarify whether the MA organization must provide continuity of coverage for care an enrollee is receiving if their provider is leaving the network. And another commenter commented on the use of the term "palliative care" as a component of primary care in the proposed rule, stating that the way it is listed implies that palliative care

comes at the end of a serious illness and not along with any other treatment or rehabilitation, which evidence shows is an incorrect misconception because palliative care is appropriate at any age or stage of a serious illness. The commenter therefore requested that CMS clarify that in the final rule by changing palliative care to end-of-life care if that is what CMS meant.

Response: To address the question of MA organizations who may not have a record of new enrollees' entire health history, we would like to clarify that when identifying which enrollees to notify in accordance with § 422.111(e), MA organizations must use all information that is available to them, including claims data, and if they have any reason to believe that they do not have an enrollee's entire health history, then they may need to reach out to the terminating provider to determine whether the enrollee saw that provider within CMS's required lookback period. Regarding the question on providing continuity of care, yes, if necessary in order to meet immediate access needs, the MA organization must provide continuity of coverage for care an enrollee is receiving if their provider is leaving the network. Per § 422.112(a)(1)(iii), as finalized in this rule, the MA organization must arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs (see section III.C. of this final rule). Furthermore, it may be necessary for MA organizations to allow care to continue to be furnished on an interim, transitional basis, by providers who have been terminated from the network in order to adequately address continuity of care needs for affected enrollees. This is longstanding CMS guidance from section 110.1.2.2 of Chapter 4 of the MMCM, therefore, we expect MA organizations to be complying with this interpretation and application of the obligations on the MA organization to ensure that its provider network is adequate to furnish medically necessary covered benefits to enrollees.⁹³ Lastly, we agree with the commenters' concerns that "palliative care" is appropriate at any age or stage of a serious illness,

⁹³<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

so our references to the scope of primary care in this final rule include both “palliative care” and “end-of-life care” because we believe that both are key elements of primary care.

Comment: We received several comments on our proposed changes to § 422.2267(e)(12). A commenter opposed requiring MA organizations to include a list of names and phone numbers of alternative in-network providers instead of just a link to the MA organization’s current provider directory. Another commenter believed CMS should allow for electronic delivery for written notices if the enrollee opted into electronic communication.

Response: We respectfully disagree with these comments on § 422.2267(e)(12). We strongly believe that enrollees whose providers are leaving their network unexpectedly should be provided a list of other providers that they may access for continued care. As paragraph (e)(12)(ii)(B) states, MA organizations have the option to supplement this list with a link to their provider directory as well. Regarding the method of delivery of the provider termination notice, we did not propose any changes to our current requirement at § 422.2267(e)(12)(i) that the notice be provided in hard copy via U.S. mail, therefore, we decline the suggestion to allow for electronic delivery as the only means for delivering this written notice. MA organizations may send a supplemental notice using electronic delivery if consistent with an enrollee’s preference. Thus, we are finalizing our proposed changes to § 422.2267(e)(12)(i) and (ii)(B) as proposed.

Comment: Generally, commenters were supportive of CMS’s proposal to consider an enrollee who is impacted by a provider contract termination to be someone who is experiencing an exceptional condition and therefore eligible for the SEP specified in § 422.62(b)(26). One commenter proposed that CMS provide MA organizations time to attempt to resolve an enrollee’s transition needs before informing an enrollee that they may contact 1-800-MEDICARE to request an SEP. The commenter was concerned that calls to 1-800-MEDICARE may be classified by CMS as complaints and adversely impact the MA organization’s overall Star Rating.

Two commenters requested that information on the SEP for exceptional conditions be featured more prominently in CMS publications.

We also solicited comment on alternative approaches; specifically, the adoption of a new SEP for this type of provider contract termination, with explicit standards for when termination of a provider from the network should serve as a basis for SEP eligibility. One commenter requested that CMS expand the SEP for Significant Change in Provider Network at § 422.62(b)(23) so that it would be available to any plan enrollee who wishes change plans mid-year in order to continue to see their provider(s). Another commenter requested that CMS create a new SEP for any enrollee whose provider is terminated, stating that such an event is a common, not unique, event that should not need to be reviewed on a case-by-case basis. This commenter requested that the new SEP be three months in length and be available to any enrollee who receives a notice of provider termination sent in accordance with § 422.111(e).

Another commenter requested that CMS take the position that that any enrollee who has ever received care from a particular provider or facility is eligible for an SEP upon termination of that provider or facility, including an enrollee who attests to having confirmed a provider's or facility's in-network status when making a decision to join the MA plan.

One commenter who expressed opposition to offering an SEP to an enrollee who is impacted by a provider contract termination stated that an enrollee should not be eligible for an SEP if other providers are available in the network. Another stated that notifying enrollees of a potential SEP may create confusion when a provider retires and there are other providers available in the network.

Response: We appreciate the commenters' support for our proposal to consider an enrollee who is impacted by a provider contract termination to be someone who is experiencing an exceptional condition and therefore eligible for the SEP specified in § 422.62(b)(26). We also appreciate the response to our solicitation for feedback on alternative approaches, such as the adoption of a new SEP for this type of provider contract termination. We did not propose any

changes to the SEPs at §§ 422.62(b)(23) and 422.62(b)(26), so this final rule will not include any changes to these regulations; however, we will consider this feedback in future rulemaking and policy development.

Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulations. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed changes to § 422.111(e) with the following modifications:

- In proposed regulation text § 422.111(e)(1)(i), we are removing the phrase “both written and telephonic notice” and adding the phrase “written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have not opted out of calls regarding plan business as described in § 422.2264(b).” Thus, we are revising (e)(1)(i) to read as follows: “Provide written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have not opted out of calls regarding plan business as described in § 422.2264(b),”

- In proposed regulation text § 422.111(e)(1)(iii), we are 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.” Thus, we are revising (e)(1)(iii) to read as follows: “To all enrollees who are currently assigned to that primary care provider and to enrollees who have been patients of that primary care or behavioral health provider within the past three years.”

We are finalizing changes to § 422.2267(e)(12) as proposed.

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

1. Introduction

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

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

In addition, CMS regulations at § 422.101(a) and (b) require that MA plans provide coverage of all basic benefits (that is, services covered under Medicare Parts A and B, except hospice care and the cost of kidney acquisitions for transplant) and that MA plans must comply with Traditional Medicare national coverage determinations (NCDs) and local coverage determinations (LCDs) applicable in the MA plan’s service area.⁹⁴ In recent years, CMS has received feedback from various stakeholders, including patient groups, consumer advocates, providers and provider trade associations that utilization management in MA, especially prior authorization, can sometimes create a barrier to patients accessing medically necessary care. Stakeholder feedback has included concerns about the quality of MA plans’ prior authorization decisions (for example, coverage denials being made by plan clinicians who do not have expertise in the field of medicine applicable to the requested service) and process challenges (for example, repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care).

In addition, in April 2022, the Office of the Inspector General (OIG) released a report⁹⁵ titled, “Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care,” which summarized the results of a study by the OIG of MA plan denials of requests for prior authorization of services. The OIG found that some prior authorization requests were denied by MA plans, even though the requested services met Traditional Medicare coverage guidelines. In other cases, the OIG found that prior authorization requests were inappropriately denied by MA organizations due to errors that were likely preventable through process or system changes by MA organizations. Citing a concern that such inappropriate denials may prevent or delay beneficiaries from receiving medically necessary care, the OIG recommended that CMS: (1) issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews; (2) update its

⁹⁴The terms “Traditional Medicare” and “Original Medicare” are used interchangeably throughout this section and both mean the Medicare Fee-For-Service program.

⁹⁵<https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>

audit protocols to address the issues related to MA organizations' use of clinical criteria and/or examining particular service types; and (3) direct MA organizations to take steps to identify and address vulnerabilities that can lead to manual review errors and system errors.⁹⁶

CMS understands that utilization management tools are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. In light of the feedback we have received from stakeholders and the findings in the OIG report, however, we have concluded that certain guardrails are needed to ensure that utilization management tools are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans. We proposed to clarify requirements for the coverage criteria that MA plans use when making medical necessity determinations. We also proposed additional beneficiary protection requirements in order to improve continuity of care and integration of health care services and to increase plan compliance with regards to utilization management policies. Our proposals interpreted and implemented the requirements in section 1852 of the Act regarding the provision and coverage of services by MA plans and were, therefore, proposed under our authority in section 1856 of the Act to adopt standards to carry out the Part C statute and MA program.

As originally stated in the June 2000 final rule (65 FR 40207), MA organizations must cover all Part A and B benefits, excluding hospice services and the cost of kidney acquisitions for transplant, on the same conditions that items and services are furnished in Traditional Medicare. This means that MA organizations may not limit coverage through the adoption of policies and procedures—whether those policies and procedures are called utilization management and prior authorization or the standards and criteria that the MA organization uses to assess and evaluate medical necessity – when those policies and procedures result in denials of coverage or payment where the Traditional Medicare program would cover and pay for the item

⁹⁶<https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>, pg. 3

or service furnished to the beneficiary. In addition, this means that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to set the scope of basic benefits as defined in § 422.100(c).

MA organizations have flexibility to furnish and cover services without meeting all substantive conditions of coverage in Traditional Medicare, but that flexibility is limited to and in the form of supplemental benefits. As stated in the June 2000 final rule, MA organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the MA program. If Traditional Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Traditional Medicare benefits (that is, basic benefits) component of an MA plan. MA organizations may cover the same service when the conditions are not met, but these benefits would then be defined as supplemental benefits within the scope of §§ 422.100(c)(2) and 422.102 and must be included in the supplemental benefits portion of the MA plan's bid. For example, when services are furnished by a type of provider other than the type of provider who may furnish the service in Traditional Medicare, those services are supplemental benefits. We proposed policies that provide less flexibility for MA organizations to deny or limit coverage of basic benefits than provided in the 2000 final rule. However, as provided by section 1852(a)(3) of the Act and reflected in §§ 422.100(c)(2) and 422.102, MA plans may cover benefits beyond what is covered (and when it is covered) under Traditional Medicare by offering supplemental benefits. Our proposal was primarily directed at ensuring that minimum coverage requirements are met and that MA plans do not deny or limit coverage of basic benefits; we were not proposing to limit the scope of permissible supplemental benefits, but our proposal applies certain requirements for the use of utilization management for all covered benefits as discussed in section III.E. of this proposed rule.

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

The final rules adopted here related to utilization management requirements and limitations, coverage criteria and medical necessity determinations, use of prior authorization and continuity of care requirements for MA plans are additional standards to implement the statutory requirements at section 1852(a) of the Act that MA plans provide to their enrollees (by furnishing directly or through contracted providers, arranging for, or paying for) basic benefits (that is, all Part A and Part B benefits with limited exceptions) and such supplemental benefits the MA plan elects to offer. CMS has authority to adopt standards to carry out the applicable MA provisions in Title XVIII of the Act and to add new contract terms that we find necessary, appropriate, and not inconsistent with the statute in sections 1856(b) and 1857(e) of the Act. In addition, section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. To the extent that these new minimum standards for MA organizations and how they cover benefits would not implement section 1852 of the Act, establish standards to carry out the MA program under section 1856(b) of the Act (which CMS does not concede, as these are important protections to ensure that MA enrollees receive Medicare covered services), or be contract terms

that we are authorized to adopt under section 1857(e)(1) of the Act, we believe that our negotiation authority in section 1854(a)(6)(B) of the Act permits creation of minimum coverage requirements. While the rules finalized here do not limit our negotiation authority (which is addressed in § 422.256), they provide minimum standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids, in addition to establishing important protections to ensure that enrollees have access to medically necessary items and services that are covered under Part A and Part B.

2. Coverage Criteria for Basic Benefits

a. Application of Coverage Criteria

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

Section 1852(a)(1) of the Act and CMS regulations at § 422.101(a) and (b) require all MA organizations to provide coverage of, by furnishing, arranging for, or making payment for,

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

We proposed to amend § 422.101(b)(2) by removing the reference to “original Medicare manuals and instructions” and clarify that MA organizations must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, when making coverage decisions. Our proposal was designed to prohibit MA organizations from limiting or denying coverage when the item or service would be covered under Traditional Medicare and to continue the existing policies that permit MA organizations to cover items and services more broadly than original Medicare by using supplemental benefits. In proposing this change to § 422.101(b)(2), we reiterated that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to define the scope of basic benefits. By removing the reference to “original Medicare manuals and instructions,” we were not diminishing the content and value that these manuals and instructions provide in interpreting and defining the scope of Part A and Part B benefits. These manuals contain significant explanations and interpretations of Traditional Medicare laws governing Part A and Part B benefits, most of it longstanding, to provide instructions and procedures for day to day operations for those responsible for administering the Medicare program. Our goal to ensure that MA enrollees receive the same items and services as beneficiaries in the FFS program is accomplished when the same coverage policies and approaches are used. We expect that MA plans will consult the Medicare Benefit Policy Manual, Medicare Program Integrity Manual, and similar CMS

guidance materials. We note that MA organizations must agree to comply with all applicable requirements, conditions, and general instructions under the terms of their contract with CMS under § 422.504(a). The proposed revision to § 422.101(b)(2) clarifies that statutes and regulations that set the scope of coverage in the Traditional Medicare program are applicable to MA organizations in setting the scope of basic benefits that must be covered by MA plans. We also proposed to refer in § 422.101(b)(2) to specific Medicare regulations that include coverage criteria for Part A inpatient admissions, Skilled Nursing Facility (SNF) care, Home Health Services and Inpatient Rehabilitation Facilities (IRF) as examples of general coverage and benefit conditions in Traditional Medicare that apply to basic benefits in the MA program. The list of Medicare regulations referred to is not exhaustive and provides examples of substantive coverage and benefit conditions that apply to MA. In addition, we also proposed to revise the current provision that states that Traditional Medicare coverage rules apply unless superseded by regulations in this part. We proposed to revise that aspect of § 422.101(b)(2) to refer to laws applicable to MA plans in order to avoid implying that a Part 422 regulation could supersede an applicable statute.

For example, the existing rule at § 422.101(c), which states that MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of post-hospital SNF care in the absence of the prior qualifying hospital stay is a special rule in MA that deviates from coverage criteria articulated in Traditional Medicare. The regulation is based on section 1812(f) of the Act, which authorizes CMS to permit coverage of SNF care without the 3-day qualifying hospital stay in limited circumstances. (68 FR 50847-50848). This rule provides MA organizations the flexibility to cover, as a basic benefit, SNF stays for MA enrollees that would not be otherwise coverable in Traditional Medicare, if the beneficiary had not met the prior qualifying hospital stay of 3 days prior to admission in the SNF. This special rule continues to apply in the MA program; however, we proposed to redesignate this rule to paragraph (c)(2) of § 422.101 as part of our proposal to add a heading to § 422.101(c) and to expand the scope of the

paragraph. We proposed to add the heading “Medical Necessity Determinations and Special Coverage Provisions” to § 422.101(c). As such, we proposed to reassign the special rule for coverage of posthospital SNF in the absence of the prior qualifying hospital stay as § 422.101(c)(2). The proposed new heading for § 422.101(c), “Medical Necessity Determinations and Special Provisions,” is intended to signal that paragraph (c) will address medical necessity criteria and special rules that apply to MA basic benefits that do not necessarily conform to coverage rules in Traditional Medicare.

We proposed to codify at § 422.101(c)(1)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c). This means that when an MA organization is making a coverage determination on a Medicare covered item or service with fully established coverage criteria, the MA organization cannot deny coverage of the item or service on the basis of internal, proprietary, or external clinical criteria that are not found in Traditional Medicare coverage policies. Under this proposal, certain utilization management processes, such as clinical treatment guidelines that require another item or service be furnished prior to receiving the requested item or service, would violate the proposed requirements at § 422.101(b) and (c), and thus, their use by an MA organization would be prohibited unless specified within the applicable NCD or LCD or Medicare statute or regulation. We note that we did not propose to revise § 422.136, which authorizes MA plans to use step therapy policies for Part B drugs under certain circumstances; in the next paragraph, we discuss the basis for authorizing MA plan-specific step therapy for Part B drugs in § 422.136 in more detail. Otherwise, clinical criteria that restrict access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD, would be considered additional internal coverage criteria that are prohibited. When MA plans are allowed to create internal coverage criteria as specified at proposed § 422.101(b)(6), the current evidence in widely used treatment

guidelines or clinical literature relied upon to make the coverage determination may recommend clinical treatment guidelines that require another item or service first. When use of MA plan internal coverage criteria is permitted under this rule, as long as the supporting, widely used treatment guidelines or clinical literature recommend another item or service first, this approach would be acceptable under our proposed policy. We discuss adding § 422.101(b)(6) later in this section of the rule.

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

We clarified that, with respect to clinical concerns and interference with provider care, step therapy or other utilization management policies may not be used as unreasonable means to deny coverage of medically necessary services or to eliminate access to medically necessary Part B covered drugs (84 FR 23856). The requirements in the 2019 rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care. Organizations have been and remain subject to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements. Thus, this proposal was consistent with the 2019 rule in that MA plans must still comply with NCDs and LCDs when developing step therapy programs for Part B drugs.

Finally, in the May 2019 final rule, we did not authorize step therapy practices for Part A or Part B (non-drug) items or services and our proposal here was to limit the ability of MA

organizations to use such UM policies in connection with non-drug covered items or services that are basic benefits. There are a number of differences with step therapy for Part B drugs and step therapy for non-drug items and services that we cited in the proposed rule to support how our proposals on coverage criteria and utilization management would treat items and services that are not Part B drugs differently. From a clinical standpoint, there tends to be more than one drug that has demonstrated success in treating a certain disease or condition, and also there are generic alternatives, which is somewhat different than other Part A and B services. Often, there are not head-to-head comparisons between drugs in a certain class of medications, because a non-inferiority study⁹⁷ was conducted in order to bring the drug to market. This means that it is not always obvious what the clinically superior drug is for certain diseases or conditions, while there may be a significant difference in pricing. Furthermore, there are several studies⁹⁸ demonstrating how increased cost sharing for medications can, in and of itself, reduce patient adherence to those medications.

In addition, the manner in which Part B drugs are purchased and furnished is somewhat different from coverage of non-drug health care items and services. Generally, MA organizations pay the provider for both the service of administering a Part B drug and the cost of the drug, but do not directly pay drug manufacturers or suppliers for the cost of the drug. MA organizations may negotiate pricing discounts or rebates with the manufacturer, who is not the entity that directly furnishes the Part B drug to enrollees and who is not ordinarily paid directly by the MA organization for what is furnished to enrollees. As we explained in the May 2019 final rule (84 FR 23858, 23863, and 23869), we believe that § 422.136 can put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing for the beneficiary. Furthermore, as previously discussed, studies have demonstrated that increased cost sharing for medications can reduce patient adherence to those

⁹⁷<https://www.fda.gov/media/78504/download>.

⁹⁸<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/>

medications. Therefore, we did not propose to revise our current regulations regarding Part B step therapy.

Similar to MACs in Traditional Medicare, we expect MA organizations to make medical necessity decisions based on NCDs, LCDs, and other applicable coverage criteria in Medicare statutes and regulations to determine if an item or service is reasonable, necessary and coverable under Medicare Part A or Part B. In some circumstances, NCDs or LCDs expressly include flexibility that allows coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD. For example, an NCD or LCD may state that the item or service can be covered when reasonable and necessary for the individual patient. When deciding whether an item or service is reasonable and necessary for an individual patient, we expect the MA plan to make this medical necessity decision in a manner that most favorably provides access to services for the beneficiary and align with CMS's definition of reasonable and necessary as outlined in the Medicare Program Integrity Manual, Chapter 13, section 13.5.4. CMS's expectation, as previously outlined, applies to coverage determinations made before the item or service is provided (pre-certification/prior authorization), during treatment (case management), or after the item or service has been provided (claim for payment). We intended this proposal to clarify, as recommended by the OIG, that limited clinical coverage criteria can be applied to basic benefits and reinforces our longstanding policy that MA organizations may only apply coverage criteria that are no more restrictive than Traditional Medicare coverage criteria found in NCDs, LCDs, and Medicare laws. We reiterated in the proposed rule our intent that the proposed changes to the MA regulations would apply to substantive coverage criteria and benefit conditions found in Traditional Medicare regulations, such as those governing inpatient admissions and transfers to post-acute care settings, which are not governed by NCD or LCD. We explained that under our proposal, an MA organization may only deny a request for Medicare-covered post-acute care services in a particular setting if the MA organization determines that the Traditional Medicare coverage criteria for the services cannot be satisfied in

that particular setting. As we discuss in section III.E.3 of this rule, this does not restrict an MA organization's ability to use certain utilization management processes, like prior authorization or post claim review, to ensure items and services meet Medicare coverage rules; it simply limits the coverage criteria that an MA organization can apply or rely upon to deny an item or service during those reviews. We solicited comment about the specificity of the coverage conditions in Traditional Medicare regulations and whether we should consider, and under what circumstances, allowing MA organizations to have internal coverage criteria in addition to requirements in current Medicare regulations.

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

Section 1862(l) of the Act requires the Secretary to issue publicly a discussion and explanation of the factors considered in making NCDs, after following a process that affords the public an opportunity to comment prior to implementation. We proposed at § 422.101(b)(6) that MA organizations must follow a somewhat similar process when creating internal plan coverage criteria by providing a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the

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

We also proposed at § 422.101(b)(6) a requirement that an MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions (such as referring to the Infectious Diseases Society of America for the Treatment of *Clostridium Difficile*⁹⁹) or to determine appropriate level of care (such as the American Society of Addiction Medicine Criteria for placement¹⁰⁰ continued stay, and transfer or discharge of patients with addiction and co-occurring conditions). Clinical literature that CMS considers to be of high enough quality for the justification of internal coverage criteria include large, randomized controlled trials or cohort studies or all-or-none studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question published in a peer-reviewed journal with clear and consistent results.

⁹⁹Reference:

<https://www.idsociety.org/practice-guideline/clostridium-difficile> and <https://www.idsociety.org/practice-guideline/clostridioides-difficile-2021-focused-update/>

¹⁰⁰<https://www.asam.org/asam-criteria>

Evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization, or that does not comply with the standards, as previously described, would not represent proper justification for instituting internal coverage guidelines that would restrict access to care.¹⁰¹ CMS solicited comment on the definition of widely used treatment guidelines and clinical literature that would justify internal coverage criteria used in the absence of NCDs, LCDs, or Traditional Medicare statutes or regulations along with the other requirements proposed in new § 422.101(b)(6)

b. Medical Necessity Determinations and Special Coverage Provisions

Per CMS regulations at § 422.112(a)(6)(ii), MA plans must have policies and procedures that allow for individual medical necessity determinations. As a result, an MA organization's coverage rules, practice guidelines, payment policies, and utilization management policies should be applied to make individual medical necessity determinations based on the individual circumstances for the enrollee and item or benefit to be covered. CMS has longstanding guidance interpreting the obligations of MA organizations when making medical necessity determinations. Chapter 4 of the MMCM, section 10.16, provides that MA organizations make coverage determinations that are based on: (1) the medical necessity of plan-covered services based on coverage policies (this includes coverage criteria no more restrictive than Traditional Medicare described previously and proposed at § 422.101(b)(6)); (2) where appropriate, involvement of the plan's medical director per § 422.562(a)(4); and (3) the enrollee's medical history (for example, diagnoses, conditions, functional status)), physician recommendations, and clinical notes. We proposed to codify these existing standards for medical necessity decision-making at § 422.101(c)(1)(i) and proposed some new requirements to connect medical necessity determinations to our new requirements at § 422.101(b). Therefore, as previously discussed, we

¹⁰¹(for example, Oxford Centre for Evidence-Based Medicine levels of evidence <https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009> and Strength of Recommendation Taxonomy <https://www.jabfm.org/content/17/1/59#F1>)

proposed to codify at § 422.101(c)(1)(i)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as defined at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not found in those sources.

Second, we proposed at § 422.101(c)(1)(i)(B) to require MA organizations to consider whether the item or service is reasonable and necessary under 1862(a)(1) of the Act. We note that this has been a longstanding policy in MA based on how section 1852 of the Act requires MA plans to cover items and services for which benefits are available under original Medicare, however, we believe it is important to acknowledge this in the context of MA organization decisions involving medical necessity. Third, we proposed to codify existing policy at § 422.101(c)(1)(i)(C) that MA organizations consider the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes. Finally, consistent with current requirements at § 422.562(a)(4), we proposed at § 422.101(c)(1)(i)(D) that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate. We solicited comments on when it would be appropriate for the MA organization's medical director to be involved, in light of how § 422.562(a)(4) requires the medical director to be responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity.

Authority for MA organizations to use utilization management policies with regard to basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA provisions. We believe these proposals will further implement the requirements set forth in section 1852 of the Act and §§ 422.100 and 422.101, which require MA organizations to furnish all reasonable and necessary Part A and B benefits. These requirements for how MA organizations make coverage decisions will ensure that MA organizations provide equal access to Part A and Part B benefits as provided in the Traditional Medicare program; overall these

mean that MA organizations will not be able to deny coverage for basic benefits using coverage criteria that is not consistent with coverage criteria in Medicare statutes, regulations, NCDs and LCDs or that is not consistent with the limitations proposed in § 422.101(b)(6).

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

In the proposed rule, we acknowledged in the June 2000 final rule that when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, that an MA plan could choose how the covered services will be provided. We proposed 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. We explained that under our proposal at § 422.101(c)(1)(i), when care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items

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

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

how many MA organizations are currently operating in a manner that conforms with what we proposed. We solicited comment from stakeholders on the full scope of this burden.

We thank commenters for helping inform CMS's policy on coverage criteria for basic benefits in MA. We summarized comments in this section of this rule and our responses follow.

Comment: We received several comments thanking CMS for reiterating that MA plans must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, and for clarifying that this includes coverage criteria for inpatient admissions at 42 CFR § 412.3, requirements for coverage of Skilled Nursing Facility Care and Home Health Services under Part 409, and Inpatient Rehabilitation Facilities coverage criteria at § 412.622(a)(3). Several commenters requested that CMS more clearly state that the proposed revisions to 422.101(b)(2) mean that MA plans must follow the Inpatient Only (IPO) list as well as the "two-midnight rule" presumption and benchmark for hospital inpatient admissions. Some commenters also requested that CMS more explicitly state that additional coverage criteria are prohibited when the IPO list and two-midnight rule are applicable. One commenter requested that CMS explicitly state that MA plans are prohibited from making medical necessity decisions based only on the duration of a hospital stay. Another commenter requested CMS clarify if plan adherence to § 412.3 still allows case management review of inpatient admissions based on whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay. Finally, some commenters asserted that requiring MA plans to follow the two-midnight rule as applied in Traditional Medicare, which includes the two-midnight presumption and benchmark, would violate non-interference rules at 422.256(a)(2)(ii) that preclude CMS from interfering in payment rates agreed to by an MA plan and its contracted providers. Additionally, these commenters stated that the requirements at § 412.3 are payment rules and not coverage rules.

Response: We thank commenters for their comments. In our proposal at 422.101(b)(2), we stated that MA plans must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. We also stated that this includes coverage criteria for inpatient admissions at 42 CFR 412.3, requirements for coverage of Skilled Nursing Facility Care and Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities coverage criteria at 42 CFR 412.622(a)(3). We affirm here that the criteria listed at those regulations are applicable in MA.

MA organizations are required by Section 1852(a) to provide Part A or Part B items and services (with limited exceptions) through providers that have a contract with the MA organization or by payment to a provider that does not have a contract with the MA organization. CMS has interpreted those obligations in § 422.101(a) to require MA organizations to “provide coverage of, by furnishing, arranging for, or making payment for” these Part A or Part B items and services. Therefore, the distinctions between regulations that contain coverage criteria and regulations that contain criteria for Medicare payment in Traditional Medicare are not similarly applicable in the MA program because MA organizations provide coverage by furnishing, arranging for, or making payment for Part A and Part B items and services. As a result, when determining whether Traditional Medicare criteria apply in MA, it is irrelevant whether Traditional Medicare considers the criteria part of a coverage rule or a payment rule, as both address the scope items and services for which benefits are available to Medicare beneficiaries under Parts A and B. MA organizations have discretion about how much and under what conditions they pay their contracted providers that furnish services, but § 422.101(a) and (b) are about ensuring that MA enrollees receive the same items and services they would receive if they were enrolled in Traditional Medicare. We explain here what the new rule means and how it works using examples of Traditional Medicare criteria listed at § 422.101(b)(2) of this final rule.

In regards to inpatient admissions at 412.3, we confirm that the criteria listed at 412.3(a)-(d) apply to MA. We acknowledge that 412.3 is a payment rule for Medicare FFS, however,

providing payment for an item or service is one way that MA organizations provide coverage for benefits. Therefore, under § 422.101(b)(2), an MA plan must provide coverage, by furnishing, arranging for, or paying for an inpatient admission when, based on consideration of complex medical factors documented in the medical record, the admitting physician expects the patient to require hospital care that crosses two-midnights (§ 412.3(d)(1), the “two midnight benchmark”); when admitting physician does not expect the patient to require care that crosses two-midnights, but determines, based on complex medical factors documented in the medical record that inpatient care is nonetheless necessary (§ 412.3(d)(3), the “case-by-case exception”); and when inpatient admission is for a surgical procedure specified by Medicare as inpatient only (§ 412.3(d)(2)). However, it is important to clarify that the “two-midnight presumption” (the presumption that all inpatient claims that cross two midnights following the inpatient admission order are “presumed” appropriate for payment and are not the focus of medical review absent other evidence) does not apply to MA plans. The two-midnight presumption is a medical review instruction given to Medicare contractors (for example, MACs, RACs, QIOs) to help them in the selection of claims for medical necessity review. CMS guidance¹⁰² states that Medicare contractors will presume hospital stays spanning two or more midnights after the beneficiary is formally admitted as an inpatient are reasonable and necessary for Part A payment. Under this presumption, Medicare contractors will generally not focus their medical review efforts on stays spanning two or more midnights after formal inpatient admission.

However, this final rule does not dictate how MA organizations will decide which claims to subject to review. Section 1852(g)(1)(A) of the Act states that an MA organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan is entitled to receive a health service and that such determinations regarding whether or not an individual may receive a health service must be made on a timely basis. CMS has adopted

¹⁰²<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10080.pdf>

regulations governing certain minimum procedures that MA plans must use, including the timing of organization determinations, the content of denial notices, and who must review a decision that the plan expects to be a full or partial denial on the basis of medical necessity before the denial can be issued. (See also section III.G. of this rule regarding the proposal to amend §§ 422.566(d) and 433.629(k) on this last point.) In addition, the regulations in part 422, subpart M address when and why an MA organization may reopen an organization determination at § 422.616, which incorporates the reopening regulations at §§ 405.980 through 405.986. However, CMS has not established requirements or limits on how MA organizations prioritize medical claims for review akin to the instructions CMS issues to Traditional Medicare contractors. Therefore, CMS instructions to Traditional Medicare contractors regarding how to prioritize medical claim review do not apply to MA organizations, under our interpretation. Accordingly, the amendments to § 422.101(b)(2) finalized here do not include any requirement for how MA organizations select inpatient admission claims for review, but we do confirm that the criteria listed at 412.3(a)-(d) apply. We confirm that MA plans may still use prior authorization or concurrent case management review of inpatient admissions based on whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission, under either the two-midnight benchmark or the case-by-case exception.

Further, we do not believe that § 422.101(b), as finalized with our clarification about how 42 CFR 412.3 applies in the context of MA, violates the non-interference rule at section 1854(a)(6)(iii). We affirm MA organizations' rights to contract with providers of their choosing and to set the price structures, including how and how much contracted providers are paid. In addition, under the rules finalized here, MA organizations may adopt procedures, and in those situations specified in § 422.101(b)(6), internal coverage policies for making medical necessity determinations regarding whether an individual is entitled to receive a health care service under Part A or Part B, so long as the requirements and conditions set forth in the regulations are met. Our focus of this policy is not on how or how much MA organizations pay their contracted

providers, but on ensuring that MA enrollees receive items and services for which benefits are available under Part A and Part B (excluding hospice care and organ acquisitions for kidney transplants) that they would receive under Traditional Medicare.

We clarify here and amend the regulation text at § 422.101(b)(2) to state the applicability of the Inpatient Only list in MA, which, under § 419.22(n) are those services and procedures that the Secretary designates as requiring inpatient care and for which payment is not made when furnished in a hospital outpatient department under the Medicare Hospital Outpatient Prospective Payment System. We confirm that the Inpatient Only list applies to MA consistent with our read of the statute that when Traditional Medicare pays for a service only when certain conditions are met, meaning that those certain conditions must be met for the service to be considered a Traditional Medicare basic benefit, these same conditions, including setting, must be met in order for the service to be considered part of the basic benefit of an MA plan. As previously stated in this rule and in the proposed rule, if Traditional Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Traditional Medicare benefits that must be included as basic benefits covered by an MA plan. Also, we remind MA plans that they may cover the same service when the conditions are not met—such as in a different setting or from a different type of provider — as a supplemental benefit. The regulation at § 412.3(d)(2) provides that an inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Therefore, coverage of the inpatient admission for a procedure on the inpatient only list is fully established under the applicable Medicare regulations and the MA plan must cover this type of inpatient admission without application of additional internal criteria under new § 422.101(b)(6).

Comment: Many commenters expressed concern that the proposed rule limits 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 determinations. One commenter suggested that 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. Similarly, one commenter recommended that CMS provide additional clarity on what a plan must do when an NCD or LCD acknowledges that additional coverage criteria may be applied to determine medical necessity. Another commenter requested that CMS establish a process that allows plans to ask CMS questions and request clarity on Medicare guidelines, including the applicability of certain guidelines. One commenter noted that CMS allows Medicare review contractors to use evidence-based guidelines to assist reviewers in making medical necessity determinations consistent with Traditional Medicare and requirements and, as such, MA plans should be able to maintain this ability.

Response: We thank commenters for their comments and we believe that “Medicare review contractors” used in this context means MACs in Traditional Medicare. We understand that Traditional Medicare statutes, regulations, NCDs, and LCDs do not always contain specific criteria for making medical necessity determinations in every situation for every applicable Part A or B service. Thus, in the proposed rule, we stated 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. We agree with commenters that in order to adequately adhere to this requirement, MA plans need additional clarity on what it means for Traditional Medicare coverage criteria to not be “fully established”, and thus allowed to apply internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature. Based on commenter recommendations, and in order to more explicitly state the circumstances under which MA organizations may apply internal coverage criteria, we are finalizing § 422.101(b)(6) with additional modifications compared to the proposed version. We are finalizing a new paragraph (b)(6)(i) to explain in regulation text when coverage criteria are

not fully established. At § 422.101(b)(6)(i)(A)-(C) we explain that coverage criteria are not fully established when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently; NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria. This means that when any of these three circumstances are present, MA plans may develop and rely upon internal coverage criteria to make medical necessity decisions.

We agree with commenters that medical conditions and a patient's medical history can be complex and that Medicare coverage guidelines are not specific enough to address every possible scenario when benefits are available under Medicare Parts A or B for every item or service. We also acknowledge, as commenters stated, that MACs are permitted to consider evidence-based guidelines when making individual medical necessity determinations. Based on these comments, and in order to clarify when Traditional Medicare coverage criteria are not fully established, this final rule will permit MA organizations to adopt publicly accessible internal coverage criteria based on current evidence in widely used treatment guidelines when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. First, we proposed and address in more detail in the following pages how, in addition to basing internal coverage criteria on current evidence in widely established treatment guidelines, MA organizations must follow certain procedures. Second, as specified at § 422.101(b)(6)(i)(A), the MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. We will use this interpretation in monitoring and evaluating compliance with this regulation. We also require in this rule that MA organizations make this explanation publicly accessible, along with the internal coverage criteria in use, and

identify the general provisions that the internal coverage criteria supplement so that general provisions can be applied in specific factual circumstances.

We explained in the proposed rule, that in some circumstances, NCDs or LCDs expressly include flexibility that allows coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD. We also acknowledged in the proposed rule that there are some Part A or Part B benefits that do not have applicable Medicare NCDs, LCDs, or specific traditional Medicare coverage criteria in regulation for MA plans to follow when making medical necessity determinations. Commenters agreed with these statements, and therefore, we are finalizing in the regulation text at § 422.101(b)(6)(i)(B) and (C) that coverage criteria are not fully established when NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD or when there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria. When identifying whether there is an absence of applicable Medicare statutes, regulations, NCDs, or LCDs, the MA organization needs to look beyond the labels of “payment rule” or “coverage rule”, as both serve to establish coverage criteria in MA. Therefore, this rule prohibits MA organizations from applying internal coverage criteria in addition to the applicable Traditional Medicare statutes, regulations, NCDs, or LCDs, unless § 422,101(b)(6)(i)(A) or (B) apply.

As part of applying and complying with § 422.101(b)(6), we expect that MA plans will consult the Medicare Benefit Policy Manual, Medicare Program Integrity Manual, and similar CMS guidance materials. These manuals contain significant explanations and interpretations of Traditional Medicare laws governing Part A and Part B benefits, most of it longstanding, to provide instructions and procedures for day to day operations for those responsible for administering the Medicare program and for making coverage decisions. Using these resources will ensure that MA plans are covering items and services for which benefits are available under Part A and Part B for their enrollees and minimize the number of potential situations where

Traditional Medicare coverage policies have insufficient detail such that an MA plan must develop its own internal coverage criteria.

When MA plans are permitted to adopt such internal criteria, however, it must be based on current evidence in widely used treatment guidelines or clinical literature and made publicly available. We believe that permitting the use of publicly accessible internal coverage criteria in these limited circumstances and contexts is necessary to promote transparent, and evidence-based clinical decisions by MA plans that are consistent with Traditional Medicare. We do not view the use of internal coverage criteria in these instances as being more restrictive than, or applying additional criteria beyond, Traditional Medicare because that is precisely what is contemplated, for example, by the NCDs or LCDs that provide for this type of flexibility and interpretation in Traditional Medicare. Use of internal policies based on current evidence in widely used treatment guidelines or clinical literature is appropriate to fill in gaps where coverage criteria cannot specify all possible circumstances where coverage of a Part A or Part B item or service may be available for a beneficiary. These policies provide MA organizations with limited discretion to interpret Traditional Medicare coverage rules and must not create barriers to access to care in a way that is not aligned with access in Traditional Medicare.

In order to demonstrate how this rule applies, we discuss an example of an actual coverage policy to further elucidate the limited circumstances under which MA plans may apply internal coverage criteria to supplement the existing coverage guidelines. First, in NCD 220.1 for Computed Tomography (CT)¹⁰³, the NCD states that, “[s]ufficient information must be provided with claims to differentiate CT scans from other radiology services and to make coverage determinations. Carefully review claims to ensure that a scan is reasonable and necessary for the individual patient; that is, the use must be found to be medically appropriate considering the patient’s symptoms and preliminary diagnosis.” Here, the NCD recognizes that individual circumstances are relevant in determining appropriate coverage, so the policy used the

¹⁰³<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=176>

term “sufficient” in order for the medical necessity reviewer to make a more accurate coverage determination. Additionally, the NCD allows the MAC medical staff to make an individual case determination that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient’s symptoms or complaints stated on the claims form. In this circumstance, the MA plan would be allowed to apply current evidence in widely used treatment guidelines or clinical literature that is made publicly available, as defined at § 422.101(b)(6), to make consistent determinations about when it would be reasonable and necessary for the individual patient and what type of information is required to be submitted on the claim. The MA organization would need to demonstrate in its public explanation of the rationale that supports the internal coverage criteria that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. The MA organization would also need to identify the general provisions that are being interpreted or supplemented. In this case, the MA organization may use internal coverage criteria to further establish what “sufficient information” must be provided with the claim or pre-service request for coverage (including a prior authorization request).

In another example, NCD 220.2 for Magnetic Resonance Imaging (MRI)¹⁰⁴, the NCD lists indications and limitations of coverage as well as the contraindications and other non-covered indications for appropriate use of an MRI. However, it also provides for coverage under a category of “other” when “[a]ll other uses of MRI or MRA for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local MAC discretion.” Here, the NCD explicitly includes flexibility that allows for coverage in circumstances beyond the specific indications that are listed in an NCD and gives the medical necessity reviewer discretion to make this judgment. In order to make consistent determinations

¹⁰⁴<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=177>

on coverage in these “other” circumstances not specifically addressed by the NCD, § 422.106(b) as finalized permits an MA plan to adopt an internal coverage policy based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available.

We proposed at 422.101(c)(1) that MA organizations must make medical necessity determinations based on a number of factors, including the criteria in § 422.101(b), the enrollee’s medical history, and other factors. Thus, to the extent that an MA organization has developed internal coverage criteria as permitted by § 422.101(b)(6) (including compliance with the procedures set forth in paragraphs (b)(6)(i) through (ii)), the current evidence in widely used treatment guidelines or clinical literature that are the basis for the internal coverage policy should also be used in making individual medical necessity determinations. Therefore, MA organizations may use these internal criteria to deny coverage of an item or service. However, as required by § 422.568 and 422.631 (for applicable integrated plans), MA organizations must give enrollees written notice of a denial and the notice must state the specific reasons for the denial. We clarify here that if an MA organization denies care based on internal criteria, that criteria must be clearly stated in the denial notice, just as other applicable Medicare coverage criteria must be stated under § 422.568(e)(2), when used as the basis for a denial of coverage. Communicating all necessary information needed for the enrollee or provider to effectively appeal the decision, including the evidence used to support the internal coverage policy when applicable, is one of the purposes of the denial notice. The standardized Integrated Denial Notice is properly completed when it includes a specific and detailed explanation of why the medical services, items or Part B drugs were denied, including a description of the applicable coverage rule or applicable plan policy (for example, Evidence of Coverage provision) upon which the action was based, and a specific explanation about what information is needed to approve coverage must be included, if applicable.

In light of the issues raised by commenters, we are finalizing 422.101(b) with modifications to clarify when Traditional Medicare coverage criteria are not fully established and

what information about internal coverage criteria must be made publicly accessible. We will continue to conduct audit and monitoring activities to ensure that appropriate coverage criteria are applied during medical necessity reviews, and if CMS identifies abuses of this policy, we will consider future rulemaking on this topic.

Comment: We received several comments asking CMS 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, such as InterQual or MCG systems, stating that that these tools help plans consolidate Medicare regulations and assist plans in making evidence-based, clinically appropriate medical necessity determinations. Another commenter requested that CMS continue to allow plans to use independent third-party, proprietary tools to guide medical necessity determinations.

Response: We thank commenters for expressing their concerns. However, use of these tools, in isolation, without compliance with requirements in this final rule at § 422.101(b), (c), and § 422.566(d), is prohibited.

We understand that utilization management tools such as InterQual or MCG, among others, are coverage criteria products created to assist the plans, providers and others, in clinical review processes and to help guide medical necessity determinations. We understand from commenters 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. We understand from commenters that these tools are often used in conducting inpatient, post-acute and home care medical necessity reviews, in particular.

As finalized, §§ 422.101(b), (c) and 422.566(d) address different aspects of how these products appear to be used so consideration of all three regulations is necessary. As proposed and

finalized in § 422.101(b)(2), MA plans must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare, such as payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a)(3)). Thus, MA plans may not use InterQual or MCG criteria, or similar products, to change coverage or payment criteria already established under Traditional Medicare laws.

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

Under this final rule, when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, MA plans may create internal coverage criteria under specific circumstances described at § 422,101(b)(6)(i). In these circumstances, an MA plan is permitted to choose to use a product, such as InterQual or MCG or something similar, to assist in creating internal coverage criteria only so long as the requirements in § 422.101(b), (c), and § 422.566(d) are met. Specifically, MA plans must comply with § 422.101(b) and (c) as to: (i)

what coverage criteria are applied; (ii) how, if those criteria are not only from Medicare laws, NCDs or LCDs, the coverage criteria were developed and what they are based on, and (iii) how individualized determinations of medical necessity take into account the information and considerations specified in § 422.101(c)(1). In addition, if the organization determination made using the product is expected to be a full or partial denial, the MA plan must ensure that the additional review requirements in § 422.566(d) are met. (See section III.G of this final rule.)

The MA plan must therefore ensure that the coverage criteria used in these products are based on current evidence in widely used treatment guidelines and clinical literature consistent with the definitions and standards in § 422.101(b)(6) before using the product as the MA plan's internal coverage policy. Further, MA organizations must comply with specific procedures, which we discuss in more depth later in this preamble, before an internal coverage policy – including a product such as those described by the commenters - may be used; the MA plan must provide, in a publicly accessible way, the internal coverage criteria in use; a 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 an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. This includes, when applicable, how the additional criteria interpret or supplement general provisions in Traditional Medicare and provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. MA organizations must ensure that they are making medical necessity determinations based on the circumstances of the specific individual, as outlined at § 422.101(c), as opposed to using an algorithm or software that doesn't account for an individual's circumstances. Finally, MA organizations must comply with amended § 422.566(d), as in section III.G of this final rule, which requires that a denial based on a medical necessity 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 service at issue.

We understand from commenters that many of these products and their software are proprietary in nature and may be proprietary to the particular organization that uses these products. However, use of such tools and their proprietary nature does not absolve MA plans from their responsibilities under this final rule. For an MA plan to use the coverage criteria in these tools, the MA plan 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. The MA plan must make the evidence that supports the internal criteria used by (or used in developing) these tools publicly available, along with the internal coverage policies themselves. Furthermore, under § 422.504, MA organizations must provide information and access to CMS (and HHS and the OIG) as it conducts its oversight of MA plans and their compliance with MA program requirements. CMS may, therefore, review all aspects of the plan's decision-making including whatever evidence might be contained within a decision tool, or support the determinations made from the use of decision tool, including such tools provided by third-parties as discussed here. We expect MA plans already using these tools, or those that may plan to use these tools in the future, to work with third parties that provide these tools to revise any utilization management products and ensure that these products meet the requirements at § 422.101(b), (c), and § 422.566(d).

Comment: 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 stated that adhering to Traditional Medicare coverage policies will impede a plan's ability to make medical necessity decisions. 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. Several commenters warned that our proposal could lead to increased costs and duplicative and unnecessary services. Several commenters stated that our proposal will undermine the transition to value-based care and similar payment models. Some commenters expressed concern that adherence to 42 CFR § 412.3, part 409, and § 412.622

will remove the existing flexibility of MA plans to provide the same level of care in different settings. One commenter stated that removing the flexibility for plans to provide care in alternate settings could shift care from beneficiary homes to institutional settings, resulting in increased costs for both the plans and beneficiaries. For example, one commenter expressed concern that Traditional Medicare Skilled Nursing Facility payment rules in particular incentivize facilities to prolong Skilled Nursing Facility stays regardless of patient need.

Response: We proposed to codify at § 422.101(c)(1)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c). This means that when an MA organization is making a coverage determination on a Medicare covered item or service 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. MA plans may have supplemental benefits that cover items and services that are not covered under Parts A or B. In addition, where Traditional Medicare would cover services in specific or various settings or from specific or various providers or cover alternative services or treatment options for the beneficiary, an MA organization must also cover those as basic benefits. An MA plan may make its enrollees aware of other covered treatment options or encourage specific treatment options as part of the MA plan's coordination and management of care for enrollees. We reiterate that when an item or service has fully established coverage criteria under Traditional Medicare, use by an MA plan of certain utilization management processes, such as clinical treatment guidelines that require another item or service be furnished prior to receiving the requested item or service, violate the requirements proposed, and being finalized in this rule, at § 422.101(b) and (c). Utilization management processes that are specified within the applicable NCD or LCD or

Medicare statute or regulation are permissible. By contrast, when coverage criteria are not fully established and MA organizations are allowed to adopt internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature, clinical treatment guidelines that require another item or service to be furnished prior to receiving the requested item or service must be expressly cited in the evidence in order for it to be acceptable under our rule. Clinical criteria that restrict access to a Medicare covered item or service, unless another item or service is furnished first, are not based on current evidence if the evidence does not cite or discuss the use of a different item or service first. When not specifically required in a Medicare law, NCD or LCD or part of the clinical evidence that supports an internal coverage policy that is permitted because Traditional Medicare coverage criteria are not fully established, use of a “try first” or similar utilization management process would be additional internal coverage criteria prohibited by § 422.101(b)(6) as finalized in this rule. We 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. Use of this flexibility by MA organizations is only allowed when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD as stated at § 422.101(b)(6)(i).

Comment: Some commenters also 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.

Response: NCDs are made and updated through an evidence-based process, with opportunities for public participation through a public comment and review process. NCDs are updated through CMS-generated reviews and through requests by an external party for a new NCD, for reconsideration of an existing NCD, or by an aggrieved party to issue an NCD when no NCD exists as established in Final Notice 78 FR 48164 in 2013. CMS makes proposed NCD decisions available on the CMS website for a 30-day public comment period after which

comments are reviewed and a final decision is issued not later than 60 days after the conclusion of the comment period. A summary of the public comments received and responses to the comments are included in the decision memorandum. In some cases, CMS's own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). When developing LCDs, MACs use published, original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines. Further, LCDs undergo a similar process to that for NCDs, including public participation. Because Traditional Medicare follows a process of expert consultation and public review and comment in order 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, we believe that these processes are sufficient in creating appropriate coverage guidelines.

Comment: Some commenters noted that the proposed language at § 422.101(b)(2) no longer includes a reference to complying with original Medicare manuals and instructions. Some commenters noted that manual guidance often includes necessary coverage guidance not included in Medicare regulations. These commenters requested that CMS maintain compliance with manual guidance at § 422.101(b)(2).

Response: We thank commenters for their observations. Section 422.101(b)(2), with the proposed revisions (which we are finalizing with modifications) references Traditional Medicare laws and existing § 422.101(b)(1) and (b)(3) require compliance by MA plans with NCDs and LCDs based on how section 1852(a)(2)(C) and (a)(5) of the Act make clear that MA plans must cover benefits consistent with NCDs and LCDs. Although § 422.101(b) will no longer refer to "original Medicare manuals and instructions," those materials are invaluable in interpreting and understanding the scope of Part A and Part B benefits and what benefits are available under Parts A and B in order to determine what Traditional Medicare covers in specific situations. Substantive legal standards about Medicare benefits may be established through rulemaking and

NCDs. In revising § 422.101(b)(2) to refer to Traditional Medicare regulations and statutes, we are not diminishing the content and value that these manuals and instructions provide in interpreting and defining the scope of Part A and Part B benefits. These manuals contain significant explanations and interpretations of Traditional Medicare laws governing Part A and Part B benefits, most of it longstanding, to provide instructions and procedures for day-to-day operations for those responsible for administering the Medicare program and making coverage decisions on individual claims, so we expect that MA plans will consult the Medicare Benefit Policy Manual, Medicare Program Integrity Manual, and similar CMS guidance materials.

Comment: We received some comments requesting that CMS establish a minimum number of days of initial Inpatient Rehabilitation Facilities or Skilled Nursing Facility coverage.

Response: We thank commenters for their suggestion and note that the minimum scope of IRF and SNF benefits are statutory requirements under the Medicare statute. We did not propose a separate MA coverage requirement for initial Inpatient Rehabilitation Facilities or Skilled Nursing Facility coverage, nor did we propose to make changes to the structure of basic benefits covered under Parts A and B. Our proposal aims to align the applicable coverage criteria in MA with Traditional Medicare to ensure comparable coverage for beneficiaries across both programs. Therefore, we consider changes to scope or structure of Part A or B benefits outside of the scope of this rule.

Comment: Some commenters expressed concern about MA plans' ability to provide a summary of evidence for all services. One commenter stated that sources often lack evidence to support all types of care. Some commenters also requested that CMS clarify what exactly is meant by "summary of the evidence that was considered." These commenters requested that CMS clarify whether this includes a citation to an article or a comprehensive synthesis of each study used, stating that the latter would be time consuming and extremely burdensome. Other commenters requested CMS provide guidance on how this information should be shared publicly, noting that some resources may be behind a paywall. One commenter suggested that

plans be required to post this information in a visible location on their websites. 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. One commenter suggested CMS require MA plans to consult with up to date clinical databases if we determined that a full in-depth review of evidence was too burdensome. Another commenter requested that CMS require that a summary of evidence be provided upon request instead of publicly posted. One commenter requested that CMS clarify and provide examples of appropriate “widely used treatment guidelines.” Some commenters stated that consideration should be given to quality of literature and not only how often it is used. Other commenters suggested that CMS should require that the draft coverage policy be available for review and public comment. Finally, some commenters expressed concern that there is not enough data or widely used treatment guidelines available on certain conditions, including rare diseases. Given these challenges, some commenters requested CMS provide plans with flexibility in meeting this requirement. One commenter expressed concern that the public summary of evidence would require significant time and administrative effort.

Response: We thank commenters for their comments. We proposed, and are finalizing at § 422.101(b)(6), that MA organization’s internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature. In the proposed regulation text, we stated that current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. We provided an example by referring to the Infectious Diseases Society of America for the Treatment of *Clostridium Difficile*. We also explained that current, widely-used treatment guidelines include those used to determine appropriate level of care (such as the American Society of Addiction Medicine Criteria for placement, continued stay, and transfer or discharge of patients with addiction and co-occurring conditions). We proposed that clinical literature acceptable for use to justify internal coverage criteria includes

large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question. Evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization, or that does not comply with the standards described in the regulation would not represent proper justification for instituting internal coverage guidelines that would restrict access to care. These types of evidence have not undergone peer-review, are not transparent, or are not research methodologies that can plausibly establish causality. This evidentiary standard is overall consistent with published frameworks that rank the reliability of different types of studies in the clinical literature.

With regards to requiring MA plans to have a review and comment process for their internal coverage criteria, we remind commenters that per CMS regulations at §422.202(b), MA organizations that use a network of providers (for example, coordinated care plans) have obligations with regard to developing and using practice guidelines and utilization management guidelines, including establishing a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures. We believe that the regulations at § 422.202(b) provide a formal and sufficient mechanism for MA organizations to receive comment from contracted providers on internal coverage criteria, instead of having a review and comment period open to the general public. Therefore, we proposed and are finalizing a revision to § 422.202(b)(1)(i) to require practice guidelines and utilization management guidelines used by an MA organization that uses a network of providers to base those guidelines on current evidence in widely used treatment guidelines or clinical literature. Additionally, existing requirements under § 422.202(b) require that MA plans' practice guidelines and utilization management guidelines must consider the needs of the enrolled population; be developed in consultation with contracting physicians; be

reviewed and updated periodically; and be communicated to providers and, as appropriate, to enrollees. Further, decisions with respect to utilization management, enrollee education, coverage of services and other areas in which the guidelines apply must be consistent with the guidelines. We believe that an additional requirement that plans go through a comment period is redundant of these existing requirements regarding provider participation and that no additional requirements along such lines are necessary.

At 87 FR 79501, we proposed that an MA organization provide a publicly accessible summary of the evidence considered in developing the internal coverage criteria, a list of the sources of evidence, and an explanation of the rationale for the internal coverage criteria in order to protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature and to provide transparency. However, the regulation text at proposed § 422.101(b)(6)(i) through (iii) inadvertently limited the phrase “publicly accessible” to only the summary of evidence. We are finalizing the proposal with modifications to the regulation text to be consistent with the scope of the proposal described in the preamble. Additionally, we are renumbering these criteria to as (A) through (C) in newly established subparagraph (ii).

Along with the new standards being adopted at § 422.101(b)(6)(i)(A) to allow MA organizations to create internal coverage criteria when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently, we also are enhancing transparency requirements at § 422.101(b)(6)(ii)(C). When an MA organization uses internal coverage criteria in accordance with § 422.101(b)(6)(i)(A), they must also include in their publicly accessible explanation of the rationale that supports the adoption of the coverage criteria, an identification of the general provisions that are being supplemented or interpreted, and explain how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. For example, the evidence supporting use of an internal policy may

demonstrate that patients benefit from increased efficacy of treatment or increased patient safety and highly outweighs the potential for the criteria to be used as a barrier to care that delays or denies access to items or services. While we acknowledge that this new requirement in § 422.101(b)(6)(ii) will increase burden on MA organizations, we believe that the benefits of transparency in the development of internal coverage criteria balances out that burden. We note that MA organizations may cite to policies or publicly available evidence that is behind a paywall without having to provide access to the policy directly. The standard at § 422.101(b)(6) allows MA organizations to create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature; it does not require that the MA organization to provide direct access to the source, but they must make publicly available the information required at § 422.101(b)(6)(ii). This could be in the form of a written summary that summarizes the evidence and treatment guidelines or clinical literature and provides a link or citation to the location of the evidence. This transparency provides assurances that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature, which we believe will protect MA enrollees. In an effort to provide plans with flexibility, we decline to require specific mechanisms for how the information is made publicly available. However, we do recommend MA plans refer to the coverage criteria and summary of evidence presented by MACs as a guide and best practice for how to present this information publicly. We are finalizing § 422.101(b)(6)(ii) with modifications to make everything listed in paragraphs (b)(6)(i) through (iii) of the proposed rule publicly accessible and to enhance transparency requirements related to the use of internal coverage criteria.

Comment: 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.

Response: We thank commenters for their suggestions. We remind commenters that section 1854(a)(6)(B)(iii) of the Act and MA regulations at § 422.256(a)(2)(ii) 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. We note that while MA organizations can develop their own payment methodologies for in-network providers for different diagnoses or procedure codes, national standard code sets for ICD-10 codes and CPT/HCPCS codes, along with respective coding guidelines, as required under HIPAA, must be followed. In this sense, the code sets and associated coding guidelines used in Traditional Medicare are the same as those required to be used by MA organizations. Further, when submitting encounter data to CMS, MA organizations must comply with the data structure and coding vocabularies established by CMS for such data and MA encounter data must conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. (See § 422.310(d)) For non-contract providers, section 1852(a)(2) requires MA organization to pay non-contracted providers what they would receive in the Traditional Medicare program (that is, the FFS program) for furnishing the Part A or Part B services. Because Traditional Medicare uses specific codes and payment procedures, when a non-contracted provider uses those codes to request payment from an MA organization, the MA organization may not deny payment on the basis that the codes that were submitted are not used by the MA organization and its contracted providers

Comment: With respect to medical necessity determinations, 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 of 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. These commenters suggested CMS require plans to use a reviewing medical director who has specific expertise in the relevant areas.

Response: We thank commenters for their suggestions. We proposed, and are finalizing in this rule, at § 422.101(c)(1)(i)(C), that MA organizations must make medical necessity determinations based on, among other things, the enrollee's medical history (for example, diagnoses, conditions, functional status), 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. We do not believe that our regulation needs to require that MA plan medical directors have direct access to all of the relevant information available to the plan and the responsibility to review all this information before any medical necessity determinations are made. As proposed and finalized, § 422.101(c)(1)(D) requires involvement of the MA plan medical director where appropriate. Per § 422.562(a)(4), which has not been amended in this rule, MA plan medical directors are responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. MA organizations must have adequate procedures and systems in place to fulfill their obligations under part 422, including making organization determinations about coverage. (See for example, §§ 422.503(a)(4) 422.504(a)(16) and 422.566(a)). Section 422.101(c)(1)(C) requires that medical necessity determinations be made based on, among other things, the enrollee's medical history, physician recommendations, and clinical notes. This effectively means that all relevant clinical information is to be used by the MA plan in making the determination. Also, we are also finalizing the proposal to revise §§ 422.566(d) and 422.629(k)(3), in section III.G of this rule, to state that the physician or other appropriate health care professional who conducts the organization determination review must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA

organization or applicable integrated plan (AIP) issues an adverse decision on medical necessity. In response to the comment that that peer-to-peer reviews often include medical directors without relevant expertise, we interpret peer to peer review to mean a discussion between the patient's doctor and a medical professional at the MA plan to obtain a prior authorization approval or appeal a previously denied prior authorization. While CMS does not have requirements that govern who within an MA plan must conduct peer to peer reviews, we reiterate that if the MA plan issues an adverse organization determination, the physician or other appropriate health care professional who conducts the organization determination review must have expertise in the field of medicine that is appropriate for the item or service being requested.

Comment: 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.

Response: We thank commenters for their suggestions. Under the revisions to § 422.101(c)(1) that we proposed and are finalizing in this rule, physician recommendations are required to be considered when making medical necessity determinations about the specific enrollee and requested services. This will apply in all contexts, not only when an enrollee is being transferred from one level of care to another or being admitted on an inpatient basis. Specifically, CMS proposed to codify at 422.101(c) that MA organizations must make medical necessity determinations based on: 1) coverage and benefit criteria as specified or authorized at 422.101(b) and (c) (and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c); 2) whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act; 3) the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and 4) where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4). This regulation text is based on longstanding guidance in section 10.16 of Chapter 4 of the Medicare Managed Care Manual. In codifying this policy for medical necessity

determinations, we reiterate that these four factors are appropriate and necessary considerations when making a medical necessity determination.

Comment: One commenter requested CMS clarify whether the proposed rules around coverage criteria for basic benefits prevent plans from providing supplemental benefit based on functional or social determinants of health (SDOH) needs.

Response: The rules around coverage criteria for basic benefits adopted and discussed in this final rule do not prevent MA organizations from taking SDOH into account when designing or determining eligibility for Special Supplemental Benefits for the Chronically Ill (SSBCI) §422.102(f). For clarity, we remind the commenter that as discussed in the 2020 Final rule (85 FR 33796), MA plans may consider social determinants of health as one factor, when determining eligibility for an SSBCI, to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, MA plans may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

Comment: Some commenters requested that CMS clarify how we intend to enforce the requirements in section III. E of this rule, including the new requirements related to coverage criteria at § 422.101(b)(2) and § 422.101(b)(6) and medical necessity determinations at § 422.101(c). One commenter suggested CMS audit inpatient admissions to ensure the rules are followed.

Response: We thank commenters for their comments. As stated in the proposed rule, CMS currently monitors MA organization compliance with this existing policy through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations are designed to alert CMS to any issues with access to care, and CMS may require MA organizations to address these matters if they arise. CMS intends to continue these oversight operations to ensure MA organizations' compliance with the provisions in this final rule. Furthermore, as previously discussed, under § 422.504, MA organizations must provide information and access to CMS (and HHS and the OIG) as it conducts its oversight of MA plans

and their compliance with MA program requirements. CMS may, therefore, review all aspects of the plan's decision-making as necessary to ensure compliance with program rules.

Comment: We received some comments requesting that CMS delay the implementation date of the utilizations management related provisions in this rule, including the medical necessity proposals at § 422.101(b) and (c). One commenter stated that they were concerned that plans would have a limited time to review, assess, and implement changes needed to comply with these rules. Another commenter stated that compliance with these changes would require contracting, staffing, and resource infrastructure changes. Some commenters stated that providing a publicly accessible summary of evidence (considered during the development of the criteria) would require significant administrative effort in particular. Some commenters stated that the implementation date should be delayed because utilization management provisions finalized in this rule, would require significant administrative effort to implement.

Response: We thank commenters for expressing their concerns.. We believe 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. We acknowledge that compliance with § 422.101(b) and (c) will require changes to existing plan processes and create burden for MA organizations. We believe 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. As such, we are not able to fully quantify the burden of these changes. Nevertheless, we believe it is important to codify clearer rules regarding how Part A and B benefits must be covered and furnished in the MA program as soon as possible in order to ensure that all MA enrollees receive the basic benefits coverage to which they are entitled.

We solicited comment on the burden associated with our proposals. As discussed, we stated that we were unable to quantify or predict how many MA organizations are currently operating in a manner that would conform with our proposed changes to § 422.101(b) and (c).

We solicited comment from stakeholders on the full scope of this burden. As previously discussed, some commenters stated that the utilization management provisions and coverage criteria requirements in this rule would require significant administrative effort. For example, some commenters stated that providing a publicly accessible summary of evidence would require significant administrative effort. Some commenters asserted that the rules presented here would require changes to contracts, staff, resource infrastructure, and other plan related systems and processes. One commenter stated that CMS did not adequately account for the effort associated with meeting these requirements. However, we did not receive comments on our cost and burden analyses. The stakeholder comments of increased administrative burden are consistent with our statement in the proposed rule that due to its complexity and many unknowns, we cannot quantify the burden.

After careful consideration of all comments received, and for the reasons set forth in the final rule and in our responses to the related comments in sections III.E.2 of this final rule, we are finalizing the substance of our proposals for § 422.101(b) and (c) with modifications as follows:

- We are finalizing amendments to § 422.101(b)(2), largely as proposed but with modifications to clarify the scope of the requirement and to correct the citation to 42 CFR 412.622(a)(3) and to explicitly state the applicability of the inpatient only list.
- We are finalizing the regulatory language at § 422.101(b)(6) largely 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 use of internal coverage criteria.

Based on the scope of these modifications and clarifications, we have slightly reorganized paragraph (b)(6) to add a new paragraph (b)(6)(i) to address when Medicare coverage criteria are not fully established and a new paragraph (b)(6)(ii) to address the

procedural and transparency requirements that apply when an MA organization adopts internal coverage criteria for basic benefits.

- We are finalizing the modifications at 422.101(c) as proposed; and
- We are finalizing the re-designation of *Exception for qualifying hospital stay* paragraph from 422.101(c)(1) to 422.101(c)(2) as proposed.

3. Appropriate Use of Prior Authorization

Except for emergency, urgently needed, and stabilization services (§ 422.113(a)), and out-of-network services covered by MA PPO plans, all services covered by MA coordinated care plans (including MSA network plans, which are coordinated care plans under 422.4(a)(iii)(D)), may be subject to prior authorization. In addition, MA PFFS and MA MSA plans are not permitted to use prior authorization policies or “prior notification” policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS or MSA plan in advance that services will be furnished. See § 422.4(a)(2)(i)(B) and (a)(3)(iv). Appropriate prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care. Therefore, we proposed to codify this at new § 422.138(a). Specifically, we proposed a new § 422.138(a) to provide that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only when the prior authorization processes are consistent with new § 422.138. We explained that, for purposes of this proposal, we used the term “processes” to include prior authorization policies and procedures that address any and all aspects of how prior authorization is used by an MA organization in a coordinated care plan.

We also proposed a new § 422.138(b)(1) through (3) to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits

are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate.

The standard “clinically appropriate” used for supplemental benefits is consistent with longstanding guidance in Chapter 4, section 30.2, of the MMCM (and also stated in the CY 2021 Final Rule [86 FR 5864]) that supplemental benefits must be medically necessary. Special Supplemental Benefits for the Chronically Ill (SSBCI) may be non-primarily health related so a standard based on medical necessity may not always be appropriate. Regular supplemental benefits must be medically necessary, but SSBCI need to have a reasonable expectation of improving or maintaining the health or overall function of the enrollee as required at § 422.102(f)(1)(ii) and discussed in CY 2020 Final Rule (85 FR 33796).

To illustrate how these proposed prior authorization policies would work, we discussed an example regarding coverage of acupuncture. Traditional Medicare currently has an NCD for Acupuncture for Chronic Lower Back Pain (cLBP).¹⁰⁵ This NCD authorizes acupuncture for Medicare patients with chronic Lower Back Pain (cLBP) for up to 12 visits in 90 days under the following circumstance: lasting 12 weeks or longer; nonspecific, in that it has no identifiable systemic cause (that is, not associated with metastatic, inflammatory, infectious disease, etc.); not associated with surgery; and not associated with pregnancy. Here, an MA plan may require prior authorization, before authorizing treatment as a covered basic benefit, to verify the patient’s pain is not the result of metastatic, inflammatory, infectious disease, as specified in the NCD. In this example, the plan is using the prior authorization to confirm a diagnosis specified in appropriate Medicare Part B coverage policy (in this case an NCD). Hence, prior authorization is used in this case to confirm the appropriate use of clinical standards in order to verify that Traditional Medicare coverage criteria are met, thus ensuring appropriate care, which is acceptable. CMS guidance (section 10.16 of Chapter 4 of the MMCM) currently states that if the plan approved the furnishing of a service through an advance determination of coverage, it may

⁹⁹<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373>

not deny coverage later on the basis of a lack of medical necessity. This means that when an enrollee or provider requests a pre-service determination and the plan approves this pre-service determination of coverage, the plan cannot later deny coverage or payment of this approval based on medical necessity. The only exception here would be medical necessity determinations for which the plan has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616. This has been longstanding sub-regulatory guidance (section 10.16 of Chapter 4) that we proposed to codify at § 422.138(c) to ensure the reliability of an MA organization's pre-service medical necessity determination. Therefore, we did not believe there was any additional impact on MA organizations caused by the proposal to codify this at proposed § 422.138(c) and we solicited stakeholder input on the reasonableness of this assumption. We also solicited comment whether combining all of our proposals on prior authorization (here and in section III.E.4 of this proposed rule discussing proposed changes to § 422.112(b)(8)) in proposed new § 422.138 would make applying and understanding these requirements clearer for the public and MA organizations.

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

We explained that a complete estimation of impact from proposed § 422.138(a) and (b) cannot be given because we would need detailed knowledge of proprietary plan information on the frequency and specific services for which prior authorization is done in each plan. (As noted

in a prior paragraph, proposed § 422.138(c) would only codify existing guidance to MA organizations.) We solicited comment from stakeholders on the impact and any additional information that would assist CMS in making an estimation. Some commenters stated that publicly posting a summary of evidence considered during the development of the criteria would require significant administrative effort. However, we did not receive specific comments on our estimates. The stakeholder comments of increased administrative burden are consistent with our statements in the proposed rule, that due to its complexity and many unknowns we cannot quantify the burden. We thank commenters for helping inform CMS's policy on the appropriate use of prior authorization and the requirements proposed at § 422.138. We summarize the comments and our responses follow.

Comment: Some commenters asserted that this proposed rule goes against sections 1852(c)(1)(G) and (c)(2)(B) of the Act, and the MA regulations at § 422.4(a)(1)(ii) which reference a MA plan's application of utilization management tools, like prior authorization and other "procedures used by the organization to control utilization of services and expenditures." Other commenters expressed concern that limiting prior authorization will lead to redundant, unnecessary, and inappropriate care.

Response: In the proposed rule, we acknowledged that utilization management tools, including prior authorization, are expressly referenced at section 1852(c)(1)(G) and (c)(2)(B) of the Act, as part of the disclosure obligations of MA organizations. We also stated that section 1852(g)(1)(A) of the Act states that MA organizations shall have a procedure for making determinations regarding whether an enrollee is entitled to receive a health care service and that such determinations must be made on a timely basis; that provision applies to both prior authorization determinations and to post-service decisions about coverage and payment. We proposed at § 422.138(a) 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 specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental

benefits is clinically appropriate. Thus, under our proposal and as finalized here, coordinated care plans are still permitted to use prior authorization as a utilization management tool. However, the use of prior authorization is subject to a number of new limitations, which we proposed to ensure that MA enrollees receive the Part A and Part B benefits to which they are entitled.

We proposed, and are finalizing, at § 422.138(b)(1) through (3) 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 determinations for the specific item or service, to ensure basic benefits are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate. With regards to supplemental benefits at § 422.138(b)(3), we state that MA organizations may use prior authorization to ensure that the furnishing of supplemental benefits is clinically appropriate. The regulation text uses the term “clinically appropriate” as opposed to “medically necessary” because while supplemental benefits must be medically necessary based on long standing guidance, certain supplemental benefits (that is, SSBCI) may be non-primarily health related. Thus, a standard based on medical necessity may not always be appropriate and using the term “clinically appropriate” is more inclusive of SSBCI that may or may not be primarily health related. As discussed in section III.E.2 of this rule, MA plans are still permitted to use additional coverage criteria when Traditional Medicare coverage criteria are not fully established to determine medical necessity as specified at § 422.101(b)(6). This codifies CMS’s existing expectations about the appropriate use of prior authorization and will provide important beneficiary protections that prior authorization processes are not used as a barrier to accessing medically necessary services.

Comment: Several commenters thanked CMS for acknowledging prior authorization as an acceptable and useful utilization management tool. Some commenters stated that prior authorization is necessary to manage care and prevent overutilization. Many of these

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). Other commenters suggested that CMS do more to limit the use of prior authorization, in general. For example, some commenters suggested CMS prohibit prior authorization for certain covered services. One commenter suggested CMS require MA plans to exempt providers participating in value-based models from prior authorization requirements. Another commenter requested that CMS require plans to post prior authorization criteria. Others suggested CMS implement greater oversight over prior authorization policies by requiring plans to submit their policies for CMS to review.

Response: We thank commenters for their comments and suggestions. As previously stated, CMS believes that prior authorization is an acceptable utilization management tool and authorized under the Medicare Advantage statutory provisions at section 1852(c) and (g)(1)(A) of the Act. However, we also believe that appropriate limitations on the use of these policies is necessary, so we are relying on our authority under section 1856(b) and 1857(e)(1) of the Act to adopt regulatory limitations designed to protect beneficiaries and ensure their access to medically necessary (or clinically appropriate in the case of certain supplemental benefits) covered benefits. Section 1852(a) of the Act requires MA plans to cover basic benefits and authorizes coverage of supplemental benefits. 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.

As to suggestions that CMS do more to prohibit the use of prior authorization, we do not believe that we have authority for a sweeping prohibition on *all* use of prior authorization. As to prior authorization requirements for specific services, we did not propose such broad limitations and believe that appropriate investigation and study of such a policy is warranted before it could

be adopted. Our proposals at § 422.138, which we are finalizing, address when and how MA plans may use prior authorization generally, except where prohibited by other rules (for example § 422.113). As previously discussed, the proposals at § 422.138(b)(1) through (3) were made to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate. We are also finalizing, 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.

In response to the suggestion that CMS require MA plans to exempt providers participating in value-based models from prior authorization requirements, we note that MA plans determine through negotiations with providers, the terms by which contracted health care providers are paid, and section 1854(a)(6)(B)(iii) of the Act and CMS regulations at §422.256(a)(2)(ii) prohibit CMS from requiring an organization to contract with a particular health care provider or to use a particular price structure for payment under such a contract. MA organizations have the flexibility to, but are not required to, incorporate value-based payment into their payment arrangements with providers, including the terms on which payments are made (for example, whether payment is available if prior authorization procedures have not been met). We consider participation in such payment arrangements to be a contractual matter between organizations and their contracted providers. Given these limitations, we do not believe CMS has the authority to adopt requirements for these contractual arrangements related to payment between MA organizations and contracted providers.

As to the comment requesting that CMS require MA plans to make prior authorization criteria publicly available, we do not believe adopting that requirement in this rule is necessary. Currently, § 422.111(b)(7) requires MA plans to disclose to enrollees any prior authorization rules and other review requirements that must be met in order to ensure payment for the services. In addition, § 422.202(b)(2) requires MA plans that use a network of providers to communicate practice guidelines and utilization management guidelines to providers and, as appropriate, to enrollees. Finally, the proposed rule “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program” (“Interoperability proposed rule”), which appeared in the Federal Register on December 13, 2022, includes proposals to revise the timelines on which MA organizations make prior authorization decisions, to require use of an application programming interface to identify the covered items and services for which prior authorization is required and related documentation requirements, and for MA organizations to report certain metrics regarding use of prior authorization.¹⁰⁶ Given that proposed rule is pending and the scope of current requirements for MA organizations, we will continue to monitor this area to determine if additional requirements are necessary.

Comment: Some commenters made recommendations regarding PA policies. Many of these 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. Some commenters requested that CMS establish standards for prior authorization requests in regards to

¹⁰⁶ The scope of that proposed rule is broader than summarized here.

both format and contents. Comments also suggested CMS establish standards regarding timelines for payers to respond to requests. Some commenters requested CMS require MA plans to publicly post prior authorization denial rates. Another commenter requested that CMS clarify whether prior authorization policies or procedures that dictate specific definitions of medical diagnoses is considered more restrictive than Traditional Medicare.

Response: We thank commenters for their suggestions. Existing regulations governing organization determinations, which include pre-service requests and prior authorization requests, address many of the issues raised by these commenters. Under the rules at § 422.572(a)(1) related to an expedited organization determination request for a medical item or service (which could include an item or service subject to prior authorization), the MA organization must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. For a standard organization determination request for a medical item or service (again, which could include an item or service subject to prior authorization), the rules at §422.568(b)(1) require the MA organization to notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. Under certain limited circumstances, an MA organization may extend these adjudication timeframes. Existing regulations also specify that when an MA organization denies an organization determination request for an item or service, the denial notice must use approved notice language in a readable and understandable form; state the specific reasons for the denial; inform the enrollee of his or her right to a reconsideration; describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and comply with any other notice requirements specified by CMS. See §§ 422.568(e) and

422.2267(e)(14) and (e)(16). We did not propose to change the timing requirements for organization determinations.

In addition to these existing requirements that apply to organization determinations that involve PA, CMS recently released the Interoperability proposed rule, , which includes proposals to expand access to health information and streamline certain procedures used for prior authorization. The Interoperability proposed rule includes proposals requiring implementation of a HL7® Fast Healthcare Interoperability Resources® (FHIR®) standard Application Programming Interface (API) for electronic access to certain information about pending and approved prior authorization requests, including the reason for a denial of a prior authorization request. In addition, there are proposals to require MA organizations to send decisions within 72 hours for expedited (that is, urgent) requests and seven calendar days for standard (that is, non-urgent) requests, and publicly report certain prior authorization metrics. We believe the proposals in the Interoperability proposed rule, if finalized, may address these commenters' recommendations. As we continue to monitor the needs of the program, we will consider these comments for future rulemaking. Finally, in response to whether prior authorization policies or procedures that dictate specific definitions of medical diagnoses is considered more restrictive than Traditional Medicare, we consider coverage policies that dictate specific definitions of medical diagnoses to be additional coverage criteria that are only authorized in accordance with § 422.101(b)(6) as finalized in this rule. We do not consider internal coverage criteria authorized under § 422.101(b)(6) to be more restrictive than Traditional Medicare when the requirements of that regulation are met. We believe that permitting the use of publicly accessible internal coverage criteria in these limited circumstances and contexts is necessary to promote transparent, and evidence-based clinical decisions by MA plans that are consistent with Traditional Medicare. Additionally, we are finalizing requirements at § 422.137 that require MA plans' UM committees to review all utilization management procedures used by the MA plan. Under these requirements, UM committees are required to ensure compliance with a number of MA rules,

including approving only utilization management policies and procedures that use or impose coverage criteria that comply with the requirements and coverage standards at § 422.101(b) and medical necessity criteria at § 422.101(c)(1).

Comment: Some commenters recommended that CMS clarify how we intend to enforce these new utilization management rules and the prior authorization requirements at new section § 422.138. One commenter suggested CMS establish third party reviews of prior authorization denials. Another commenter suggested that CMS develop a process for providers to report when MA organizations are not following these rules.

Response: We thank commenters. 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.

Comment: Some commenters requested that CMS revise the proposed good cause language at 422.138(c), stating that the proposed language is too broad and may be interpreted too broadly by plans. Some commenters suggested that CMS should not continue to allow coverage decisions to be reopened under the provisions at § 422.616. Another commenter suggested we revise § 422.138(c) to state that "...unless the MAO has evidence of good cause or fraud or similar fault" to prevent plans from abusing their authority here.

Response: We thank commenters for their comments and suggestions. Under the reopening rules at § 422.616(a), an organization determination made by an MA organization is one of the types of decisions that may be reopened and revised by the MA organization under the rules in 42 CFR part 405, subpart I. The application of the reopening rules at § 405.980(b) permit an MA organization to, among other reasons, reopen an organization determination within 1 year from the date of the initial determination for any reason; in addition, reopenings are

permitted within 4 years for good cause; at any time to where there is reliable evidence that the initial determination was procured by fraud or similar fault; and for other specified reasons. However, under the new provision we proposed at § 422.138(c), if an MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity. We proposed that if the MA organization has the authority to reopen on the basis of good cause or fraud or similar fault, it may do so consistent with the rules at § 422.616 which cross-reference the reopening rules at § 405.980. An MA organization may reopen an approved organization determination made through a prior authorization or pre-service determination within 4 years from the date of the organization determination for good cause as defined in § 405.986 or at any time if there exists reliable evidence as defined in § 405.902 that the organization determination was procured by fraud or similar fault as defined in § 405.902. Under new § 422.138(c), an MA organization is not permitted to reopen an organization determination on the basis of a lack of medical necessity for any of the other reasons described in § 405.980(b) (for example, for any reason within 1 year) if the approval was made pursuant to a prior authorization or pre-service organization determination process. In other words, an MA organization cannot subsequently reopen and revise such a decision on a later finding of a lack of medical necessity.

We believe that the commenter's suggested revision with respect to an MA organization having evidence of good cause or fraud or similar fault is redundant of what is already stated in the proposed regulation text and therefore, there is no need to revise the proposed regulation text exactly as suggested. However, for added clarity, we are finalizing the regulation text with modifications to make clear that the types of decisions contemplated in § 422.138(c) cannot be reopened except for good cause (as provided in § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. We further clarify in §

422.138(c) that the definitions of the terms “reliable evidence” and “similar fault” in § 405.902 of this chapter apply to this provision.

Comment: Some commenters supported CMS’ decision not to propose an amendment to § 422.136 and to, therefore, continue the current rules permitting step therapy for Part B drugs. Some commenters disagreed with CMS’ clarification that we did not authorize step therapy practices for Part A or Part B (non-drug) items or services as part of adopting the Part B drug step therapy regulation, and requested that CMS allow plans to apply step therapy to covered non-drug items and services. Other commenters expressed disappointment with CMS’ continued allowance of step therapy of Part B drugs and suggested that the continued allowance of step therapy for Part B drugs contradicts our proposal that MA plans not impose clinical criteria that are stricter than original Medicare. Some commenters requested that CMS more explicitly differentiate and explain the rules around step therapy for part B drugs and the step therapy for other non-drug Part A and B services, including DME. One commenter suggested that if CMS keeps step therapy for Part B drugs, we should require step therapy policies to be consistent with clinical guidelines and peer-reviewed supporting evidence, adopt certain Part D oversight policies, and require plans to disclose all step therapy policies to beneficiaries before enrollment. This commenter also requested that CMS prohibit plans from requiring an off-label Part B drug when an on-label drug is available.

Response: We thank commenters for expressing their comments and concerns. To clarify, the utilization management policies discussed in this rule do not limit MA organizations’ ability to use step therapy for Part B drugs when it is permitted under § 422.136. Under this final rule, certain utilization management processes, such as clinical treatment guidelines that require an item or service (that is not a Part B drug) to be furnished prior to receiving the requested item or service, would violate § 422.101(b) and (c), and thus, those utilization management processes are prohibited unless it is specified within the applicable NCD or LCD or Medicare statute or regulation when Traditional Medicare coverage criteria are fully established. When Traditional

Medicare coverage criteria are not fully established under § 422.101(b)(6)(i), this final rule permits utilization management policies as part of an internal coverage policy when the current evidence in widely used treatment guidelines or clinical literature expressly supports the use of such utilization management policies and the MA organization complies with policies at § 422.101(b)(6).

We believe there are a number of differences between step therapy for Part B drugs and guidelines for non-drug items and services that require another item or service be furnished prior to receiving the requested item or service. From a clinical standpoint, there tends to be more than one drug that has demonstrated success in treating a certain disease or condition, and also there are generic alternatives, which is somewhat different than other Part A and B services. Additionally, as discussed in the proposed rule, we believe that § 422.136 can put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing and potentially other out of pocket costs like premiums or costs for other benefits for MA enrollees. Reducing drug costs for beneficiaries remains a top concern of CMS. Additionally, as stated in the 2019 rule (84 FR 23856), MA plans have been and remain subject to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols for part B drugs cannot be stricter than an NCD or LCD with specified step therapy requirements. We believe that this interpretation of § 422.136 is consistent with this rule.

We acknowledge the concerns about the potential for step therapy programs for Part B drugs to deviate from existing clinical guidelines and peer-reviewed supporting evidence, but believe that § 422.136 adequately addresses this. Per § 422.136(b)(5), the P&T committee used by an MA plan to review and approve its Part B step therapy programs must base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as the P&T committee determines appropriate. Similarly, we believe existing

MA regulations adequately address disclosure of Part B step therapy policies to beneficiaries before enrollment. Per § 422.136(a)(2), MA organizations must have policies and procedures to educate and inform providers and enrollees of any Part B step therapy program used by the MA plan. Per § 422.111(b)(2), MA plans are required to disclose accurate information about benefits coverage, including applicable conditions and limitations on benefits coverage. MA plans that apply step therapy to Part B drugs must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) (when initially adopted or subsequently changed) and Evidence of Coverage (EOC) documents as part of their obligations under § 422.111 (84 FR 23854). As to the recommendation that CMS prohibit MA plans from requiring an off-label Part B drug when an on-label is available, we did not propose this additional limitation to the existing rule at §422.136(c). Step therapy for Part B drugs regulations at §422.136(c), state that an MA plan may include a drug supported only by an off-label indication in step therapy protocols only if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices. This type of substantive change in the regulation would require additional rulemaking; we may consider this issue as part of future policy development but currently believe that the reasons for adopting § 422.136(c) are sufficient (See 84 FR 23855 and 23863). Finally, in response to this recommendation that we adopt certain Part D oversight methods and apply them to Part B drug step therapy programs, we did not propose any changes to §422.136, thus we cannot finalize any of these recommendations in this rule. However, we will continue to monitor step therapy for Part B drug programs in MA and will consider these recommendations in any future rulemaking on this subject.

Comment: Some commenters expressed concerns about the OIG report. One commenter stated that the study only looked at 250 denials during a short time period and thus was not enough to indicate a complete understanding of the use and impact of prior authorization in Medicare Advantage. This commenter also asserted that a Kaiser Family Foundation (KFF)

study,¹⁰⁷ which used CMS data, presented different findings from the OIG report and thus does not demonstrate a problem with prior authorization in MA. Another commenter stated that the OIG report stated that among payment requests that were denied, 18 percent met Medicare coverage rules and MAO billing rules and that most of the payment denials in their sample were caused by human and system processing errors. This commenter asserted that the findings of the report were based on human error and that as the proposal does not focus on issues related to human error, it will have a limited impact. Another commenter stated that the OIG report highlighted a small percentage of denials and thus CMS proposals based on the report will have a limited impact.

Response: We thank commenters for their comments. The OIG report found that, among the prior authorization requests that MA organizations denied, 13 percent met Traditional Medicare coverage rules and that these services likely would have been approved for these beneficiaries under Traditional Medicare. This is an important finding and we believe that modification of MA coverage rules is appropriate and necessary to ensure MA enrollees have access to Part A and B services as required by the Medicare statute. In response to the comment that the OIG report was too limited to make any broad statements about MA, we note that a Health Affairs study¹⁰⁸ came to similar conclusions and similarly found that 15 percent of denials were tied to additional plan coverage criteria. Thus, we do not believe that the OIG's findings, as detailed in their report, are isolated. With respect to the differences between the KFF and OIG studies, we note that different data and methods were used. The KFF study analyzed data from the CMS 2021 Parts C and D Reporting Requirements Public Use File (PUF).¹⁰⁹ These data represent a contract-level reporting of, among other things, all Part C Organization Determinations and Reconsiderations for the 2021 coverage year. In other words, these data are

¹⁰⁷<https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/>

¹⁰⁸<https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01054>

¹⁰⁹ <https://www.cms.gov/files/zip/2021-parts-c-and-d-reporting-requirements-puf-not-incl-part-d-mtm-data.zip>

reported at a high level and only account for the number of appeals for each contract that are at a particular stage in the appeals process.¹¹⁰ As KFF noted in their presentation regarding the data limitations, “Medicare Advantage insurers are not required to indicate the reason a denial was issued in the reporting to CMS, such as whether the service was not deemed medically necessary, insufficient documentation was provided, or other requirements for coverage (such as trying a more basic service first) were not met.”¹¹¹ Thus, the CMS Reporting Requirements in the PUF do not account for more granular and detailed data that one would find in the full case record for each determination, including medical records and a medical necessity review conducted by a physician. By contrast, the OIG study did include “reviews by health care coding experts and the clinical reviews by physicians” from the case records studied.¹¹² Therefore, we believe the OIG study presents appropriate and sufficient evidence regarding the reasons for MA coverage denials and how they differ from coverage policy in Traditional Medicare.

In response to the assertion that the OIG report found that denials were based on human error, we note that the OIG report stated that among the payment requests that MAOs denied, 18 percent met Traditional Medicare coverage rules but that many of the payment denials in their sample were caused by human error during manual claims-processing reviews as well as system processing errors. This statement was made in regards to payment denials, not prior authorization requests. Prior authorization requests and payment requests are not the same as described by OIG in the report.¹¹³ Prior authorization requests are made to receive authorization for certain services before the MAO will provide coverage and payment where payment requests are made to receive reimbursement for services that the providers have already delivered to beneficiaries.¹¹⁴ The OIG report attributed human errors to payment requests specifically and we do not believe that is a basis to dismiss the totality of the OIG report findings and the concerns

¹¹⁰ <https://www.cms.gov/files/zip/2021-reporting-requirements-puf-tech-specs.zip>

¹¹¹ <https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/>

¹¹² <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>

¹¹³ <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>

¹¹⁴ <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>

raised about whether MA plans are furnishing, arranging for, and paying for Part A and B benefits for their enrollees. Finally, while we believe the OIG findings are significant, even if only a few MA organizations are using more restrictive criteria than used in Traditional Medicare, it is important to codify clearer rules on how coverage of Part A and B benefits must be covered and furnished in the MA program to ensure that utilization management tools are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans.

Comment: We 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 (87 FR 76238).

Response: We thank commenters for their suggestions. We believe 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, we do not believe that these requirements present such burden that they should be delayed. In regards to basic benefits, these requirements state that prior authorization may only be used to confirm diagnosis or other medical criteria that are the basis for coverage determinations for the specific item or service and to ensure that an item or service is medically necessary based on the new standards specified in § 422.101(c)(1). However, we believe providing further clarification to coordinated care plans on how Parts A and B benefits should be covered and furnished, including the appropriate role or prior authorization, is necessary. We believe it is important to implement these rules as soon as possible.

After careful consideration of all comments received, and for the reasons set forth in the final rule and in our responses to the related comments in sections III.E.3 of this final rule, we are adopting the new regulation at § 422.138 substantially as proposed with minor modifications

to clarify the text. Specifically, we are including that prior authorization processes include all policies and procedures used in prior authorization unless otherwise noted.

4. Continuity of Care

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

a. Stakeholder Feedback

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

b. Proposed Regulatory Changes

We believe the inclusion of additional continuity of care requirements at § 422.112 will help ensure coordinated care plans comply with and implement the statutory requirement (in section 1852 of the Act) that MA plans provide access to all medically necessary Traditional Medicare (that is, Part A and Part B) benefits that MA plans must cover. We proposed to add a

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

and following the prescribed or ordered course of treatment as outlined by the provider for a particular medical condition.

Additionally, we proposed at § 422.112(b)(8)(i)(B) that MA organizations offering coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. We explained that this includes enrollees who are new to an MA coordinated care plan having either been enrolled in a different MA plan with the same or different parent organization, or an enrollee in Traditional Medicare and joining an MA coordinated care plan, and beneficiaries new to Medicare and enrolling in an MA coordinated care plan.

We explained that under our proposal, during the initial 90 days of an enrollee's enrollment with an MA coordinated care plan, the MA coordinated care plan would not be permitted to subject any active course of treatment (as defined at the proposed § 422.112(b)(8)(ii)(B)) to additional prior authorization requirements, even if the service is furnished by an out-of-network provider. We explained how we expect any active course of treatment to be documented in the enrollee's medical records so that the enrollee, provider, and an MA plan can track an active course of treatment to avoid disputes over the scope of this proposed new requirement. We also explained that we intended that an active course of treatment covered by the proposal could include scheduled procedures regardless of whether there are specific visits or activities leading up to the procedure. We explained that under the proposal, if an enrollee has a procedure or surgery planned for January 31st at the time of enrollment in a new MA coordinated care plan effective January 1st, the new MA coordinated care plan would be required to cover the procedure without subjecting the procedure to prior authorization because it is within the 90-day timeframe. In this example, the planned surgery is a

part of an active course of treatment and thus would not be subjected to prior authorization by the MA coordinated care plan in which the beneficiary has newly enrolled under the proposed new § 422.112(b)(8)(B). In proposing to limit the way MA coordinated care plans use prior authorization for enrollees undergoing an active course of treatment, CMS seeks to ensure the availability and accessibility of basic benefits, which is consistent with section 1852 of the Act. CMS proposed to use a 90-day transition policy here because it mirrors Part D transition requirements and using the same period will ensure consistency across the MA and Part D programs. In addition, use of one consistent transition period will likely make it easier for new enrollees to understand their transition coverage. We solicited public comment on alternative timeframes for transition periods of ongoing treatment, including the clinical and economic justification for alternative proposals.

We outlined in the proposed rule CMS's authority to adopt the proposed new requirements for MA coordinated care plans. In addition, we noted and briefly explained how CMS implemented a similar policy regarding coverage during a transition period using CMS's authority to negotiate bids and with a similar explanation in the 2005 final rule (70 FR 4193); CMS has similar negotiation authority in the MA program. As explained in the December 2022 proposed rule, we believe it is appropriate to incorporate a similar beneficiary protection and coverage requirement in the MA program to address the transition for new enrollees.

Coordinated care plans are already required to ensure continuity of care and integration of services through arrangements with contracted providers at 422.112(b). Therefore, some MA organizations may already be exercising discretion to eliminate or waive prior authorization for enrollees undergoing an active course of treatment. However, prior to our proposed rule, CMS received anecdotal feedback from stakeholders that care transitions can be difficult for enrollees due to MA plan processes that require new coverage decisions when an enrollee transitions from one MA plan to another. We are not aware of the extent to which current MA plans are already ensuring continuity of care in the way our proposals would require, nor do we have a strong basis

upon which to quantify how often this type of transition occurs. Therefore, we solicited stakeholder input on both of these assumptions: that some MA plans are providing continuity of care, as defined in the proposed § 422.112(b)(8) today and the lack of available data by which to quantify it.

In summary, CMS proposed to add new continuity of care requirements to § 422.112(b)(8), to require that approval of a prior authorization be valid for the entire duration of the approved course of treatment, and that plans 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. We thank commenters for their input on CMS's proposed new MA continuity of care requirements.

We received the following comments on this proposal, and our response follows:

Comment: A 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. Supporters cited that MA plans often approve treatments in increments that may not be clinically supported or medically appropriate, which can be disruptive to care. Other commenters requested clarification as to whether a plan is required to approve the exact course of treatment included in the original coverage request, or whether an MA plan may approve a course of treatment that differs from what was ordered or prescribed by the provider. Several commenters requested that CMS give deference to providers when establishing a 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. Some commenters suggested that

there are situations where a prior authorization and plan of care should be revisited, and the course of treatment be revised, if the patient is not responding as expected. Some commenters suggested that CMS allow limitations on the duration of approvals to ensure there are opportunities to reassess medical necessity at reasonable intervals.

One commenter suggested that CMS modify the proposal to allow limits on the duration of the prior authorization that are consistent with guideline-suggested reassessment of disease, in cases where treatments may be indefinite (for example, in cases of chronic illnesses). Another commenter suggested that the definition of “active course of treatment” should be aligned with industry standards, specifically: (1) a course of treatment for a serious and complex condition, which includes a condition that is serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm, or a condition that is life threatening, potentially disabling, degenerative, or congenital, and requires specialized medical care over a prolonged period of time; (2) course of institutional or inpatient care; (3) scheduled nonelective surgery, including related postoperative care; (4) a course of treatment for a pregnancy; and (5) treatment for a terminal illness. Several commenters requested clarification as to whether there are a minimum number of days that constitute a “course of treatment.” Another commenter requested that CMS explicitly define “course of treatment” in reference to Traditional Medicare coverage and benefits benchmarks (for example, the mean Length of Stay for a given Medicare Severity Diagnosis Related Group). Finally, one commenter requested additional examples of what is and is not permissible to ensure treatments that are not medically necessary under Traditional Medicare guidelines are not required to be covered under this policy.

Response: CMS would like to thank all commenters for providing feedback on the proposed regulation. We 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, we 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 we 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, we believe this proposal is essential to minimize such delays and disruptions to care for MA enrollees.

We agree that clarification of the policy being finalized will help ensure the new regulation is implemented appropriately. Therefore, we are finalizing the revisions at § 422.112(8)(i)(A) with modifications from the proposed rule, to require that an 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, in accordance with applicable coverage criteria, the patient's medical history (for example, diagnoses, conditions, functional status), and the treating provider's recommendation. The determination of medical necessity to establish the duration of the approved course of treatment must be made consistent with § 422.101(c); any adverse determination on medical necessity, such as approval of a duration that is less than the requested duration for the course of treatment, must be reviewed in accordance with § 422.566(d) (and § 422.629(k) for an applicable integrated plan) before an MA plan may issue the determination. Further, the coverage policies governing these determinations must also comply with § 422.101(b). This will ensure that services delivered during the approved and previously authorized course of treatment remain consistent with Medicare coverage guidelines, are reasonable and necessary for the individual enrollee, and do not overly burden the provider with unnecessary and repeated prior authorization requests.

CMS is not requiring a minimum or maximum number of days for a course of treatment, since the necessary scope and duration of a course of treatment can vary widely from enrollee to enrollee and should be based upon the individual's needs and medical necessity. We believe flexibility is necessary to accommodate the varying complexities of a multitude of conditions for

which an enrollee may be receiving care, and recognize that many treatment courses last for varying periods of time and may require varying amounts of interventions that are unique to the individual being treated.

In response to comments expressing concern over the potential for treatment continuing indefinitely or recommending that treatments should be revisited at certain intervals, we believe that in many cases additional evaluation of the patient to ensure ongoing medical necessity and efficacy of treatment at certain intervals will be required or recommended and supported by the relevant coverage criteria, or by the patient's medical needs and the treating provider's recommendation. Under this final rule, all decisions for prior authorization, including those involving the authorization of treatment that lasts over a period of time, must be made in accordance with §422.138. This means that prior authorization may only be used to confirm the presence of a diagnosis or other medical criteria that are the basis for coverage or to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1). In order for an approval of a prior authorization request for a course of treatment to last indefinitely, it would have to be medically necessary and supported by the applicable coverage criteria, and the patient's medical condition and provider's recommendation. Therefore, we believe it would be uncommon that a MA organization would be required to approve a request for a treatment indefinitely. Additionally, where prior authorization is used by fee-for-service Medicare, the use of prior authorization by the MA organization on the same services must apply the fee-for-service Medicare standards based on §422.101(b)(2). Further, pursuant to §422.138(c), if the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity unless the MA organization has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616.

An MA plan may approve and authorize treatment for a different period of time than the treating provider's ordered course of treatment if the plan has determined that what was ordered or prescribed by the treating provider was not medically necessary or appropriate based on the enrollee's condition or diagnosis. The following example illustrates how this modification will work in practice:

The patient is a type 1 diabetic. The treating provider orders a course of treatment that consists of continuous subcutaneous insulin infusions for a period of 3 months. The treatment is subject to prior authorization. In order to apply prior authorization, the MA plan must follow the requirements of § 422.101(b), and apply any applicable coverage criteria for the service. The applicable NCD¹¹⁵ for infusion pumps requires that "continued coverage of the insulin pump would require that the patient be seen and evaluated by the treating physician at least every 3 months." Additionally, the patient's medical history does not indicate a need for more frequent evaluations. Here, it would be appropriate, under our proposal, for the MA plan to issue a prior authorization approval of the service for a period of 3 months because the NCD requires that the patient be evaluated at least every 3 months, and the treating provider ordered the course of treatment for 3 months. If the patient's medical history and the treating provider suggests possible complications in treatment, it may be appropriate for the MA plan to authorize approval of the service for a period of less than 3 months.

However, MA plans should not shorten authorization periods that are outlined in Traditional Medicare coverage criteria. The only instances where an MA plan may use a shorter (or different) periodicity or frequency of evaluation or other such review would be if the change were consistent with the relevant coverage criteria, and supported by the evidence in the patient's medical record, and by treatment guidelines or clinical literature that is widely available. This must be clearly documented and referenced by the MA plan in the prior authorization decision. Moreover, in all instances, we expect the MA plan and its contracted provider to coordinate care

¹¹⁵ <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=223&ncdver=2>

to ensure that the prior authorization is approved for a period that ensures that care is delivered for as long as is medically necessary and that minimizes disruptions in care for the enrollee. In other words, the MA plan may not establish blanket rules for the duration of an authorization associated with course of treatment decisions for purposes of convenience or simplicity; the duration of a prior authorization must be valid for as long as medically necessary to avoid disruptions in care and not in conflict with applicable coverage criteria.

Comment: A few commenters stated that care should not be based solely on a physician's order, but include other provider types when appropriate.

Response: As outlined in the preamble and proposed regulatory text, a course of treatment is a prescribed or ordered course of treatment for a specific individual with a specific condition that is outlined and decided upon ahead of time with the patient and the treating provider. 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 we proposed and are finalizing at § 422.112(b)(8)(ii)(A) includes courses of treatment ordered by non-physician health care providers.

Comment: 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. One commenter requested clarification that the continuity of care proposal include all new enrollees who are actively receiving physician-administered drugs that are covered under Medicare Part B, not just existing enrollees.

Response: As discussed in the preamble, 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. In order to provide additional guidance and clarity, we are finalizing § 422.112(b)(8)(i) with changes from the proposal to ensure that enrollees do not have disruptions in care due to additional prior authorization requirements; these changes from the proposal are in response to comments. We are finalizing § 422.112(b)(8)(i)(A) to require that an 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 applicable coverage criteria, the patient's medical history, and the treating provider's recommendation. In cases where a drug being used indefinitely is medically necessary and consistent with the relevant coverage criteria, the patient's medical history and the provider's recommendation, we encourage MA coordinated care plans to work with the provider to assess continued efficacy and medical necessity as is reasonable; this type of coordination is consistent with how § 422.112(b) requires MA organizations offering these plans to have arrangements (which meet the minimum requirements in paragraphs (b)(1) through (b)(8)) to ensure continuity of care and integration of services.

In response to the comments, we clarify that the transition period required by § 422.112(b)(8)(i)(B), as proposed and finalized, applies, beginning with coverage January 1, 2024, to all new enrollees who are undergoing an active course of treatment—including where the active course of treatment is taking a physician-administered drug covered under Part B. An MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

Comment: Several commenters requested that CMS clarify whether a course of treatment includes inpatient services, skilled nursing facilities (SNF), home health care (HHC), and other post-acute care. One commenter suggested that the regulatory text be amended at 422.112(b)(8)(ii)(B) so that continuity of care applies where “an active course of treatment includes transfer of a patient to another inpatient provider.”

Response: We clarify here that an active course of treatment may include situations when a patient is transferred from an acute inpatient setting to a SNF, HHC, and care in other post-acute care settings. However, this new regulation does not change or affect how section 1853(g) of the Act and § 422.318 assign financial responsibility for inpatient services from one of the facilities listed in § 422.318(a) (a “subsection (d) hospital” as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the Act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)) that begin before, and carry over to, the effective date of enrollment in a new MA plan. Under section 1853(g) and § 422.318, when MA plan coverage begins during an inpatient stay, the previous MA plan or Traditional Medicare if the enrollee is joining an MA plan from Traditional Medicare is responsible for payment. CMS reminds commenters that all other relevant Traditional Medicare regulations must also be followed, including those regarding inpatient admissions and terminations.

Comment: One commenter requested that, in addition to ensuring that prior authorizations remain active for a patient’s entire course of treatment, CMS adopt language to ensure that surgical or other procedures/services performed incident to a procedure that has received prior approval may not be denied for failure to obtain prior approval.

Response: We thank the commenter for the suggestion, but decline to explicitly prohibit an MA plans from denying coverage of a service provided incident to a course of treatment but not expressly included in the approved course of treatment, because of a failure to obtain prior approval. In the case where a service is provided incident to a procedure, it may be appropriate for the MA plan to conduct a concurrent or retrospective review to determine medical necessity of the incidental procedure. Our proposal was about prior authorization, and we are not adding requirements or limitations on concurrent or retrospective reviews in the final rule.

Comment: 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. Some commenters were concerned that the proposal could potentially require an MA plan to be held responsible for the long-term cost of care provided by an out-of-network provider, or for a treatment that may not meet the standards of their internal coverage criteria, where such criteria are consistent with CMS policies, but utilization management policies may vary. A few commenters stated that the goal of this proposal is already achieved through existing plan specific practices where prior authorization approvals are continued, allowing a provider to demonstrate to the new MA plan that the prior approval already took place and was granted by the previous plan. Several commenters suggested that the transition requirement will put patients at risk of receiving care that is no longer medically necessary. Other commenters expressed concern that requiring a blanket transition period on all services creates a significant burden to MA plans from a technical and procedural perspective, as well as from a claims adjudication perspective. Other commenters requested additional guidance regarding how CMS expects MA plans to implement this requirement. One commenter requested clarification on whether the continuity of care provisions proposed in this rule are satisfied by a plan approving continuation of services or treatment for 90 days to ensure continuity of care if a new member is receiving care from a non-contracted provider when their enrollment in the plan becomes effective, while working with the enrollee to find in-network providers as needed. Finally, a few commenters expressed concern that the transition period may be used as a tactic to delay care by either the plan or by providers aiming to receive a different reimbursement rate—that is, postpone care until the new plan takes over and is, therefore, responsible for paying for services.

Response: As outlined in the preamble and proposed regulatory text, 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. See also our discussion in the proposed rule at 87 FR 79504 through 79505 about active courses of treatment. As proposed and finalized at § 422.112(b)(8)(ii)(B), an active course of treatment is one in which a patient is actively seeing the provider and following the 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.

For example, if an enrollee is undergoing an active course of treatment that is 60 days in duration, and the enrollee transfers to a new MA plan 30 days into that course of treatment, then the MA plan may not subject that course of treatment to a prior authorization requirement for the next 30 days. After that time, the course of treatment is complete and any future treatments may be subject to prior authorization as appropriate. This does not mean that an MA plan may not apply prior authorization to *any* services in the first 90-days of enrollment, but only that active courses of treatment may not be subjected to prior authorization within a 90-day timeframe. We expect that MA plans would use this period to coordinate with the treating provider, or find (or help the enrollee find) a new provider as needed, to satisfy any utilization management policies that may apply at the completion of the 90 days to ensure that there is not a disruption in treatment for the patient. Further, § 422.112(b)(8)(i)(B), as proposed and finalized, does not prohibit concurrent or retrospective review of an active course of treatment. A plan may conduct concurrent reviews as necessary, as long the review does not interfere with an active course of treatment. The MA plan cannot deny coverage of such active courses of treatment on the basis that the active course of treatment did not receive prior authorization (or was furnished by an

out-of-network provider) but may review the services furnished during that active course of treatment against permissible coverage criteria when determining payment.

In response to the comments that the proposal is redundant due to many MA plans already utilizing internal practices for continuing prior authorization approvals, or allowing for a continuation of services, CMS continues to believe that codification and standardization are necessary. While some plans may have internal processes in place to allow for a continuation of services, we are not aware that these practices have been universally adopted and consistently applied by all plans. If plans are already allowing for these types of transitions, then existing practices may already comply with what is proposed.

Finally, since the provision only applies to active courses of treatment, CMS does not foresee the possibility that medically necessary services could or would be delayed solely for the purpose of requiring another plan to pay for that service. If treatment is medically necessary at the time it is ordered, it would be highly inappropriate for that treatment to be delayed solely for the purposes of shifting payment responsibility. While, as stated in the preamble, we have interpreted active course of treatment to include scheduled procedures, regardless of whether there are specific visits or activities leading up to the procedure, it would seem unrealistic for a plan or a provider to know in advance that an enrollee is anticipating leaving an MA organization to join another plan, anticipate the enrollee's departure, and decide to delay a course of treatment so as to pass those costs onto the new plan. Such an action would be a violation of our rules to provide all necessary and appropriate care to enrollees. Further, the new rule requires that the course of treatment must be *active* at the time the patient's enrollment in the new MA plans becomes effective, so the 90-day transition period would not be implicated if care had not begun at the time of enrollment.

Comment: Several commenters requested clarification as to whether after 90 days a plan may apply out-of-network limits, conduct a new review, and issue a new decision. Some commenters stated that plans should be required to extend coverage, on a case-by-case basis, for

patients receiving care after the 90-day period expires and should not impose additional prior authorization requirements (for example, in cases of life sustaining care). Several commenters requested that CMS require plans to notify new enrollees about the transition period, and any changes in benefits.

Response: As outlined in the preamble and the proposed regulation, the minimum 90-day transition period prohibits an MA plan from disrupting or requiring reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days. The transition period is intended to provide enrollees with an assurance of continued care when changing plans, and to minimize disruptions when moving to a new plan that may have differing benefits. After the transition period, a plan may reassess medical necessity and apply out-of-network limits in accordance with plan benefits and other relevant requirements as appropriate. We clarify that § 422.112(b)(8)(i)(B) does not mandate that the new MA plan cover the active course of treatment regardless of other applicable coverage rules (for example, § 422.101(b) or plan coverage policies for supplemental benefits). The MA plan cannot deny coverage of such active courses of treatment on the basis that the active course of treatment did not receive prior authorization or was furnished by an out-of-network provider, but may apply permissible coverage criteria.

At this time, CMS is not adding a requirement for notification to enrollees because pursuant to §422.111(b)(7), MA organizations are required to disclose information to enrollees regarding prior authorization and review rules. This includes the continuity of care provisions outlined in this proposal. CMS urges plans and their contracted providers to work with these transitioning enrollees and their previous treating providers, even if those previous treating providers are not contracted with the receiving plan, during the transition period to ensure that care is continued in the least disruptive manner possible. CMS also notes that the 90-day transition period is a minimum requirement. Therefore, if an active course of treatment is approved by the previous treating provider or plan to last longer than the 90-day minimum, an

MA plan that is newly covering the enrollee may elect to permit the enrollee to finish the course of treatment, which lasts beyond 90 days, before imposing additional prior authorization(s). CMS will consider adding an additional notice requirement during future policymaking.

Comment: One commenter requested CMS require plans to notify enrollees that they should check whether an enrollee's ongoing prescriptions would be covered with the same level of cost-sharing after the initial 90 days of enrollment and, if so, whether any utilization management protocols will apply to these medications.

Response: As outlined in the previous comment response, CMS is not requiring any additional notification requirements at this time. If an on-going Part B prescription is an active course of treatment under the definition at § 422.112(b)(8), then the MA plan may not subject the treatment to additional prior authorization for the first 90 days of enrollment. After the 90-days, prior authorization may be applied in accordance with the prior authorization provisions in this rule. Cost-sharing levels will be based on the specific plan, and are not within the scope of this rule.

Comment: One commenter requested that the 90-day transition period apply when an enrollee who is currently undergoing treatment switches to a new MA plan, switches from a traditional Medicare plan to an MA plan, or is new to Medicare. Another commenter requested clarification on whether MA plans must provide the proposed transition period for any ongoing course of treatment that had been covered under a traditional Medicare coverage policy, regardless of whether there was a prior authorization requirement for that course of treatment in traditional Medicare.

Response: As stated in the regulatory text at § 422.112(b)(8)(i)(B), the transition requirement applies to "...enrollees new to a plan and enrollees new to Medicare..." who are currently undergoing an active course of treatment. This means the requirement applies for any active course of treatment when an enrollee switches to a new MA plan, switches from a traditional Medicare plan to an MA plan, or is new to Medicare. Further, the plan must provide

the transition period, wherein an active course of treatment may not be subjected to prior authorization, for all new enrollees who are undergoing an active course of treatment, regardless of whether the treatment was subject to a prior authorization by a previous plan. As a reminder, “course of treatment” and “active course of treatment” are defined at § 422.112(b)(8)(ii).

Comment: CMS solicited public comment on alternative timeframes for transition periods of ongoing treatment, including the clinical and economic justification for alternative proposals. Several commenters stated that a 30-day policy would provide a more reasonable timeframe to review a previously approved and ongoing plan of treatment, but longer periods could be permitted if medically necessary. One commenter requested that CMS modify the proposal at § 422.112(b)(8)(i)(B) to require MA plans to provide continued coverage for an active course of treatment authorized by the member’s prior plan for the remainder of the authorized period or units of service. At least one plan provided feedback that they already have 90-day continuation of care policy in place, and other plans indicated they have similar policies for continuing approvals for ongoing treatments. A few commenters commented that the Part D transition period and the proposed transition period are not analogous. Commenters stated that the costs of Part D drugs are often lower than the costs for medical services, and that differing clinical opinions can lead to differing courses of treatment based on the resources available to the MA plan. Some commenters stated that a 90-day timeframe would be both financially and administratively burdensome to MA plans.

Response: While some commenters indicated that a 90-day timeframe could be financially and administratively burdensome to some MA plans, CMS did not receive specific details to demonstrate that the burden to MA plans outweighs the value of ensuring continuity of care for enrollees. Further, we believe that 90 days is an appropriate amount of time to minimize disruptions in treatment, and to allow plans and providers to ensure continuity and coordination of care. As outlined in the proposed rule, we believe a 90-day transition policy is beneficial because it mirrors Part D transition requirements and using the same period will ensure

consistency across the MA and Part D programs. We understand that there are differences in the costs associated with Part D drugs and with certain medical procedures, however the Part D transition period mandates coverage, whereas § 422.112(b)(8), as previously explained, only prohibits the application of prior authorization requirements for the pre-existing active course of treatment.

Regarding the comments that different plans may offer differing courses of treatment, we do not find this a compelling reason to alter the transition time frame. Since this requirement only affects active courses of treatment, altering the course of treatment when the enrollee enrolls in a new MA plans is precisely the type of disruption this requirement aims to eliminate.

Comment: One commenter requested that CMS clarify that the 90-day transition period applies only to basic benefits and not to supplemental benefits.

Response: As proposed and finalized, the new rules at § 422.112(b)(8)(i) apply to basic benefits only. Per this new regulation, MA coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization for basic benefits that include the new restrictions on use of prior authorization for a course of treatment and an active course of treatment for a new enrollee. An MA organization may elect to extend this policy to supplemental benefits. We note that MA PFFS plans may not use prior authorization processes at all and that MA PPO plans may not use prior authorization processes for out of network services.

Comment: One commenter requested that plans be permitted to conduct their own prior authorization or utilization management review for treatments extending beyond the 90-day transition period. The commenter stated that plans should also be permitted to support an enrollee's transition to an in-network provider at the end of the transition period.

Response: The 90-day period prohibits prior authorization on active courses of treatment, including when the service is furnished by an out-of-network provider. Once the 90 days has elapsed, the plan is permitted to impose prior authorization requirements on the service. After

the 90-day transition period is complete (or the course of treatment has concluded, whichever comes first), the new plan may direct care through in-network providers and apply prior authorization.

Comment: CMS solicited stakeholder input as to whether some MA plans are already providing continuity of care consistent with what CMS proposed at § 422.112(b)(8), as well as any additional information that may be useful for CMS to quantify the burden associated with this proposal. Several stakeholders indicated that some MA plans provide some similar level of continuity care today. Commenters did not provide additional information regarding quantifying the burden associated with implementing the proposal.

Response: CMS thanks the commenters for their feedback.

Comment: 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. Other commenters suggested an effective date of 2026 would align with CMS' proposed 2026 effective date for its Advancing Interoperability and Improving Prior Authorization proposed rule that also impacts MA plans.

Response: CMS appreciates 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 we continue to receive feedback from stakeholders that medically necessary care is being disrupted by unnecessary prior authorization, we believe that it is important to implement this requirement as soon as possible. The new requirements at § 422.112(b)(8) are applicable beginning on and after January 1, 2024, for MA coordinated care plans.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, we are finalizing § 422.112(b)(8) largely as proposed but with modifications. We are finalizing § 422.112(b)(8)(i)(A) 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.

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

We proposed procedural improvements to ensure that utilization management policies are reviewed on a timely basis and have the benefit of provider input. Any authority for MA organizations to use utilization management policies with regard to basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA provisions. In light of the feedback we received and our concern that enrollees may be facing unreasonable barriers to needed care, we proposed to require MA organizations to establish a Utilization Management (UM) committee to operate similar to a Pharmacy and Therapeutics, or P&T, committee. We proposed to add requirements pertaining to this UM committee in a new regulation at § 422.137.

a. Review and Approval of UM Policies

At § 422.137(a), we proposed that an MA organization that uses UM policies, such as prior authorization, must establish an UM committee that is led by an MA plan's medical director (described in § 422.562(a)(4)). Section 422.562(a)(4) requires every MA organization to employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity and establishes that the medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We also proposed, at § 422.137(b), that an MA plan may not use any UM policies for basic or supplemental benefits on or after January 1, 2024, unless those policies and

procedures have been reviewed and approved by the UM committee. This proposal would ensure that plan policies and procedures meet the standards set forth in this final rule beginning with the contract year after the finalization of this proposed rule. We explained that we anticipate that there will be sufficient time between our issuance of a final rule and January 1, 2024, for each MA organization to engage in the necessary administrative activity to establish the UM committee and have its existing UM policies reviewed and, if they meet the standards in this proposed regulation, approved for use.

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

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

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

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

Currently, § 422.202(b) requires MA organizations to establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures; that formal mechanism for consultation must ensure that

certain standards are met. Specifically, § 422.202(b)(1)(i) through (iv) require that MA plan practice guidelines and UM guidelines must: (i) be based on reasonable medical evidence or a consensus of health care professionals in the particular field; (ii) consider the needs of the enrolled population; (iii) be developed in consultation with contracting physicians; and (iv) be reviewed and updated periodically. We proposed to modify § 422.202(b)(1)(i) to align it with our standard for creating internal coverage criteria. We therefore proposed to replace the requirement that practice and UM guidelines be based on reasonable medical evidence or a consensus of health care professionals in the particular field with a requirement that UM guidelines be based on current widely used treatment guidelines or clinical literature. This is consistent with the proposed coverage criteria requirements at § 422.101(b)(6), which are discussed in detail in section III.E.2. of this final rule.

We solicited comment on whether we should also require the UM committee to ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure that the MA organization, as required by § 422.202(b)(2), communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees; and whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies. We also proposed at § 422.137(d)(3) that the committee must revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines. We explained that mandating annual review of utilization management policies using these standards will help ensure that medically necessary services are accessible to all enrollees. Because prior authorization and referral or gatekeeper policies are included in UM policies and procedures,

these proposed requirements would apply as well to those policies and CMS expects MA organizations to update their UM policies after the UM committee approves or revises them.

As this final rule as a whole makes clear, ensuring that enrollees have access to and are furnished covered benefits is a priority. We solicited comment on whether to require the UM Committee to review all internal coverage criteria used by the MA plan. We also solicited comment on the extent to which the proposed regulation text sufficiently and clearly establishes the standards and requirements discussed here.

b. Utilization Management Committee Membership

At § 422.137(c)(1) through (4), we proposed 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 of conditions are adequately considered in the development of the MA plan's utilization management policies. These composition requirements are in addition to the proposal that the medical director, required for each MA plan under § 422.562(a)(4), lead the UM committee.

We solicited comment on recommendations for other types of providers, practitioners, or other health care professionals that should also be included on the UM committee and whether additional standards for composition of the UM committee are necessary with regard to expertise, freedom from conflicts of interest, or representation by an enrollee representative. We also solicited comment on whether we should include a requirement, that when the proposed UM committee reviews UM policies applicable to an item or service, that the review must be conducted with the participation of at least one UM committee member who has expertise in the use of, or medical need for that specific item or service.

c. Documentation of Determination Process

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

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

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

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

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

In summary, CMS proposed to require at § 422.137 that all MA organizations that use utilization management policies, such as prior authorization, must establish an UM committee that is led by an MA plan's medical director. Further, we proposed 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. We thank all commenters for their input on CMS's proposed new requirements. We received the following comments on this proposal, and our response follows:

Comment: 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. One commenter requested clarification as to the number of UM committees required, and whether committees are required per plan or per MA organization. One commenter stated that if an MA organization is permitted to use one committee for multiple MA plans, then the final rule should contain specific

requirements related to UM committee membership composition and input from external stakeholders.

Response: CMS appreciates the comments and input regarding this issue. We will allow MA organizations the discretion regarding whether the UM committee is best served at the organization or plan level, and we 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. If at any time it appears that MA organizations are not fulfilling regulatory requirements regarding the UM committee, then we may engage in further rulemaking regarding whether the UM committee must operate at the organization or the plan level.

As proposed, § 422.137(a) requires the UM committee to be led by a plan's medical director. In light of our decision to interpret and implement § 422.137 by permitting one UM committee to serve multiple MA plans offered by the same MA organization, one plan's medical director may fulfill this role for the MA organization.

Comment: 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. Some commenters also requested that CMS require MA plans to be accredited. One commenter questioned if it would be permissible to incorporate an UM committee with a credential committee, since both are provider specific and include applicable attendees. CMS also solicited

comment on whether plans should be permitted to use existing P&T Committee to serve as the UM committee. Commenters were generally supportive, but requested that MA plans retain discretion when deciding whether and how to adapt committees to serve multiple functions.

Response: CMS thanks all commenters for providing input regarding the proposed regulations. We 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 we do not believe requiring MA plans to be accredited is necessary or within the scope of this rule, we 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. We emphasize, however, that this flexibility does not change or lessen the composition requirements or duties of the UM committee; all of the requirements in § 422.137 finalized in this rule must be met for the UM committee and if the MA organization is also using that committee to satisfy the requirements of §§ 422.136 and 423.120 for a P&T committee, those requirements must be met as well.

Comment: 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. One commenter expressed concern that the requirement to review all policies by January 1, 2024, will result in “good” policies being discarded and cause confusion among providers and enrollees. The commenter suggested that policies should remain active during the review period and be reviewed in accordance with the transparent processes. Some commenters requested CMS delay the implementation date to 2026 to better align with the requirements in the Interoperability rule (87 FR 76238).

Response: CMS declines these suggestions. We are finalizing the proposal that beginning on and after January 1, 2024, MA plans may not use any policies that have not been reviewed or approved by the UM committee established for the plan. Any policy that has not been reviewed or approved by the deadline may not be used by the MA plan until it has been reviewed (and revised as necessary) and approved by the UM committee. 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), we believe there is sufficient time for MA organizations and MA plans to form UM committees and review UM policies within the proposed timeframe. Further, § 422.111(d) permits MA plans to change plan rules (including prior authorization and utilization management policies) during the plan year. To make mid-year changes, MA plans must provide a minimum 30-day notice to enrollees, submit the notice to CMS for review, and comply with the model notice specified at § 422.2267(e)(9). This means that if an MA plan's UM committee reviews policies and approves them on a rolling basis, the reviewed and approved policies can be issued during the plan year even if all the reviews are not complete before January 1, 2024.

Comment: CMS solicited comment regarding whether to require UM committees to ensure that the UM policies and procedures are developed in consultation with contracted providers. Numerous commenters supported this requirement. One commenter requested that if UM policies are required to be developed in consultation with contracted providers, the regulation also include a provision that acknowledges MA organizations may not receive responses from providers, therefore an attempt to engage will meet the requirement.

Response: CMS appreciates the feedback received and will take it into consideration for future rulemaking. We encourage MA plans to work with contracted providers while developing UM policies and procedures, and remind plans that under § 422.202(b)(2), MA organizations

must communicate information about practice guidelines and UM policies to providers and, when appropriate, to enrollees.

Comment: 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. One commenter suggested amending § 422.202(b)(1)(iii) to state MA plan practice guidelines and UM guidelines “must be developed in consultation with contracting physicians or practitioners.”

Response: CMS thanks all commenters for their input. 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. We believe the request to amend § 422.202(b)(1)(iii) is outside the scope of this proposal and that the existing requirements on this issue and on incorporating adequate information about clinical practices are sufficient in light of other amendments in this final rule regarding coverage criteria, medical necessity determinations and use of utilization management policies.

Comment: Many commenters were supportive of a requirement for the UM committee to have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies. A few commenters expressed concern that this requirement could be administratively burdensome on the UM committee. One commenter suggested that the UM committee be required to engage in internal oversight of plan operations, including randomized audits, assessment of rates of and reasons for denial, and duration of time between denials issued. Another commenter suggested that the UM committee review appealed cases and caseloads to determine whether MA plan operations are complying with the relevant requirements so as to not unduly burden provider, MA plan, and the Office of Medicare Hearings and Appeal resources through unnecessary appeals. Another commenter suggested the UM committee conduct

retroactive review of organization determinations throughout the year and assess whether the approved practice guidelines and UM policies are being followed. Another commenter suggested a regulatory revision that would require the UM committee to “...undertake appropriate diligence and oversight to ensure that the MA plan’s coverage or medical necessity decisions under any UM policy are consistent with such policy and any revisions to it made by the UM committee.” One commenter suggested revising proposed § 422.137(d)(1)(i) to read as follows: “The services to which the utilization management applies, including the total number of cases or requests reviewed under a specific policy being reviewed, the number of approvals for cases or requests under such policy, the number of denials for cases or requests under such policy, and a review of a subset of patient determinations whose cases were denied under such policy, based on the most recent 6 months of data and information available.”

Response: CMS appreciates the feedback received and will take it into consideration for future rulemaking. Because MA plans are required to follow the relevant coverage criteria and other requirements pertaining to the use of utilization management adopted in this rule, CMS does not believe it is necessary to require the UM committee to have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies at this time. CMS encourages MA plans to involve the UM committee in such decisions to the extent practicable.

Comment: Several commenters expressed concern over how proposed § 422.137 will be enforced, as well as who will be responsible for enforcement. One commenter suggested that CMS require regular submission of committee determinations and associated documentation to CMS to allow for CMS audit and oversight. Another commenter suggested CMS conduct ongoing audits throughout the year to ensure decisions made by the MA plan are in line with the final approved guidance from the UM committee

Response: CMS currently monitors MA plan compliance through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations

alert CMS to any issues with access to care and plan compliance, and CMS may require MA plans to address these matters if they arise. We intend to use these oversight operations to ensure MA organizations comply with the final rule. Further, § 422.137(d)(5) requires the UM committee to document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. CMS may request and review such documentation as part of its monitoring and oversight.

Comment: CMS solicited comment regarding whether the proposed regulation text sufficiently and clearly establishes the standards and requirements discussed in the proposed rule. A few commenters requested that the regulations should establish a clear process to ensure transparency with stakeholders, including posting detailed meeting minutes and policies to websites, making the composition of the committee available to the public, and mandating regularly scheduled meetings. Additionally, several commenters requested that there be an opportunity for the public to provide input and comment on UM policies and procedures to ensure transparency and clinician engagement. Several commenters suggested that the UM committee be required to meet and/or review and revise UM policies and procedures more frequently than annually. One commenter suggested that the committee be required to revise UM policies and procedures “at any time.” Another commenter stated that policies should remain active during the review period. A few commenters suggested that the UM committee participate in the development of UM policies and procedures. One commenter suggested that the UM committee conduct quarterly or bi-annual reviews of UM policies and programs and their effects on organizational determinations, patient access and clinical validity. One commenter suggested the committee annually update its list of novel therapies and make available to the public the clinical literature and research linked to treatment criteria. A few commenters suggested that CMS revise the regulatory text to require that the clinical members of the UM committee be “appropriately licensed and skilled physicians or other qualified health care providers” opposed to “practicing physicians.”

Response: CMS appreciates the feedback received. While § 422.137, as proposed and finalized, requires that prior authorization policies and procedures be reviewed and approved at least annually by the UM committee, the regulation does not prescribe the frequency with which the committee is required to meet or prohibit UM committees from reviewing policies more frequently to address changes in clinical guidelines, coverage criteria, or similar considerations. CMS believes there is value in giving flexibility to UM committees to review UM policies more frequently than once a year, and acknowledges that more frequent meetings are likely warranted. The minimum requirement is that the relevant policies be reviewed and approved annually. We intend to take the feedback from commenters into consideration for future policy development.

Comment: Several commenters addressed the documentation requirements for the UM committee, including 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. Several commenters requested that the regulation establish a clear process to ensure transparency with stakeholders, including posting detailed meeting minutes and policies to websites, and making the composition of the committee available to the public. Commenters also stated that MA plans do not regularly release minutes from P&T meetings in a timely manner, and that when these minutes are released, they do not contain detailed information. Several commenters requested that CMS require UM criteria documents to be publicly posted. One commenter requested that such documents should not be required to contain a detailed summary of each piece of evidence considered or rationale for adopting the policy due to potentially containing proprietary information.

Response: CMS thanks commenters for their feedback. As outlined in the preamble, MA organizations must make relevant documentation available to CMS upon request. The documentation should provide CMS with an understanding of the UM committee's rationale for their decision, and may include, but is not limited to, information such as meeting minutes outlining issues discussed and any relevant supporting documentation. Supporting

documentation could include relevant coverage criteria that comply with § 422.101 that was relied on in the decision-making process. As to P&T committee documentation, § 422.136(b)(9) requires that MA plan P&T committees document their decisions regarding the development and revision of step therapy programs and to make that documentation available to CMS upon request; we appreciate the commenter's concerns that information is not always made available publicly or with regularity. Should an MA organization use a P&T committee to fulfill the requirement of the UM committee, that committee must meet all of the requirements outlined in § 422.137, which includes the requirement to make documentation available to CMS upon request. We will consider these comments for future rulemaking.

Comment: Many commenters supported implementing a requirement for the UM committee to review all internal coverage criteria used by the MA plan. Some commenters expressed opposition to the proposal and to any requirement that the UM committee review all internal coverage criteria used by the MA plans, citing that many MA plans have separate committees tasked with reviewing UM policies and coverage criteria. One commenter requested clarification as to which policies and procedures the UM committee is required to review.

Response: Per § 422.137(d), as proposed and finalized, the UM committee is responsible for reviewing UM policies and procedures used by the MA plan(s) served by the committee. The UM Committee must approve only UM policies and procedures that use and are consistent with the relevant coverage criteria that comply with § 422.101 and other applicable regulations. In addition, the UM committee is charged with making any needed revisions to such policies and procedures to ensure that the standards in § 422.137(d)(1) and (2) are met. Such revisions should be made expeditiously when inconsistencies are identified.

Comment: 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. A few commenters suggested that physician committee members be members of the American College of Physician Advisors, board certified through board of medical specialists or American Board of Medical Specialties. Many commenters supported the inclusion of an enrollee representative. One commenter suggested that more than one provider should be free from conflict, and another commenter suggested that members should have to annually attest to being free from conflict.

Response: CMS appreciates the feedback received and will take it into consideration for future rulemaking. We believe the proposed composition requirements are sufficient because they represent a diverse group of medical professionals, with the relevant expertise necessary to fulfil 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. Further, § 422.137(c)(4) requires that the committee include members representing various clinical specialties to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies. We believe this requirement will ensure that a diverse range of specialists are represented. Section 422.137(c)(2) requires that *at least* one physician be independent from the MA plan and free of conflict. We believe this is sufficient because the other requirements for the UM committee clearly establish the parameters in which the UM committee must review and approve UM policies and procedures, and therefore additional independent committee members are not necessary to ensure appropriate decisions are being made. We encourage plans to include an enrollee representative on the UM committee as we believe enrollee representation will add a valuable perspective to the review process.

Comment: 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. One commenter suggested that the UM committee be required to seek outside assistance when the committee does not have expertise in a certain area.

Response: CMS appreciates the feedback received and will take it into consideration as part of future policy development. We believe 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. Therefore, we are not adopting an additional requirement for the UM committee to have specialty focused subcommittees and workgroups.

We are not finalizing an additional requirement for participation or involvement by a specific specialty provider or health care provider with expertise related to each individual UM policy. We believe that is unnecessary because, as previously noted, all utilization management policies must comply with § 422.101(b), which requires any permissible internal coverage criteria must be based on current evidence in widely used treatment guidelines or clinical literature. Current widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Therefore, we do not believe it is necessary for additional involvement of specialists when reviewing utilization management policies and procedures. CMS encourages plans to include relevant experts when feasible during the review process.

Comment: One commenter requested clarification on the definition of “practicing physician who is an expert regarding care of elderly or disabled individuals.”

Response: CMS considers someone an expert who, per the dictionary definition of “expert,”¹¹⁶ has special skill or knowledge derived from training or experience; here that level of skill or knowledge must be in the area of providing care for elderly or disabled individuals. Because the UM policies under review by the committee will be used for coverage and services furnished to Medicare beneficiaries, it is critical to ensure that a provider with knowledge relevant to the population eligible for enrollment in the MA plan (that is, Medicare enrollees) is represented on the UM committee. We encourage MA organizations that offer SNPs to include providers with experience and expertise related to the special needs of the enrollees served by the SNP.

Comment: A commenter suggested that the UM committee be required to review any prior authorization policies used by the MA organization, including those developed and managed by third party entities. Another commenter requested clarification as to how proposed § 422.137 would apply when an MA plan has delegated utilization management functions, including whether and how the requirements of proposed § 422.137 would be shared or divided between the MA plan and its delegate(s)

Response: Per § 422.138 as proposed and finalized, the UM committee is required to, at least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. This means that any UM policy or procedure that is used by the plan, whether developed or managed by a third-party entity, must be reviewed and approved by the UM committee.

Comment: A few commenters requested that CMS not require a committee to review and approve all UM policies and procedures.

¹¹⁶<https://www.merriam-webster.com/dictionary/expert>

Response: CMS declines this suggestion. For the reasons outlined in the proposed rule and our responses to other comments and in light of feedback CMS has received and concern that enrollees may be facing unreasonable barriers to needed care, CMS believes ensuring UM policies and procedures are reviewed on a timely and consistent basis to ensure that the UM policies meet minimum standards is of paramount importance.

Comment: A commenter supported involving the UM committee in developing mechanisms to address system vulnerabilities. Another commenter suggested revise § 422.137(d) to require the UM Committee to review data on manual review errors, system errors, and excessive denials, to revise UM policies and procedures as appropriate to reduce the risk of such errors, and to identify and implement system changes to mitigate the risk of manual review errors and system errors.

Response: CMS thanks the commenters for their comment. At this time, we decline to make these revisions and are finalizing as proposed. We will consider these suggestions in future rulemaking.

We thank all commenters for their comments. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, as previously summarized, we are finalizing the new regulation § 422.137 and the modification to § 422.202(b)(1)(i) as proposed.

6. Additional Areas for Consideration and Comment

CMS solicited comment on three areas: (1) termination of services in post-acute care, (2) gold carding, and (3) addressing vulnerabilities that can lead to manual review errors and system errors. Since no regulations were proposed, we are not finalizing anything in these areas at this time. We thank commenters for their input, and will consider all comments during future rulemaking.

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

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

Cost plans are coordinated care plans and share many of the same features as Medicare Advantage plans, but have a separate statutory authority (section 1876 of the Act) and are paid on a reasonable cost basis. In addition, unlike with MA plans, enrollees in cost plans may receive services from original Medicare in addition to services from the cost plan’s network; when they receive benefits from health care providers that are not contracted with the cost plan, cost plan enrollees are covered by Traditional Medicare, with the same cost sharing and coverage as the Traditional Medicare program. The CARES Act did not include the zero cost-sharing provision for section 1876 cost contract plans (cost plans), so using its authority under section 1876(i)(3)(D) of the Act, which authorizes CMS to impose “other terms and conditions not inconsistent with [section 1876]” that are deemed “necessary and appropriate,” CMS established a requirement for cost plans to use cost sharing that does not exceed the cost sharing in Traditional Medicare for a COVID-19 vaccine and its administration in an interim final rule, titled Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health

Emergency, which appeared in the **Federal Register** on November 6, 2020.¹¹⁷ Because of the cost sharing used in Traditional Medicare per sections 1833(a)(1)(B) and 1861(s)(10)(A) of the Act, this is effectively a requirement to cover this benefit with zero cost sharing. In a newly adopted § 417.454(e)(4), we specified the timeline for coverage of a COVID-19 vaccine and its administration with zero cost-sharing for cost plans coverage of cost-sharing for cost plans that may not exceed cost sharing under Traditional Medicare as the “duration of the PHE for the COVID–19 pandemic, specifically the end of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Act, which is the PHE declared by the Secretary on January 31, 2020 and any renewals thereof.” However, the CARES Act did not specify an end date for the zero cost-sharing requirement for MA plans and we believe that it is appropriate that enrollees in a section 1876 cost plan have the same cost sharing protection for a COVID vaccine and its administration that enrollees in Traditional Medicare and in MA plans have when these cost plan enrollees get this benefit from health care providers that are in-network with the cost plan. Therefore, we proposed to replace the provision adopted at § 417.454(e)(4) in the November 2020 interim final rule with a new requirement that section 1876 cost plans cover the COVID–19 vaccine and its administration without cost-sharing as described in section 1861(s)(10)(A) of the Act. This proposal is based on authority in section 1876(i)(3)(D) of the Act to add requirements for cost plans.

CMS believes that it is necessary and appropriate to ensure that cost plan enrollees, like other Medicare beneficiaries, are provided access to the COVID-19 vaccine and its administration without cost-sharing in-network. Requiring cost plans to comply with the same cost-sharing protections available to Medicare beneficiaries in Traditional Medicare and those enrolled in MA plans would ensure equitable access to care and that cost is not a barrier for beneficiaries to receive the COVID-19 vaccine. CMS has extended to cost plans other statutory

¹¹⁷See interim final rule with request for comments titled “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” CMS 9912 IFC, 85 FR 71142.

requirements related to cost-sharing via regulation for those services that the Secretary determines require a level of predictability and transparency for beneficiaries. For example, in a final rule which appeared in the **Federal Register** on April 15, 2011, CMS, using its authority under section 1876(i)(3)(D) of the Act, extended to cost plans the statutory requirements specifying that in-network cost-sharing for MA enrollees could not be higher than cost-sharing for Traditional Medicare enrollees for chemotherapy administration services, renal dialysis services, and skilled nursing care in those cost sharing protections are § 417.454(e)(1) through (e)(3).

Comment: Several commenters expressed support for our proposal requiring cost plans to cover the COVID-19 vaccine and its administration without cost-sharing.

Response: We thank the commenters for their support of our proposal.

We received several supportive comments on this proposal and are finalizing the provision as proposed.

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 (§§ 422.566, 422.590, and 422.629)

We proposed to revise §§ 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. This is the same standard of review with respect to expertise that applies to physician review of reconsiderations at § 422.590(h)(2). The rule at § 422.590(h)(2) interprets and implements the

requirement in section 1852(g)(2)(B) of the Act that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity be made only by “a physician with appropriate expertise in the field of medicine which necessitates treatment” to mean a physician with an expertise in the field of medicine that is appropriate for the covered services at issue. As stated in the proposed rule, we believe it is appropriate to adopt this standard for the medical necessity review of organization determinations by physicians and other appropriate health professionals in §§ 422.566(d) and 422.629(k)(3) where the plan expects to issue an adverse decision.

We received the following comments on the proposal related to the 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.

Comment: Most commenters expressed strong support for this proposal and many agree that, if finalized, this standard would likely enhance the overall decision-making process and the quality of medical necessity reviews. 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. Many MA organizations noted that requiring the reviewer to be of the same specialty would be restrictive, cost-prohibitive and highly problematic. In addition, a commenter recommended that CMS develop a reasonableness standard to ensure that this approach, if finalized, is balanced and sensitive to the clinical workforce shortage that could be impacted by an overly decisive policy. This commenter cited the example of an internal medicine or family practice physician who has experience caring for the elderly and the disabled as an appropriate health care professional who could review medical necessity. Another commenter referenced the example from the proposed rule that if a plan intends to deny a request for a home nebulizer, the organization determination request should be reviewed by a health professional with respiratory

expertise, such as a respiratory therapist. This commenter believes that the language in the final rule should provide sufficient flexibility to support plan use of a physician specialized in, for example, internal medicine. The commenter further stated that internal medicine physicians are also familiar with the reasons why a home nebulizer may be medically necessary, such as for severe asthma or Chronic Obstructive Pulmonary Disease (COPD). Many commenters were supportive of flexibility for plans to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition and recommended that we make this clear in the regulatory text.

Response: CMS thanks the commenters for their support of this proposal. As noted in the proposed rule, our goal is to strengthen the quality of medical necessity reviews at the organization determination level when the plan expects to issue a partially or fully adverse medical necessity determination. We believe requiring expertise in the field of medicine or health care that is appropriate for the requested service advances that goal. If the plan reviewer is not of the same specialty or subspecialty as the treating physician, it's our expectation that the physician or other appropriate health care professional have specialized training, certification, or clinical experience in the applicable field of medicine in order to satisfy the requirement of expertise in the field of medicine that is appropriate for the requested item or service.

Comment: A few 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. A commenter was particularly concerned by the lack of detail provided by CMS under this proposal and the challenges it creates in terms of implementation noting that, as proposed, it would be difficult for a plan to identify that a provider has expertise in a specific field. Another commenter provided that there is marginal benefit seen in practice when common specialty cases are reviewed peer-to-peer, which begs the question of whether this proposal will improve medical necessity determination accuracy or reduce burden. Commenters also expressed concern about the limited availability of

some provider specialties and the difficulty for plans to hire enough providers to cover all possible utilization management review cases. A commenter questioned how CMS expects plans to comply with this requirement in the event that the item or service involves a more unusual medical specialty or item or service. Another commenter, requested that CMS consider the difference in resources available to large, dominant national MA organizations and those with a more limited geographic footprint and resource availability. The commenter noted that in many service areas that are served by small and medium-sized MA organizations, there may only be one or two specialists of a certain type, or all the specialists of the same type are in the same group, resulting in a conflict of interest, as this would necessitate those physicians reviewing the care in which they have an economic interest.

Several commenters were also concerned about the cost associated with implementing this requirement. A commenter suggested that this proposal could result in plans being required to scale back available benefits due to the cost of specialist reviews. Commenters also expressed concern that the requirement to find a specialist with appropriate expertise could delay access to necessary care as plans work to find the appropriate reviewer and recommended that, if finalized, we provide as much flexibility for plans as possible in determining what constitutes appropriate expertise on a case-by-case basis. Another commenter, indicated that the costs could be excessive and further add to administrative expense, thereby increasing beneficiary premiums, especially when not scalable to smaller regional not-for-profit health plans that may not see the volume of subspecialty review over a given period. Another commenter provided the example of MA plans offering dental, vision and hearing benefits as a supplemental benefit, and questioned if CMS expects each MA plan to have these provider types on call 24/7 for medical necessity review. This commenter indicated that most plans do not have dentists, for example, on staff, so to require these physician types be on call, this requirement will be costly and CMS should evaluate the aggregate costs of this proposal across the program and determine whether the benefit outweighs the cost.

Response: We appreciate the commenters' concerns related to staffing, associated costs and implementation, but we believe the proposed approach strikes a reasonable 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. We did not propose to require that plans use reviewers of the same specialty as the enrollee's treating physician. In addition, unlike the requirement at the reconsideration level that requires review by a physician, plans are able to utilize other appropriate health care professionals to review organization determinations that involve medical necessity. We believe there is sufficient overlap in training and clinical knowledge among health care providers to ensure flexibility in how plans allocate their staffing resources. While we acknowledge there will be some unique circumstances that may necessitate input by a specialist, because the revisions to §§ 422.566(d) and 422.629(k) do not require the plan reviewer to be of the same specialty or subspecialty, there is a degree of flexibility for plans to manage clinical staffing resources. As proposed and finalized, the level of expertise in the field of medicine or health care that is appropriate for the services at issue is the same standard that applies at the reconsideration level. Plans should implement this requirement at the organization determination level with respect to reviews performed by physicians or other health care providers in the same manner as plans have implemented the existing requirement for expertise of physician reviewers at the reconsideration level. Further, as proposed and finalized, this requirement does not apply to all organization determinations. Rather, per our proposal, the requirement applies to those organization determination requests where the plan expects to issue a partially or fully adverse decision on medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) based on the initial review of the request.

Comment: Several commenters noted the nationwide shortage of primary care physicians and recommended that CMS include registered nurses, clinical psychologists, and pharmacists as appropriate reviewers in the final rule.

Response: As proposed and finalized, the review at the organization determination level may be by a physician or other appropriate health care professional, , which could include a registered nurse, so long as the individual has expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria. In addition, the existing regulations at §§ 422.566(d) and 422.629(k)(3) require that the physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We reiterate our intended approach that plans determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee’s health condition. In satisfying this requirement, plans should be guided in determining what constitutes appropriate expertise in a given case by the related requirements on medical necessity determinations that are being finalized in § 422.101(c) of this final rule. Section 422.101(c) requires MA organizations to make medical necessity determinations based on: applicable coverage and benefit criteria; whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act; the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and, where appropriate, involvement of the plan’s medical director. This final rule requires the plan to exercise judgement to determine the type of reviewer (or identify an individual reviewer among its staff) who has sufficient expertise to make an informed and supportable decision whether a service is not medically necessary for the enrollee, such that coverage should be denied on the basis of a lack of medical necessity. We believe that applying the principles in § 422.101(c) to the decision-making around who is an appropriate reviewer in a given case will guide the plan to a reasonable and supportable interpretation of this review standard.

Comment: A commenter requested that CMS clarify that “appropriate health care professional” also includes subcontracted vendors.

Response: Pursuant to § 422.566(a), each MA organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits and mandatory and optional supplemental benefits. Plan functions can be performed directly by plan employees or under an arrangement between the plan and a first tier, downstream or related entity (FDR) consistent with the regulatory requirements at 42 CFR part 422, particularly § 422.504(i). If a plan uses an FDR, which includes subcontractors, to perform plan functions, the plan remains responsible under the MA regulations and its contract with CMS.

Comment: Another commenter, requested that we establish a standard of reasonableness in how to demonstrate the appropriateness of the clinician that does not place undue burden on the process. This commenter recommends that health plans not be required to litigate these instances on a case-by-case basis. This commenter noted that health plans work to ensure that the clinician conducting medical necessity reviews has the requisite experience and expertise. Further, it was noted that, for practical reasons, health plans cannot have clinicians representing each specialty or subspecialty employed to conduct medical necessity reviews and therefore rely on qualified generalists in some circumstances to provide the necessary expertise.

Response: Our intent in proposing this change is that plans ensure that when the plan expects to issue a partially or fully adverse medical necessity determination, the plan reviewer have expertise in the field of medicine that is appropriate for the item or service that is the subject of the organization determination request. As such, the expectation is that the plan determine on a case-by-case basis which physician or other health care professional has the requisite expertise to conduct the review. We agree with the commenter on applying a reasonableness standard in determining the appropriateness of the reviewing clinician. As previously stated, when exercising judgement to determine the type of reviewer who has appropriate expertise to decide whether a service is medically necessary for an enrollee, the plan should be guided by the medical necessity principles being established in this final rule at §

422.101(c). We believe that applying these principles to the decision-making on who is an appropriate reviewer in a given case will guide the plan to a reasonable and supportable interpretation of this review standard.

We understand the commenter's concern regarding the difficulties a plan may encounter in employing a specialist in every field of medicine, which is why our proposal did not include a requirement that the plan reviewer be of the same specialty as the treating physician. To the extent a plan uses a "generalist" as suggested by the commenter, to satisfy this standard, that reviewer would need to have relevant training or experience in the field of medicine related to the requested service in order to determine the medical necessity of the requested item or service.

Comment: Numerous commenters expressed concern with the use of the term "expertise" as it relates to this proposal, suggesting it is too vague. Commenters requested that we clarify what this term means and provide additional examples. A commenter was concerned that by not including specifics about the level of training or expertise of the reviewer, there would be no meaningful change to the current review standard. Commenters offered several suggestions on how to better define the scope of "expertise" as it relates to the physician or other health care professional who must review medical necessity decisions. Specifically, another commenter recommended that CMS revise the proposal to specify years of specialized training, while other commenters suggested that CMS specify that "relevant expertise" means that the physician involved must be of the exact same specialty or sub-specialty as the treating physician. Another commenter suggested that we require the plan reviewer to be of the "same or similar specialty" relevant to the services under review. Similarly, another commenter recommended that any coverage denial should be issued by a reviewer with "equal or greater expertise" in the relevant field of medicine to the treating physician. Additionally, this commenter questioned that CMS explore various measures for determining relevant expertise, such as setting thresholds requiring reviewers to have successfully performed a set number of relevant procedures, to the extent possible. Another commenter suggested that CMS require physician reviewers comply with the

same requirement as Traditional Medicare where the physician must be engaged in the active practice of medicine in the State and be a specialist in the same field as the physician whose services are under review. It was noted that the “same specialty” standard for physician reviewers is verifiable by documentation of physician credentialing, while the proposed “expertise in the field” is not readily verifiable. This commenter also suggested that the physician reviewer should attest no less frequently than annually that they and their immediate family members do not have a conflict of interest in the MA organization for whom they provide medical necessity review services. Numerous commenters requested that CMS strengthen the proposed policy by requiring the physician reviewer to have the same clinical expertise as the health care professional under FFS who can request the item or service. Several commenters cited the example of a determination on a request for a patient to be admitted to an inpatient rehabilitation facility (IRF) and stated their opinion that the plan should utilize the expertise of a physician trained in inpatient rehabilitation, as is required for patients to be admitted by an IRF in traditional Medicare. Other commenters offered examples of what they believe should constitute an appropriate reviewer in the context of this proposal, such as, decisions involving treatment of patients with cancer and blood disorders should be explicitly limited to board certification in oncology or hematology, respectively. Additionally, a commenter requested that CMS require more specific physical therapy expertise for adverse decisions on therapy services given the widespread availability of physical therapists to perform medical necessity reviews and the high rate of physical therapy and rehabilitation services that are subject to prior authorization requirements.

Response: We thank the commenters for their suggestions regarding how the concept of appropriate expertise should be interpreted if we finalize this proposal. We did not propose that the plan reviewer be of the same specialty or subspecialty as the treating physician. This proposal attempted to balance enhancing the quality of medical reviews at the organization determination level when the plan expects to issue a partially or fully adverse medical necessity

determination, with maintaining plan flexibility in leveraging reviewer resources. We recognize that where there are few practitioners in a highly specialized field of medicine, a plan may not be able to retain the services of a physician of the same specialty or sub-specialty to review the organization determination. Nor did we propose that an appropriate reviewer have a minimum number of years of specialized training in the field of medicine related to the requested service. We believe there are a number of ways a plan can ensure that the reviewing physician or other health care professional has expertise in the field of medicine that is appropriate for the item or service being requested. In some instances, we expect that plans will use a physician or other health care professional of the same specialty or subspecialty as the treating physician. In other instances, we expect that plans will utilize a reviewer with specialized training, certification, or clinical experience in the applicable field of medicine. As stated in the proposed rule, we intend the revisions to §§ 422.566(d) and 422.629(k) to permit plans to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition. Ultimately, the goal of determining the appropriate reviewer for the requested service is to ensure that denials based on medical necessity are based on a thorough clinical review by someone with sufficient expertise so that enrollees receive the benefits to which they are entitled. Decisions to deny coverage on the basis of medical necessity require the exercise of clinical judgment based on the considerations specified in § 422.101(c) as finalized in this rule.

With respect to the IRF example cited by several commenters, the plan reviewer reviewing a request for IRF care would need to have the background and knowledge to determine that the enrollee's medical condition requires intensive rehabilitation, continued medical supervision, and coordinated care. Accurately assessing the enrollee's diagnoses, conditions and functional status requires clinical expertise that is appropriate to the requested item or service and could be made, for example, by a physical medicine and rehabilitation doctor, a neurosurgeon, a physical therapist or a rehabilitation nurse.

Finally, given the related provisions in this rule with respect to determinations of medical necessity and utilization management tools, including prior authorization, we do not believe that this review standard requiring appropriate expertise needs to be unduly prescriptive to make an overall positive impact in the thoroughness of medical necessity reviews. For example, the codification of existing policy at § 422.101(c)(1)(i)(C) that MA organizations consider the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes dovetails with the proposed requirement that plans utilize reviewers with appropriate expertise in the requested service. In addition, there are several other related provisions in this rule regarding utilization management and prior authorization at §§ 422.112, 422.137 and 422.138 that we believe will strengthen medical necessity reviews, such as the proposal that prior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary based on standards specified in this rule. Again, decisions to deny coverage on the basis of medical necessity require the exercise of clinical judgment based on the considerations specified in § 422.101(c) as finalized in this rule. Exercising that type of judgment necessarily requires that the reviewer have knowledge and experience relevant to the requested services to reasonably determine when a requested service is reasonable, necessary and covered under the clinical coverage criteria that plans must use under § 422.101(b) as finalized in section III.E of this rule. We believe the totality of the provisions addressed in this rule will enhance the overall decision-making process and the quality of the review conducted at the organization determination level, particularly when a prior authorization or other utilization management requirement is involved.

Since we did not specifically propose that the reviewer be of the same specialty or sub-specialty as the physician requesting the service on the enrollee's behalf, we decline to finalize this proposal with such a requirement. As stated in the proposed rule, CMS's goal is to balance strengthening clinical review in the organization determination process when the plan expects to

issue a partially or fully adverse medical necessity determination, with plan flexibility and operational efficiency in selecting appropriate reviewers. We plan to monitor implementation of this standard to assess whether future rulemaking may be necessary related to additional specificity on what constitutes expertise appropriate to the requested service.

Comment: A commenter recommended CMS use the term “qualified health professional” rather than “other health professional” to avoid ambiguity and to align with the National Committee for Quality Assurance (NCQA) utilization management terminology.

Response: The existing regulation at § 422.566(d) related to who must review organization determinations states that if the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We did not propose to modify this existing reference to “appropriate health care professional” as we believe it affords proper flexibility for plans in selecting and allocating reviewer resources while establishing the level of qualification necessary to protect beneficiaries.

Comment: Several commenters recommended that CMS strengthen the proposed policy by specifying that medical necessity decisions must be made by a licensed physician in the state where care is being provided and the reviewing physician must have experience in the treatment being requested. Another commenter suggested that CMS require the physician reviewer to have an active licensure or relevant certification in the field of medicine specific to the request.

Response: Existing regulations at § 422.566(d) require the reviewing physician or other appropriate health care professional to have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We do not believe that it is necessary for the reviewer be of the same specialty as the treating physician because we also believe there is sufficient overlap in training and clinical knowledge among health care providers to ensure appropriateness in decision making. Additionally, the requirement at § 422.590(h), which requires a physician with expertise in the field of medicine that is appropriate for the service at issue to reconsider an adverse organization determination, does not require the physician to be of the exact same specialty or subspecialty as the treating physician. This is a longstanding requirement in the MA program, which has demonstrated that enrollees are adequately protected by requiring the reviewer to have expertise in the field of medicine appropriate to the service at issue. The reviewer could satisfy the expertise standard in a number of ways including, but not necessarily limited to, specialized training, a certification in the applicable or related field of medicine, or related clinical experience.

Comment: Multiple commenters expressed concern related to CMS' allowance of plan discretion. Specifically, a commenter was concerned in instances where there are few practitioners in a highly specialized field of medicine, and the plan may not be able to retain the services of a physician of the same specialty or sub-specialty to review the organization determination. This commenter recognized that while it may be difficult for MA organizations to retain the services of the wide variety of specialists and sub-specialists needed to adequately review adverse determinations, it detrimentally impacts patient safety to have coverage determinations reviewed by health care professionals that lack the requisite knowledge, experience, and training of the relevant specialist or sub-specialist. This commenter suggested that rather than allowing MA organizations to risk beneficiary safety due to inadequate staffing, CMS should instead require that MA organizations retain the services of the necessary specialists

and sub-specialists prior to implementing a particular utilization management policy, and further, suggested that impacted PA requirements due to inadequate staffing should be suspended until the MA organization can secure adequate staffing to review medical necessity decisions. We received a similar comment related to care that is often unavailable at other institutions, noting that it may not be possible to meet this standard if the treatment in question is for the specialized and sub-specialized care provided only at teaching hospitals. This commenter suggested that when it is not possible for the reviewing physician to have the same level of expertise and training as the treating physician, then the reviewing physician should be required to consult with the treating physician to inform their decision making.

Several commenters expressed concern related to the plan's discretion to determine the appropriate expertise on a case-by-case basis. These commenters recommended that CMS require MA organizations to develop a list to be shared with its contracted providers each year of services which require prior authorization and delineate the specific provider types and specialties, noting requisite training and rationale, who will be conducting medical necessity reviews, prior authorization reviews and peer-to-peer consults for those services. Another commenter suggested that the Utilization Management Committee, as proposed in this rule, should play a prominent role in developing this list of provider types and specialties in order to ensure compliance. A commenter requested that CMS ensure that this proposal also extends to inpatient care decisions and to the reporting of medical diagnoses that support inpatient care.

Response: CMS thanks the commenters for their perspective and feedback. Our proposal did not include a requirement that plans be required to develop a list that delineates the specific provider types and specialties, noting requisite training and rationale, who will be conducting medical necessity reviews, prior authorization reviews and peer-to-peer consults for services subject to PA. MA organizations are currently required under § 422.202(b) to establish a formal mechanism to consult with its contracted physicians regarding the organization's medical policy, quality improvement programs and medical management procedures to ensure that certain

standards are met. These standards include practice guidelines and utilization management guidelines that are developed based on reasonable medical evidence or a consensus of health care professionals in a particular field and in consultation with contracting physicians. Further, these guidelines are reviewed and updated periodically and are communicated to providers, and, as appropriate, to enrollees. We will consider the merit of these suggestions for future policy proposals. In terms of the comment suggesting that when it is not possible for the reviewing physician to have the same level of expertise and training as the treating physician, then the reviewing physician should be required to consult with the treating physician to inform their decision making, § 422.101(c) requires MA organizations to make medical necessity determinations based on: applicable coverage and benefit criteria; whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act; the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and, where appropriate, involvement of the plan's medical director. In exercising its judgement to determine the type of reviewer that has the appropriate expertise to decide whether a service is medically necessary for an enrollee, the plan should be guided by medical necessity principles set forth at § 422.101(c). As a whole, this final rule adopts new provisions and requirements designed to strengthen the prior authorization process. We believe these provisions will strengthen the overall decision-making process in the adjudication of organization determinations, including those that involve utilization management.

With respect to the comment on inpatient care decisions, any organization determination where the plan expects to make an adverse decision based on medical necessity will be subject to this provision. If an organization determination is requested for authorization of an inpatient admission and the plan has a prior authorization requirement that a particular diagnosis or diagnoses be present and the plan intends to issue an adverse decision based on its initial review of the request, the request 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.

Comment: 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.

Response: Under existing rules at § 422.566(a), MA plans must have a procedure for making timely organization determinations (in accordance with the requirements of 42 CFR 422 subpart M) regarding the benefits an enrollee is entitled to receive under an MA plan. This proposal is not intended to allow plans additional time to review organization determinations where the plan expects to issue a partially or fully adverse medical necessity decision. Existing regulations prescribe adjudication timeframes for organization determinations, which include pre-service requests subject to PA. Under the rules at § 422.572(a)(1) related to an expedited organization determination request for a medical item or service (which could include an item or service subject to PA), the MA organization must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. For a standard organization determination request for a medical item or service (again, which could include an item or service subject to PA), the rules at §422.568(b)(1) require the MA organization to notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. Under certain limited circumstances, an MA organization may extend these adjudication timeframes.

Comment: Many commenters requested clarification on how this requirement will be enforced. Another commenter stated the belief that MA organizations currently have the ability

to deny medically necessary care with little recourse. A commenter suggested the need for enrollees and providers to have a mechanism to challenge whether the standard has been met by the plan.

Response: CMS thanks the commenters for their interest in how we intend to enforce this standard and for the feedback related to medical necessity denials. We are assessing the best options for oversight of this requirement, including leveraging existing resources for monitoring Part C IRE reversals of plan decisions. We expect plans to implement this requirement at the organization determination level with respect to reviews performed by physicians or other health care providers in the same manner as plans have implemented the existing requirement for expertise of physician reviewers at the reconsideration level. Determining who has the appropriate expertise to conduct a review of medical necessity must be made on a case-by-case basis. Plans have additional flexibility at the organization determination level because they can utilize other appropriate health care professionals. As finalized in this rule, § 422.101(c) requires MA organizations to make medical necessity determinations based on: applicable coverage and benefit criteria; whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act; the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and, where appropriate, involvement of the plan's medical director. In exercising its judgement to determine the type of reviewer who has appropriate expertise to decide whether a service is medically necessary for an enrollee, the plan should be guided by medical necessity principles set forth at § 422.101(c). Applying these principles to the decision-making around who is an appropriate reviewer in a given case will guide the plan to a reasonable and supportable interpretation of this review standard.

Further, the enrollee (or the treating physician acting on behalf of the enrollee) always has recourse through the appeals process if the enrollee is dissatisfied with the plan's decision. This proposal in no way affects the enrollee's right to appeal a denied organization determination

or to file a grievance expressing dissatisfaction with any aspect of an MA organization's or a provider's operations or activities. As stated in the proposed rule, the goal of this proposed policy change is to enhance medical necessity reviews at the initial coverage decision level which should ultimately reduce the number of cases that get into the appeals process. We expect this policy to result in a decrease in the number of denied organization determinations because we believe requiring reviewers with appropriate expertise in the requested item or service will enhance the accuracy and overall clinical supportability of the medical necessity decisions. To the extent this requirement increases the likelihood of beneficiaries getting medically necessary covered services, the need for a beneficiary to appeal a denial will be reduced.

Comment: Several commenters recommended that we extend this proposal to apply to medical professionals who participate in peer-to-peer (P2P) discussions. These commenters suggested that many encounters during such discussions are with medical professionals who do not have applicable expertise for the service at issue, yet are responsible for making medical necessity decisions. Several commenters recommended that we add this clarification on applicability to P2P discussions to the regulatory text.

Response: We proposed that if a plan expects to issue an unfavorable organization determination decision, the request must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine that is appropriate for the item or service being requested before the plan issues an adverse organization determination decision. We note that if a P2P discussion occurs between a treating physician and a plan reviewer in the course of a plan reviewing a coverage request, the P2P discussion is not separate and distinct from an organization determination. Rather, P2P discussions take place during adjudication of an organization determination. To the extent a plan reviewer engages in a P2P with the enrollee's treating physician during adjudication of an organization determination request, this standard of review related to expertise in the field of medicine appropriate for the requested service would apply to that aspect of the organization determination process. Because a P2P is part of the

organization determination process, to the extent such a discussion occurs, and not a separate process, we do not believe the regulatory text needs to explicitly reference P2P discussions if this standard is finalized.

Comment: Several commenters suggested that CMS clarify that this proposal applies to expedited requests in addition to standard requests for prior authorization.

Response: The regulations at § 422.566 regarding organization determinations refer to the procedures plans must have in place per the rules at §§ 422.568 and 422.572. The regulations at § 422.629(k) regarding decision-making requirements for integrated organization determinations establish the individuals who make decisions per the rules at § 422.631 for standard and expedited integrated organization determinations. As proposed and finalized, this review standard applies to organization determinations where 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 regardless of the timeframe on which the plan is required to make the decision. This includes organization determinations (including those involving prior authorization) whether the organization determination is adjudicated under the standard timeframe per § 422.568, the expedited timeframe per § 422.572, or the timeframes for integrated organization determinations at § 422.631(d).

Comment: A commenter, requested that CMS explain how it envisions medical necessity review processes to work when there are multiple items and services being reviewed.

Response: As proposed and finalized, the amendment to §§ 422.566(d) and 422.629(k) does not change the plan's responsibility for making individualized medical necessity determinations based on the item or service being requested and relevant aspects of the enrollee's health condition, as well as applicable Medicare coverage rules. As previously noted, this final rule amends § 422.101(c)(1) to establish that plans must make medical necessity determinations based on specific standards and information, which will apply to all medical necessity

determinations, even if a request for multiple services is under review. If multiple services are requested, and the plan expects to issue a partially or fully adverse medical necessity determination, the plan must make a determination as to the appropriate expertise for each service and ensure that the decision to deny coverage on the basis of medical necessity for each service is made by a reviewer with the appropriate expertise. If the services are interrelated for the same condition, it may be appropriate to use a single reviewer. Again, this determination must be made on a case-by-case basis.

Comment: A commenter noted that this rule does not include the requirement which is imposed on medical necessity reviews conducted under Traditional Medicare, that is, physician reviewers must determine if the medical services which are subject to review are “reasonable and necessary”. This commenter recommended that these program integrity provisions be referenced in §§ 422.566(d) and 422.629(k)(3). The commenter believes this is necessary to provide compatible coverage between the Medicare Advantage program and Traditional Medicare program.

Response: Under existing rules at § 422.566(a), MA plans must have a procedure for making timely organization determinations (in accordance with the requirements of 42 CFR 422 subpart M) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. Organization determinations and integrated organization determinations made under the provisions at § 422.629 are made on the basis of whether the item or service is reasonable and necessary for the enrollee. The proposal related to the expertise of the plan reviewer if the plan expects to issue a partially or fully adverse medical necessity determination does not alter this existing requirement. Elsewhere in this final rule, we discuss proposed changes to amend § 422.101(b) and (c) to clarify the obligations and responsibilities for MA plans in covering basic benefits. Specifically, § 422.101(c) requires MA

organizations to make medical necessity determinations based on: applicable coverage and benefit criteria; whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act; the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and, where appropriate, involvement of the plan's medical director. In exercising its judgement to determine the type of reviewer who has appropriate expertise to decide whether a service is medically necessary for an enrollee, the plan should be guided by medical necessity principles set forth at § 422.101(c).

Comment: A commenter recommended that CMS require that plans provide documentation of the physician reviewer's compliance with qualification standards with each denial notice, in addition to the factual basis for the denial of coverage. This commenter suggested that this will provide for monitoring and enforcement of compliance with physician reviewer criteria and this information may be used in the administrative appeals process, QIO reviews, and complaints made to CMS. Another commenter recommended that CMS require physician reviewers to provide the beneficiary and treating physician with a notice/certification that their medical necessity review did not involve the use or consideration of screening criteria. Another commenter recommended that CMS require the MA organization to include its rationale for the supporting reviewer's "expertise" for a given service at issue in each denial notice.

Response: We thank the commenter for these suggestions. We did not propose that the plan be required to produce specific documentation of the plan reviewer's relevant expertise with a denial notice or that there be a certification that medical necessity review didn't use screening criteria. Existing rules require plans to have processes in place for receipt and documentation of initial determination requests. MA organizations are also required to adhere to the maintenance of records and disclosure of information requirements at §§ 422.504(d)(1)(ii) and 422.504(f)(2)(v), respectively. In addition, we expect that the administrative case file would include documentation relevant to the medical necessity review conducted in each organization determination.

Comment: Several commenters recommended that CMS add more specific guardrails to ensure appropriately qualified reviewers are involved in the decision-making around coverage for particularly complex services. Commenters suggested that CMS require MA organizations to give deference to the treating physician when the MA organization is unable to obtain a reviewer of the same specialty or subspecialty unless the patient record directly contradicts the medical necessity determination. A commenter recommended that, if this proposal is finalized, coverage be mandatory in cases where sections §§ 422.566(d) and 422.629(k)(3) are violated; that is, where the physician reviewer did not have expertise in the field of medicine appropriate to the case or where required documentation was not maintained by the MA organization and provided to the enrollee and the physician whose order for services become the subject of a notice of denial of coverage. This commenter also recommended that decisions to deny coverage be effective no earlier than the date a denial notice is communicated in writing and received by the affected enrollee and the practitioner whose order for medical services was subject to medical necessity review.

Response: We appreciate the commenter's suggestions, but our proposal to establish minimum requirements for who reviews an organization determination before the plan issues a denial on the basis of medical necessity did not include requirements for mandatory or automatic coverage of the requested service in the event the plan reviewer does not have expertise in the field of medicine related to the requested item or service. Further, we did not propose a change to existing requirements related to denial notices. Plans are responsible for determining the medical necessity of an organization determination request on a case-by-case basis and nothing about this proposal obviates the need for an individualized review of medical necessity. Section III.E. 2.b. of this final rule amends § 422.101(c)(1) to establish that plans must make medical necessity determinations based on specific standards and information, which will apply to all medical necessity determinations, even if a request for multiple services is under review.

Comment: A commenter strongly opposed this proposal and requested that it be withdrawn. The commenter stated that it is not practical or advisable at the organization determination level of review. This commenter asserted that there is evidence that many clinicians are leaving frontline medicine to become consultants who perform independent reviews. The commenter also suggested that this proposal would result in increased demand for clinicians to perform these roles and create shortages in hospitals and medical practices. Further, the commenter stated that under current Medicare Advantage rules, consumers have access to specialists during the independent review process and requiring specialists to participate in organization determinations will increase pressures on the workforce and costs for taxpayers and beneficiaries.

Response: We appreciate the commenter's perspective and concerns related to staffing issues. In developing this proposal, we attempted to balance enhancing the quality of medical reviews at the organization determination level with maintaining plan flexibility in leveraging reviewer resources. Based on that balance, we did not propose and are not finalizing a requirement that plans must use a physician or other health care professional with the same specialty as the treating physician. We believe it is reasonable for plans to have physicians and other health care professionals with various types of clinical expertise in order to conduct robust medical reviews in addition to the beneficiary protections afforded by the independent review entity level of adjudication.

Comment: A commenter requested clarification related to how this proposal would affect reviews under Part D, while another commenter recommended that this requirement also apply to Part D. We also received a comment related to consistency on the part of the IRE, noting that if there is not uniformity, the IRE could make a difference in clinical judgement on a case.

Response: We thank the commenters, but these comments are outside the scope of this rule.

Based on the feedback we received from commenters, we are finalizing this 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.

We also 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). We did not receive comments on this technical correction and we are finalizing this correction.

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

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

In accordance with our authority to interpret and implement the requirements and limitations in sections 1851(h), 1851(j), 1852(c), 1860D-1(b)(1)(B)(vi), 1860D-4(a), and 1860D-4(l) of the Act, §§ 422.2267(a)(2) and 423.2267(a)(2) of the regulations require MA organizations and Part D sponsors to translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. In addition, per § 417.428, cost plans with contracts under section 1876 of the Act must follow the same marketing and communication regulations; we apply the same standards to cost plans under this regulation based on our authority in section 1876(i)(3)(D) of the Act. Each fall, we release an HPMS memorandum announcing that plans can access in the HPMS marketing review module a list of all languages that are spoken by 5 percent or more of the population for every

county in the U.S.¹¹⁸ In the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drugs Benefit Program; Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency final rule, which appeared in the May 9, 2022 **Federal Register** (87 FR 27704) (hereinafter referred to as the May 2022 final rule), we also adopted a requirement that MA and Part D plans use a multi-language insert (MLI), which informs the reader in the fifteen most commonly spoken non-English languages used in the U.S., as well as any additional non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area, that interpreter services are available for free. In accordance with §§ 422.2267(e)(31) and 423.2267(e)(33), the MLI must be included with all CMS required materials provided to current or prospective enrollees. As discussed in the May 2022 final rule, CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision making process; ensuring beneficiaries with limited English proficiency are aware of and are able to access interpreter services provides a clear path for this portion of the population to properly understand and access their benefits (87 FR 27821). We remind MA organizations and Part D sponsors that as recipients of Federal financial assistance, they have independent language access requirements under Title VI of the Civil Rights Act of 1964 and section 1557 of the Affordable Care Act and implementing regulations at 45 CFR Parts 80 and 92, respectively.

In addition, MA organizations and Part D sponsors must comply with section 504 of the Rehabilitation Act of 1973 and section 1557 of the Affordable Care Act, and the Department of Health and Human Services implementing regulations at 45 CFR Parts 84 and 92. As recipients of Federal financial assistance, MA organizations and Part D sponsors must provide appropriate

¹¹⁸CMS released the contract year 2023 version of this HPMS memorandum titled, “Contract Year 2023 Translated Model Materials Requirements and Language Data Analysis” on September 23, 2022. This memorandum can be retrieved at: <https://www.cms.gov/httpseditcmgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-hpms-memos-archive/hpms-memos-wk-4-september-19-23>

auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. Auxiliary aids and services can include braille, large print, data/audio files, relay services, and TTY communications. We further explained the obligation of plans to provide accessible communications for individuals with disabilities in an August 30, 2017, Health Plan Management System memorandum titled, “Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557).”¹¹⁹

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

The materials required under §§ 422.2267(e) and 423.2267(e) and ICPs are vital to how individuals access services and make decisions about their health care. These materials furnish important information about coverage and benefits under Medicare health and drug plans. We noted our belief that our proposal would make it easier for beneficiaries to understand the full

¹¹⁹CMS Office of Hearings and Inquiries, “Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557), August 30, 2017. Retrieved from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3>.

scope of available Medicare benefits (as well as Medicaid benefits available through the D-SNPs, where applicable), increasing their ability to make informed health care decisions, and promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care.

At 87 FR 79521 through 79522 of the proposed rule, we described the need for providing materials in non-English languages and in any accessible formats. We explained that communication and language barriers are associated with decreased quality of care and poorer health outcomes. In addition, individuals with limited English proficiency are less likely to have routine health visits, more likely to defer needed health care, and more likely to leave the hospital against medical advice.¹²⁰ Effective communication or meaningful access are critical to providing high-quality care.

We believe that it is a substantial burden for enrollees to have to request each material in a non-English language or accessible format and that requiring enrollees to do so could impede access to care. It is also possible that enrollees may require materials in both an alternate format and a non-English language (for example Spanish braille). In addition, to ensure the ICPs are developed in consultation with the enrollee as required at § 422.101(f)(1)(ii), it is important that ICP materials be provided in the enrollee's primary language and, where appropriate, in an accessible format. As described at 87 FR 79522 of the proposed rule, research has found patients with limited English proficiency experience negative health outcomes due to the barriers they encounter, including when interacting with their doctors and care team members. We have become attuned to this issue through our work with Medicare-Medicaid Plans (MMPs), as explained at 87 FR 79522 of the proposed rule.

We believe that there are many ways for MA organizations and Part D sponsors to learn of an enrollee's need for an accessible format and language needs and maintain this information. We outlined examples at 87 FR 79522 of the proposed rule.

¹²⁰Refer to <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.2.435>.

We would like to minimize barriers for enrollees (and potential enrollees) with limited English proficiency and/or with disabilities who need materials in non-English languages and accessible formats and remove any ambiguity associated with MA and Part D plan responsibilities. Therefore, we proposed to re-designate the paragraphs at §§ 422.2267(a)(3) and 423.2267(a)(3) as §§ 422.2267(a)(5) and 423.2267(a)(5) and add new paragraphs at §§ 422.2267(a)(3) and 423.2267(a)(3). In these new paragraphs, we proposed to require that MA organizations and Part D sponsors provide materials to enrollees on a *standing basis* in any non-English languages 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) and proposed §§ 422.2267(a)(4) and 423.2267(a)(4), which are discussed later in this section, and in any accessible formats upon receiving a request for the materials in another language or otherwise learning of the enrollee's preferred language or need for an accessible format. This means that once a plan learns of an enrollee with limited English proficiency's primary language and/or an enrollee with a disability's need for an alternate format – whether through an enrollee requesting a material in a primary non-English language or alternate format, during a health risk assessment, or another touch point – the plan must provide required materials in that language and/or accessible format as long as the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide required materials in a different manner. We also proposed language at §§ 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. The proposed requirement would allow enrollees to avoid having to submit a request to receive required materials in their primary language and/or alternate format each time the MA or Part D plan distributes a required material. We note that plans are responsible for providing materials in both an identified non-English primary language and accessible format when needed (for example Spanish braille). These modifications at §§ 422.2267 and 423.2267 and other requirements at Parts 422 and 423 regarding translation obligations and accessible formats are in addition to plan

obligations under 45 CFR Parts 80 (Title VI), 84 (Section 504), and 92 (Section 1557) that govern meaningful access for individuals with limited English proficiency and effective communication for individuals with disabilities. MA and Part D plans must comply with both the rules at § 422.2267 and § 423.2267 and the non-discrimination requirements in 45 CFR Parts 80, 84, and 92. Where one set of regulations imposes a higher or different standard, but it is possible for the plan to comply with both, the plan must comply with both. Because cost plans, per § 417.428, are subject to the regulations in part 422, subpart V, these requirements also apply to cost plans.

As we noted in the proposed rule at 87 FR 79523, there are no information collections related to creating a standing request for translated materials or materials in alternate formats. We believe the burden associated with these proposed requirements is exempt from the requirements of PRA as defined in 5 CFR § 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We believe most cost plans, MA organizations, and Part D sponsors have translators on staff or access them via contractors because of existing translation and auxiliary aid requirements.

We received the following comments, and our responses follow.

Comment: Many commenters supported CMS' plan to require MA plans to provide standardized materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5 percent of individuals in a plan benefit package service area and in accessible formats. They noted that untranslated materials can create barriers in accessing care and poor outcomes for patients with limited English proficiency (LEP). A few commenters appreciated that disability communication access is also a part of the effort to address language and cultural barriers to care and stated that the standardization of language access requirements will help patients reliably expect what their language access to health information will be. Another commenter noted that without access there can be no equity, and the CMS proposal

changes the emphasis to ensure everyone has access to necessary care as a foundation for equity. A commenter was pleased to see the proposed requirement extend to individualized plans of care (ICPs) for special needs plans and noted that research has shown enrollees often are not aware of benefits that address social needs or do not know how to access them. A commenter also expressed that enrollees should not have to repeat requests for information, including critical information like ICPs, from plans as this poses unnecessary barriers to needed care and such communication and language barriers are associated with decreased quality of care and poorer health outcomes.

Response: We appreciate the widespread support for our proposal. We agree that the proposed requirements will help to strengthen access to care and improve equity.

Comment: A few commenters opposed the proposal and stated that the current policy was sufficient to meet enrollee needs. Several commenters noted that information regarding how to access translation services is included in materials. Another commenter stated that providers can assist enrollees in understanding the information.

Response: We appreciate the perspective raised by these commenters. However, as stated in the proposed rule at 87 FR 79522, we believe that it is a substantial burden for enrollees to have to request each material in a non-English language or request alternate formats for each material and that requiring enrollees to do so could cause a critical delay to timely access to care.

Comment: A number of commenters expressed concern over the financial investment that would be needed in developing an organization-wide process for capturing language and alternate format needs and implementing the requirement on a standing basis, including an investment in IT and vendor contracts. Numerous commenters also noted that it would take time to implement these processes including the system updates, updating vendor contracts, staff training, etc., and requested that CMS delay implementation until CY 2025. A commenter also requested a delay in implementing this requirement since these materials are often prepared well in advance of open enrollment for the following plan year. A few commenters expressed concern

over the cost of translating materials into several languages on a standing basis. A commenter believed the proposed requirement would necessitate plans translating materials into more than 30 languages. Another commenter noted that they will still have to provide English versions of the materials for providers, even when enrollees request information in other languages.

Response: We appreciate the commenters' concerns regarding the infrastructure updates that will be needed to capture an enrollee's preference for receiving materials in non-English languages and/or accessible formats and then using this information to send out materials in the requested format on a standing basis.

We also understand that some commenters are concerned about the cost of translating materials into several languages on a standing basis. Each fall, we release an HPMS memorandum announcing that plans can access in the HPMS marketing review module a list of all languages that meet the 5 percent threshold for plan service areas, which is the threshold for translation.¹²¹ For contract year 2023, the threshold requires few contracts to translate into languages beyond Spanish: 16 MA contracts meet the threshold that requires translating materials into Chinese, and 19 MA and PDPs meet the threshold that requires translating materials into other Asian languages. There are no other service areas with additional languages that currently meet the 5 percent threshold for translation. As a result, there are very few MA organizations or PDPs that will be required to translate required materials and, for MA SNPs, ICPs into more than one language. Therefore, we do not agree that plans will be required to translate materials into several languages. Also, the current regulations at §§ 422.2267(a)(2) and 423.2267(a)(2) already require plans to translate required materials into languages that meet the 5 percent threshold. We also remind MA organizations and Part D sponsors that, as recipients of Federal financial assistance, they have independent language access requirements under Title VI

¹²¹CMS released the contract year 2023 version of this HPMS memorandum titled, "Contract Year 2023 Translated Model Materials Requirements and Language Data Analysis" on September 23, 2022. This memorandum can be retrieved at: <https://www.cms.gov/httpseditcmgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-memos-archive/hpms-memos-wk-4-september-19-23>

of the Civil Rights Act of 1964 and section 1557 of the Affordable Care Act and implementing regulations at 45 CFR Parts 80 and 92, respectively.

For auxiliary aids and services, section 504 of the Rehabilitation Act of 1973, section 1557 of the ACA, and the regulations at 45 CFR 92.102(b) already require plans to provide appropriate auxiliary aids and services in alternate formats to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. The requirement we are finalizing at §§ 422.2267(a)(3) and 423.2267(a)(3) only clarifies that plans must provide the materials based on the enrollee's preference on a standing basis.

While we understand that plans may need to make some adjustments to vendor contracts and make system updates, plans should already have resources in place to provide these materials translated into the languages required currently under §§ 422.2267(a)(2) and 423.2267(a)(2) and accessible formats. In addition, plans should have systems in place that can be adjusted to track standing requests since they are already required to track a request for hard copy materials as described in §§ 422.2267(d)(2)(i)(E) and 423.2267(d)(2)(i)(E). We believe the benefit of ensuring access to materials that can be easily understood by enrollees so that they can receive timely access to care outweighs any additional effort that plans may need to undertake. As stated earlier in this section and in the proposed rule at 87 FR 79522, we believe it is a substantial burden for enrollees to have to request each material in a non-English language or request accessible formats for each material and that requiring enrollees to do so could cause a critical delay to timely access to care. Thus, we are finalizing the provisions at §§ 422.2267(a)(3) and 423.2267(a)(3) as proposed, without a delay in implementation.

Comment: Many commenters recommended that CMS provide plans with flexibility to meet the requirements in other ways and believe that it is critical to provide materials in a way that is preferred by the enrollee or what the plan believes is in the best interest of the enrollee. They noted that an enrollee may not want all communications in the same language or format.

Other commenters inquired if they may ask the enrollees whether they would like a material in an alternate format as a one-time request or as a standing basis. A commenter questioned whether the plan could offer telephonic translation services to the member, by bringing a translator or TTY on the line to help answer any questions in lieu of fulfilling the translated or alternate format document request. Some commenters noted that verbal communication is the most valuable language access method. A commenter noted that enrollees may not find value in an audio recording of the formulary or provider directory, or receiving an entire EOC in large print that would be nearly 600 pages and arrive in a box.

Response: We thank commenters for suggestions to allow flexibility to provide materials based on the request of the enrollee, provided the request is reasonable. We agree that materials should be provided in the manner requested by the enrollee. We note at 87 FR 79522 and earlier in the preamble of our proposed rule that once the plan receives a request for materials in another language or for using auxiliary aids and services, the plan must provide required materials in the language and/or accessible format as long as the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide materials in a different manner. CMS believes that enrollees are in the best position to determine their needs for translation or an accessible format, and the plan should ensure that there is flexibility to accommodate different needs for different materials as requested by the enrollee. However, if a plan has concerns that a specific format may not be an effective way to provide information based on the enrollee's needs, then it is appropriate for the plan to reach out to the enrollee to confirm their need for specific materials, provided that this outreach meets the entity's obligations for translation or interpretation services under Title VI (45 CFR part 80), Section 504 (45 CFR part 84), and Section 1557 (45 CFR part 92). For example, if an enrollee states that they would rather receive certain information included in specific materials translated verbally instead of a translated written copy of the document, it is acceptable for the plan to fulfill that request without sending a written copy. However, the plan must ensure that it documents this information in the plan's systems. It is also acceptable for the

plan to inquire whether an enrollee would like a material in a non-English language or alternate format on a one-time or standing basis.

Comment: Numerous commenters raised concerns regarding the turnaround time needed to create non-standardized enrollee-specific materials in non-English languages and alternate formats, such as braille or non-English braille. Some commenters described concerns about producing materials quickly, such as coverage determination or organization determination notices which must be provided under tight timelines. These commenters stated that they would need to provide the materials first in English and then in non-English language(s) and the alternate formats to meet timeliness standards. Some commenters also noted that the turnaround time to create translations such as braille can be as much as four weeks. A commenter also expressed concerns that this requirement would further burden contracted vendors that work with multiple plans that would all be subject to these new requirements and believed that this would result in reduced capacity.

A commenter noted that the proposed rule is in addition to existing obligations under 45 CFR Part 92 and that plans are expected to comply with both, even if one imposes a higher or different standard, unless it is impossible to do so. This commenter stated that the lack of clarity in the proposal on whether the standards under 45 CFR Part 92 for determining reasonableness apply to the draft regulation could cause confusion for plans in implementing the guidance and, in turn, result in differential application across payers. The commenter explained that such ambiguity could result in beneficiary confusion and unnecessary cost for plans. The commenter included an example where a visually impaired enrollee could request an alternate format of braille, which the commenter noted under 45 CFR Part 92 plans are permitted to determine the reasonableness by applying the applicable standards. The commenter suggested that CMS revise the current proposal to include explicit language that the same standards under 45 CFR Part 92 apply to the proposed CMS requirement for providing all CMS required materials in both the preferred format and/or language.

A few commenters raised concerns regarding their ability to meet the September 30 deadline for providing a translated or accessible format Annual Notice of Change (ANOC) to current enrollees. Several commenters recommended that CMS establish a stakeholder workgroup that includes translation contractors to discuss how turnaround times can be improved and which communications can be translated fast enough to meet the need of the beneficiaries.

Response: We appreciate the commenters' concerns regarding the turnaround time needed for required materials, and we acknowledge the specific concern for enrollee-specific materials, such as coverage determination notices. However, the proposed requirement to provide materials on a standing basis did not change a plan's current obligation to provide materials timely in alternate languages under § 422.2267(a)(2) or alternate formats under 45 CFR Part 92, nor do they change a plan's current obligations under 45 CFR Parts 80 and 84.

As outlined in the HPMS memorandum titled, "Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557)" dated August 30, 2017,¹²² which is guidance that interprets these laws, MA plans are responsible for having appropriate processes in place to meet the applicable regulatory adjudication and notice timeframes at 42 CFR § 422 Subpart M and § 423 Subpart M. This includes cases where an MA plan has to produce a notice in an alternate format. This guidance informs MA plans of their obligation to provide materials in an alternate format, if requested by the enrollee, so long as the requests are reasonable requests. MA plans are responsible for

¹²²CMS Office of Hearings and Inquiries, "Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557), August 30, 2017. Retrieved from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F2017-Qtr3>.
<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F2017-Qtr3>.
<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F2017-Qtr3>.
<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F2017-Qtr3>.

complying with the timely-notice requirements (set forth at § 422, Subpart M, and § 423, Subpart M, respectively) in all cases. If there are certain facts and circumstances when the plan has difficulty producing an alternate format within the applicable adjudication timeframe, the plan should first work proactively with the individual to achieve equivalent communications, but nevertheless document the facts and circumstances, including an explanation of why the documentation could not be produced within the regulatory timeframe, and make best efforts to communicate the information to the individual via the most effective means. If communications are not provided in a timely manner, potential impacts include disadvantaging an individual's opportunity to take full advantage of enrollment periods, the appeals process, the opportunity to pay premiums in a timely manner, etc.

Section 504 and section 1557 require reasonable modification. For example, the August 30, 2017 memorandum describes one scenario which could occur if an individual with a disability used an out-of-network provider and now requests instructions in an alternate format. This scenario describes how an individual could request that the MA plan reimburse them for the out-of-pocket claim. If the MA plan requires the claim to be filed within a certain amount of time, the August 30, 2017 memo states that the MA plan must take into account any added time needed to provide the instructions in the alternate format if the request is reasonable as required under section 504 and section 1557. If it took the MA plan an extra three days to put the instructions into the alternate format, three days should be added to the length of time in which the MA plan will accept the individual's claim.

The MA plan should document how it ensured that the individual had an equal opportunity to participate in the program or activity. If an MA plan denies a request, the MA plan should document its decision and be able to share it with CMS or the HHS Office for Civil Rights (OCR) upon request. If CMS or HHS OCR reviews an MA plan's decision, it will give weight to the individual's request based on the communications standards in 45 CFR §§84.52(d), and 92.102.

We note that CMS provides translated models for the ANOC and EOC each summer in Spanish and Chinese so that plans then can focus on including the plan-specific information prior to the September 30 annual deadline. For CY 2023, CMS also provided Spanish and Chinese versions of the ANOC and EOC for the D-SNP specific models. We plan to provide these translated models for CY 2024 as well. Finally, we will consider establishing a stakeholder workgroup to discuss how turnaround times can be improved. We believe the benefit of ensuring access to materials that can be easily understood by enrollees so that they can receive timely access to care outweighs any additional effort that plans may need to undertake. For these reasons and those noted previously, we are finalizing and implementing these requirements for CY 2024. As such, these requirements will be applicable for all required materials related to CY 2024.

Comment: A commenter suggested that CMS ensure any requirements imposed on plans are consistent and implemented in coordination with changes issued by the HHS OCR. They suggested that CMS delay the requirements of this rule, since any change in OCR regulations that CMS wishes to impose on plans will not have been available for public comment.

Response: We appreciate the comment. We do not believe that the requirements we are finalizing conflict with obligations for MA and Part A plans under section 1557 of the ACA. Further, as discussed in more detail in other responses to public comments, we do not believe that the scope of this final rule necessitates a delay in the requirements we are finalizing at §§ 422.2267(a)(3) and 423.2267(a)(3). We also note that the OCR Section 1557 proposed rule was published on August 4, 2022, and there was the opportunity to comment on that rule until October 3, 2022.

We are finalizing the requirements at §§ 422.2267(a)(3) and 423.2267(a)(3) as applicable for all required materials related to CY 2024. We expect the tracking and use of standing requests can begin with requests received from enrollees in connection with materials for coverage in CY 2024. Unless an MA plan already has an existing process to track and use

standing enrollee requests, we do not expect MA plans to go back to past enrollee requests to apply them as standing requests for 2024 materials. Consistent with Question 14 in the August 30, 2017 HPMS memo, an MA plan must make a best effort to ensure that an enrollee needs to only make the request of an MA plan once during the time the beneficiary is enrolled with the MA plan. If the enrollee leaves the MA plan and returns, the individual may need to make the request to the MA plan again.

Comment: A commenter encouraged CMS to clarify the application of this requirement in regard to 42 CFR § 422.2267(d)(2)(i).

Response: Sections 422.2267(d)(2)(i) and 423.2267(d)(2)(i) state that, without prior authorization from the enrollee, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The option for plans to use electronic delivery is not changed by this final rule, but if a plan elects to use the procedures for electronic delivery of those materials, the notice informing the enrollee how to electronically access these materials is a required material subject to the translation requirements in existing paragraph (a)(2) and new paragraphs (a)(3) and (a)(4), as finalized in this rule, of §§ 422.2267 and 423.2267. In addition, §§ 422.2267(d)(2)(i)(E) and 423.2267(d)(2)(i)(E) indicate that the notice must provide the enrollee with the option to request hard copy materials; requests for the hard copy materials may be material specific and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again. Delivery of the hard copy materials is also subject to the translation requirements.

This means that plans can send the notice in the enrollee's primary non-English language or accessible format stating how the enrollee can access the materials electronically in lieu of sending a hard copy in the primary non-English language or accessible format. However, if an enrollee confirms that they want a hard copy of the material on a standing basis in their primary

that even for items that the plan can translate, ICPs often involve complex and technical terms—terms that may not be easily translated immediately.

Response: We appreciate the commenters' perspectives on this issue and understand the effort that it takes to translate an ICP and/or provide it in an accessible format. Section 422.101(f)(1)(ii) requires SNPs to develop and implement a comprehensive ICP through an interdisciplinary care team in consultation with the beneficiary, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided. We agree that SNPs should have the care team verbally review and develop the ICP in consultation with the enrollee. However, we have often found through CMS program audits that SNPs do not always discuss ICPs with enrollees. In addition, we believe it is essential for enrollees to have ICP information in writing in a format that they can understand so that they can refer to it beyond an initial meeting with a care team and work towards the goals included in the ICP. We also note that enrollee-facing ICP information should be provided in an easily understandable manner. While an ICP may include physician notes and medical terminology, we encourage plans to keep the ICP focused on enrollee-specific goals and objectives, including measurable outcomes and the specific services to be provided. In addition, as previously described, the 5 percent threshold requires few contracts to translate into languages beyond Spanish.

Comment: A few commenters requested that CMS clarify which materials are required to be provided in alternate formats or languages. A commenter suggested that CMS clarify that the requirement does not apply to supplemental documents, such as health education materials. Other commenters requested that CMS confirm expectations for providing materials on a standing basis.

Response: We are happy to clarify which materials are required to be provided in non-English languages and accessible formats. The requirement we are finalizing at § 422.2267(a)(3) applies to all of the required materials described at § 422.2267(e) and ICPs, but it does not

extend to other supplemental documents, such as health education materials. We also noted at 87 FR 79522 of the proposed rule that on a standing basis means that once a plan learns of an enrollee's primary language and/or need for an alternate format—whether through an enrollee request, during a health risk assessment, or another touch point—the plan must provide required materials in that language and/or accessible format as long as the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide required materials in a different manner. We also reiterate that it is acceptable for an enrollee to request to receive a material in a non-English language or alternate format on a one-time or standing basis and that the plan may inquire as to the enrollee's needs.

Comment: A commenter requested that we define the word enrollee. Another commenter questioned how an enrollee can request alternate formats and whether a representative can make the request. This commenter questioned if CMS can provide model scripting to discuss requests with enrollees. Another commenter questioned if CMS has considered developing model documents in large print and the 15 nationally most-common languages and braille and Spanish braille.

Response: We are happy to clarify this information for the commenters. As defined at § 422.2 and § 422.561, an MA plan enrollee, or enrollee, means an MA eligible individual who has elected an MA plan offered by an MA organization. The terms Part D enrollee and enrollee are used in a similar way in 42 CFR Part 423. At 87 FR 79522 of the proposed rule, we described multiple enrollee touch points that plans can use to capture an enrollee's preference for alternate languages or accessible formats. Examples of these touch points include welcome calls, health risk assessments, nurse advice lines, and other interactions associated with member services, enrollment, prescription services, appeals and grievances, and care management. As described at § 422.119, MA plans must make information accessible to current enrollees or the enrollee's personal representative. Therefore, they can make a request for non-English languages or alternate formats on behalf of an enrollee. Since, as previously described, there are a variety of

ways a plan can obtain information regarding an enrollee's preference for alternate languages or accessible formats, CMS does not provide model scripting to discuss requests with enrollees. In addition, we noted in the August 30, 2017 HPMS memorandum titled "Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557)"¹²⁴ that it is the responsibility of the MA plans to produce its materials in accessible formats when requested.

Comment: A commenter requested that CMS clarify that both existing and proposed translation standard requirements do not apply to third-party marketing organizations (TPMOs) or first-tier, downstream, and related entities (FDR) unless otherwise agreed upon between the MA organization and the TPMO or FDR, or the Part D sponsors and the TPMO or FDR.

Response: We clarify that per § 422.2274(g), in addition to all applicable FDR requirements at § 422.504(i), when doing business with a TPMO, the MA organization is responsible for ensuring that the TPMO adheres to any requirements that apply to MA plans, including the existing and proposed translation standard requirements.

Comment: Several commenters requested that CMS expand the list of languages provided in HPMS for MA contracts to the 15 most commonly spoken non-English languages spoken in a service area. These commenters believed that this change would allow plans to see how close service areas are to meeting the 5 percent threshold for updating materials and content and plan accordingly. A few of them also recommended that CMS designate the effective date

¹²⁴CMS Office of Hearings and Inquiries, "Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557), August 30, 2017. Retrieved from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3>.<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3>.<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3>.<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3>.

for updating new materials and content as the plan year that begins a year after the date the 5 percent threshold is met and recommended that CMS delay enforcement for a period of time.

Response: We appreciate the comments. Sections 422.2267(a)(2) and 423.2267(a)(2) require that MA organizations and Part D sponsors translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area. In HPMS, we currently provide MA organizations and Part D sponsors with information noting the languages they are required to translate materials into based on this standard. We will consider expanding the list of languages provided in HPMS for MA and Part D plans to the 15 most commonly spoken non-English languages in a service area in a future HPMS update to assist plans in monitoring which languages may be getting close to the 5 percent threshold. We remind plans that they must also comply with translation requirements under 45 CFR § 92.101 and any future requirements under 45 CFR Parts 80 and 92. We also acknowledge the recommendation that CMS designate the effective date for updating new materials and content as the plan year that begins a year after the date the 5 percent threshold is met and the recommendation that CMS delay enforcement for a period of time. We note that the languages requiring translation based on the 5 percent threshold have not changed for several years. Thus, we do not anticipate that plans will need to translate required materials in many new languages in the future and decline to delay the applicability date of the requirement we are finalizing at § 422.2267(a)(3) to the year after the date the 5 percent threshold is met. Also, we decline to delay enforcement of the requirement. We believe that the benefits of enrollees being provided required materials in non-English languages and alternate formats outweighs any additional burden by plans and are finalizing the requirement as applicable for all required materials related to CY 2024.

Comment: A few commenters requested that CMS revisit the threshold requirement at §§ 422.2267(a)(2) and 423.2267(a)(2) for translation by MA and Part D plans. The commenters recommended setting a threshold that, in addition to the percentage of individuals in a PBP

service area, includes a numerical threshold based either on the number of enrollees speaking a non-English language in the PBP service area or the number enrolled in the plan. They noted that with very few exceptions, the 5 percent standard means that the translation requirement applies only to Spanish, yet close to one million Medicare beneficiaries speak a non-English language other than Spanish. They also stated that using a percentage measure without any reference to the absolute number of individuals in a service area leaves significant swaths of individuals with LEP, particularly those in large diverse service areas, without access to any translated materials from their MA plans.

Response: We appreciate the commenters' perspectives and agree that there are few service areas in which plans are required to translate materials in non-English languages beyond Spanish. The requests for us to change the threshold for the translation requirement at §§ 422.2267(a)(2) and 423.2267(a)(2) are out of scope of this regulation. We believe policy making on this issue would benefit from further study and engagement with interested parties, including notice to the public and the opportunity to submit comments on this topic. We require MA and Part D plans to provide the multi-language insert that will inform the reader in the fifteen most commonly spoken non-English languages used in the U.S., as well as any additional non-English language that is the primary language of at least 5 percent of the individuals in a PBP service area, that interpreter services are available for free. We remind plans that they must also comply with translation requirements under 45 CFR § 92.101 and any future requirements under 45 CFR Parts 80 and 92.

Comment: A few commenters stated that the translation requirement should also apply to original Medicare materials such as the Medicare & You Handbook.

Response: We appreciate the comments. Materials sent directly by CMS are beyond the scope of this rulemaking, but we note that when individuals request the Medicare & You Handbook in Spanish or an accessible format, we continue to send them the Medicare & You

Handbook every year in the requested format (and use that preference for other CMS mailings as well).

Comment: A commenter requested that CMS increase its oversight of plan performance through secret shopper testing of language access, monitoring of language access grievances, focus groups, and other measures to hold plans accountable for compliance with language access requirements.

Response: We appreciate the suggestions for oversight of plan performance for language access. Oversight of plan performance is very important to us, and we will continue to use multiple methods to ensure that plans meet the regulatory requirements and enrollees have access to the information needed to make informed health care decisions.

Comment: A commenter highlighted the opportunity plans have to use community-based organizations (CBOs) to create, operationalize, and maintain the capacity to supply translation services as well as auxiliary aids and supports. The commenter asserted that such plan-CBO capacity-building can reach historically-underserved and linguistically and culturally diverse pockets of the country with 1) adaptive interventions and 2) interventions to improve provider-patient interactions and relationships. They noted the importance of working with community partners who may be best suited to provide these language and cultural competencies, but they also emphasized that Medicare language is “highly technical in nature” and not every CBO partner can translate this type of language. The commenter highlighted how State Health Insurance Assistance Program (SHIP) offices and their agencies are stepping up to fulfill the need for translation services where that capacity does not currently exist. They stated that CMS’s proposed language access provisions for the 2024 calendar year are necessary because SHIP counselors have limited resources and are merely scratching the surface to meet the need for translation services in their communities.

Another commenter expressed that health plan materials should provide clear information on plan benefits to both enrollees and providers, and care coordinators and navigators should be

available to discuss the options with enrollees. They noted that accountable care organizations (ACOs) can help with this, because they are more likely to have a longitudinal relationship with the patient and have a care team in place to help with outreach and coordination. The commenter also stated that ACOs and practices participating in advanced alternative payment models often have the infrastructure to use data to better identify, outreach, and successfully engage harder-to-reach patients, but they cannot do it as efficiently on their own. According to the commenter, the more standardization there is in how health plans communicate to patients and providers on how to access benefits and what resources are available to them, the better partners primary care physician practices can be in helping dually eligible individuals navigate the complex health care landscape.

Response: We thank the commenters for highlighting the important roles that CBOs, SHIPs, and ACOs play in providing potential enrollees and enrollees with their health care options. We agree that these organizations can play a vital role in working with Medicare beneficiaries with LEP since they often have close relationships with these communities.

Comment: A commenter noted the importance of using medical interpreters as a means of improving the quality of care provided to patients with LEP and patients with sensory impairments. This commenter expressed concern about the cost of providing interpreter services and that limited reimbursement is available for language access services. The commenter noted the cost of these services should be paid for by health plans and not providers. The commenter also stated that it is important that MA organizations, cost plans, and Part D sponsors adequately inform their enrollees of the ability to access interpreters and/or with written materials in their primary language or an accessible format. Finally, the commenter indicated that CMS needs to ensure the competency of interpreters. Another commenter encouraged CMS to ensure access to a translation service that helps address gaps between patient and provider fluency by continuously evaluating the quality of interpreters.

Response: We appreciate the commenters' perspectives on this issue. These comments

are outside the scope of this rulemaking to address the requirement of MA, cost, and Part D plans to provide written materials to enrollees on a *standing basis* in any non-English languages that is the primary language of at least 5 percent of the individuals in a plan benefit package service area and in accessible formats. However, we note that 45 CFR § 92.101(b)(2) discusses language assistance services requirements and requires that services must be provided free of charge, be accurate and timely, and protect the privacy and independence of individuals with LEP. Section 92.101(b)(3) also requires that services be provided by an interpreter who adheres to generally accepted interpreter ethics principles, including client confidentiality; has demonstrated proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology. In addition, 45 CFR § 92.102 discusses effective communication for individuals with disabilities. It requires entities to take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in such programs and activities. Section 92.101(b) also requires that a recipient or State exchange provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

In addition, we note that, per §§ 422.2267(e)(31) and 423.2267(e)(33), MA plans and Part D plans are required to include a multi-language insert with all required materials noting that free interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, Japanese and any additional languages that meet the 5 percent service area threshold. In addition, §§ 422.2267(e)(35) and 423.2267(e)(36) requires a statement about the availability of accommodations for persons with special needs, including a telephone number; this notice must

be in disclaimer form or within the body of the material on any advertisement of invitation to education and marketing events.

Comment: A few commenters requested that CMS extend the standing basis proposed rule to interpreter services. They stated that if an enrollee with LEP has requested an interpreter for live, real-time communication (for example, over the phone or in connection with a visit to an in-network provider), the enrollee should have the option to establish a standing order for interpretation. They also indicated that the same rule should apply to CMS itself. When requested by any enrollee who is LEP, CMS should as a matter of course note in the enrollee's Medicare record a standing order for interpretation and the language required, to be used for both incoming and outgoing calls.

Response: We thank the commenters for their input. While not addressed in this final rule, CMS did propose new standards governing interpretation services furnished in connection with plan call centers at section III.K. of the proposed rule (87 FR 79512). That proposal would require MA organizations and Part D sponsors to use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology. We did not propose to require provision of interpreter services on a standing basis nor did the proposed rule address Medicare interpreter services. As a result, this comment is out of the scope of the regulation. We learned from oversight activities, enrollee complaints, and stakeholder feedback that enrollees often must make a separate request each time they would like a written material in a non-English language or need materials in alternate formats. Since our experience was based on feedback about written materials, we focused our proposal on written materials. We will consider extending the standing basis policy to interpreter services for future rulemaking.

After considering the comments received and for the reasons outlined in our proposed rule and responses to comments, we are finalizing the proposed changes to re-designate current paragraph (a)(3) in §§ 422.2267 and 423.2267 to paragraph (a)(5) and to adopt a new paragraph (a)(3) in both regulations to require plans to provide required materials to enrollees on a standing basis in a non-English language or accessible format upon receiving a request for the materials in a non-English language or accessible format or when otherwise learning of the enrollee's primary language or need for accessible format.

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

Over 1.8 million individuals dually eligible for the Medicare and Medicaid programs speak a language other than English at home or do not speak English fluently.¹²⁵ In addition, dual eligibility is a strong predictor of poorer outcomes in an array of Medicare programs,¹²⁶ and dually eligible beneficiaries are far more likely than other Medicare beneficiaries to be from racial or ethnic minority groups (48 percent vs. 22 percent). Many dually eligible beneficiaries have low health literacy yet need to navigate a more complex system of coverage than non-dually eligible beneficiaries.

Per the definition of specialized MA plans for special needs individuals in § 422.2, all SNPs must be MA-PDs that comply with both Part 422 and Part 423 requirements. Sections 422.2267(a)(2) and 423.2267(a)(2) require dual eligible special needs plans (D-SNPs), like all other MA-PD plans, to translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. We proposed to amend §§ 422.2267 and 423.2267 with a new paragraph (a)(4) that requires that FIDE SNPs and HIDE SNPs, as defined at § 422.2, and applicable integrated plans (AIPs), as defined at § 422.561, translate all Medicare materials listed in §§ 422.2267(e) and 423.2267(e)

¹²⁵Refer to https://www.resourcesforintegratedcare.com/language_preferences/.

¹²⁶Refer to <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>

into any languages required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard at § 422.2267(a)(2). Generally, we expect that the Medicaid translation requirements would be the regulatory standard at § 438.10; however, a State may impose a higher or more stringent translation requirement on its Medicaid managed care plans than is required by § 438.10, so we believe referring to the capitated Medicaid managed care contract rather than § 438.10 is appropriate for this proposed new requirement. Specifically, § 438.10(d)(3) requires that entities make written materials that are critical to obtaining services available in the prevalent non-English languages in the service area. Section 438.10(a) defines prevalent as a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient. Section 438.10(d)(1) requires that the State establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. Under the definitions for FIDE SNP, HIDE SNP, and AIP, each of these types of plan has a companion or affiliated Medicaid managed care plan, which would itself be subject to § 438.10 and the applicable State's translation requirements for Medicaid materials described in § 438.10. We proposed to extend the translation standards applicable to the *Medicaid* materials used by FIDE SNPs, HIDE SNPs, and AIPs to the *Medicare* materials used by those plans to ensure that the dually eligible enrollees in all FIDE SNPs, HIDE SNPs, and AIPs receive all of the materials necessary for accessing and understanding all of their benefits (both Medicare and Medicaid) in a language that the enrollees understand.

The proposed modifications at §§ 422.2267 and 423.2267 would not create exceptions to other laws that govern translation of written materials provided to enrollees that we have previously described. Rather, our intent is to make it easier for dually eligible enrollees in FIDE SNPs, HIDE SNPs, or AIPs to understand the full scope of Medicare and Medicaid benefits available through such D-SNPs, which would increase their ability to make informed health care

decisions. It would also reduce the likelihood of an enrollee receiving materials in different languages (for example, some in English and some in Spanish) depending on whether the materials are governed by Medicare or Medicaid requirements.

As explained in the propose rule, we considered applying the proposed new requirement to additional or different groups of D-SNPs, such as limiting the proposal to AIPs or to organizations with D-SNP-only contracts as described under § 422.107(e), or expanding the requirement to all D-SNPs and D-SNP look-alikes (that is, the MA plans that meet the standards in § 422.514(d)) during a period before the D-SNP look-alike plan is nonrenewed or terminated. We decided to focus our proposal on all FIDE SNPs and HIDE SNPs, as defined at § 422.2, and AIPs, as defined at § 422.561, because these plans have capitated contracts with State Medicaid agencies and must already translate Medicaid materials to comply with their Medicaid managed care contracts, and would likely either have staff that are capable of translating materials into these languages or contract with organizations to perform these translations. In addition, an increasing number of dually eligible individuals are in FIDE SNPs, HIDE SNPs, and AIPs where the same organization provides coverage of both the Medicare and Medicaid services for the enrollee.

We received the following comments, and our responses follow.

Comment: Many commenters, including MACPAC, supported our proposal to require that FIDE SNPs, HIDE SNPs, and AIPs translate materials into any languages required by Medicare plus the Medicaid translation standard of the State in which the plan operates. MACPAC reported that dually eligible individuals are more likely to be from racial or ethnic minority groups than Medicare-only beneficiaries. For example, MACPAC noted in 2020, 17 percent of dually eligible individuals were Hispanic compared to 6 percent of Medicare beneficiaries who are not dually eligible. A commenter noted that when culturally and linguistically-appropriate services are not provided, some dually eligible recipients of home and community-based services have had trouble accessing the care they need. This commenter also

expressed that, if done well, integrating Medicare and Medicaid in a culturally-appropriate way could advance health equity. Another commenter stated that plans participating in the Financial Alignment Initiative (FAI) demonstrations have had to do targeted and culturally competent education and outreach, so some plans may have the necessary experience to do so in the D-SNP environment. A few commenters noted that a similar requirement was successfully applied to the MMPs in FAI and resulted in improved communication to plan enrollees.

Response: We appreciate the commenters' support for our proposed changes to require that FIDE SNPs, HIDE SNPs, and AIPs translate materials into any languages required by Medicare plus the Medicaid translation standard of the State in which the plan operates. Based on our experience with MMPs, we agree with the commenters that these changes can help improve access to care and advance health equity.

Comment: A few commenters recommended that CMS apply this translation requirement to all D-SNPs, including those that do not have affiliated Medicaid managed care plans. A commenter noted that D-SNPs are designed for and required to offer at least some coordination between Medicare and Medicaid benefits, even when Medicaid benefits are provided on a fee-for-service basis. This commenter explained that sending communications to a plan enrollee about Medicare in English—a language that the individual cannot understand—when that same member is receiving information about Medicaid benefits in another language the individual can understand is the antithesis of coordination. According to the commenter, conforming to State translation standards should be one of the core minimum requirements for all D-SNPs.

Response: We appreciate the commenters' perspectives on this issue. The requirement we are finalizing at § 422.2267(a)(4) will require HIDE SNPs, FIDE SNPs, and AIPs in certain States to translate Medicare materials into additional languages. The finalized requirement will not apply to HIDE SNPs, FIDE SNPs, and AIPs in all States because the Medicaid translation standard does not require translation for languages that exceed the Medicare translation standard in all States. However, based on the number of HIDE SNPs, FIDE SNPs, and AIPs offered by

MA organizations in contract year 2022, we estimate that the requirement will result in 73 plans having to translate materials into additional languages. We believe it is best to take an incremental approach by focusing on these D-SNPs that have capitated contracts with State Medicaid agencies and must already translate Medicaid materials to comply with their Medicaid managed care contracts. We believe these D-SNPs would likely either have staff that are capable of translating materials into these languages or contract with organizations to perform these translations.

Comment: A few commenters requested that CMS align translation thresholds at the Federal level rather than set State-specific standards. A commenter indicated that working across CMS' silos to create a single Medicare and Medicaid standard would also be beneficial to enrollees.

Response: We appreciate the commenters' input; however, the languages spoken by Medicare and Medicaid enrollees varies greatly throughout the country, so we prefer to set policy for translation requirements based on the languages needs for these programs within a service area.

Comment: A commenter requested that CMS specify that translation into State-required alternate languages apply to annual required communications only. The commenter noted that this would ensure enrollees receive their benefit information in their selected language while retaining the option to request translated transactional communications as needed. The commenter further explained that CMS could permit the States to specify in the State Medicaid agency contract (SMAC) the documents the State requires be translated into specific languages.

Response: We appreciate the commenter's perspective on this issue. However, we believe it is important for this population to receive all Medicare materials listed in §§ 422.2267(e) and 423.2267(e) and ICPs in their preferred language. We believe it would cause confusion for HIDE SNP, FIDE SNP, and AIP enrollees to receive all of their Medicaid

materials in their preferred language, some of their Medicare materials in their preferred language, and other Medicare materials in English.

Comment: A commenter requested that if CMS finalizes the translation requirement as proposed, CMS or the relevant State should provide the translated templates for any required communications and CMS should provide flexibility to meet the enrollee's needs using methods other than documents sent via US Mail. The commenter estimated that industry cost to implement the requirements as proposed would significantly exceed the combined \$12.5 million estimate CMS has noted. While the annual required materials could be plan-specific and the financial impact could be somewhat limited, the transactional communications are not plan-specific, so all of them would have to be translated to meet the proposed requirement. The commenter also emphasized there would be a significant ongoing cost to maintain translated communications after the initial implementation.

Response: We thank the commenter for these comments. CMS has translated several forms to Spanish and Chinese, including the EOC, ANOC, Formulary, LIS Rider, Part D transition letter, enrollment form, and Pharmacy and Provider Directories.¹²⁷ In addition, in response to the comment for flexibility to use other delivery methods besides U.S. mail, as we noted in a previous response, § 422.2267(d)(2)(i) states that without prior authorization from the enrollee, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials in their primary language or accessible format: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. Thus, plans do have flexibility with these materials. On average, we expect these plans to translate materials into one additional language based on our experience with MMPs where, out of nine states, only two states (California and Rhode Island) required translation of materials into additional languages that exceeds the Medicare translation standard. California required MMPs

¹²⁷Refer to <https://www.cms.gov/medicare/health-plans/managedcaremarketing/marketngmodelsstandarddocumentsandeducationalmaterial> and <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials>

to translate materials into nine additional languages in certain counties and Rhode Island required MMPs to translate materials into two additional languages.

Comment: Other commenters suggested that CMS defer to the State's translation standard, which is based on the State's understanding of their population and access needs. A commenter noted that the disconnect between the Medicare and Medicaid requirements will result in confusion, overlapping requirements, and burden on FIDE SNPs, because State languages are more relevant to the particular dually eligible individuals served than the nationally standardized set of languages. As an example, this commenter identified that FIDE SNPs in the State of Minnesota are required to translate documents into German, despite the very few German speakers in the State and many of the languages spoken by higher percentages of Minnesotans, like Somali and Oromo, are not included in the Medicare standard. These commenters recommended that Medicaid languages should supersede the Medicare languages to reduce burdens on both plans and consumers and to better service the populations in each State.

Response: We appreciate the commenters' perspective on this issue. We agree that States have a good understanding of their Medicaid population and the needs of that population. However, we disagree that there is a disconnect between the Medicare and Medicaid standards since the Medicare standards for MA, cost, and Part D plans are based on the population of the specific service area. It is more likely that the State Medicaid program translation standard will include those languages required by Medicare plus additional languages based on the Medicaid standard. For contract year 2023, in addition to those service areas that meet the threshold to translate materials into Spanish, only 16 MA contracts have service areas that meet the Medicare threshold to translate materials into Chinese and 19 MA plans and PDPs meet the threshold to translate materials into other Asian languages. There are no other service areas with additional languages that currently meet the 5 percent threshold for translation at §§ 422.2267(a)(2) and 423.2267(a)(2). While the commenter noted that that plans in Minnesota are required to translate materials into German, we believe that the commenter may be referring to the requirement that

all MA plans, per § 422.2267(e)(31), must include the multi-language insert in several languages, including German. While the multi-language insert itself is required to include German among other languages, there are no MA, cost, or Part D plan service areas that currently meet the Medicare 5 percent threshold to require translation into German.

Comment: A commenter requested that CMS incorporate the State-specific requirements into HPMS, along with the Medicare requirements, to save plans from having to find the information themselves and keep everyone consistent in the languages they are using.

Response: We appreciate the suggestion. We provided similar information in HPMS for MMPs and will consider updating HPMS to include the State-specific Medicaid requirements into HPMS for those plans that are impacted by this requirement. In addition, we note that FIDE SNPs, HIDE SNPs, and AIPs all have contracts with the State or an affiliated plan which should include information regarding the State's translation requirements for the Medicaid managed care organization or where they may obtain this information.

After considering the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the requirement at §§ 422.2267(a)(4) and 423.2267(a)(4) as proposed.

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)

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

We received no comments on this proposal. We are finalizing these revisions as proposed for the reasons outlined in the proposed rule.

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

In the December 2022 proposed rule, we proposed a number of changes to Subpart V of both §§ 422 and 423 regulations. These changes include submitting marketing materials into the Health Plan Management System, prohibiting the use of the Medicare name, CMS logo, and products or information issued by the Federal Government in a misleading way; prohibiting the use of superlatives (for example, words like “best” or “most”) in marketing without supporting data which reflects content for the current or prior year; prohibiting marketing of benefits in a service area where those benefits are not available; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell; prohibiting marketing based on information about the savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, costs for which dually eligible beneficiaries are not responsible, or other unrealized costs of a Medicare beneficiary; clarifying that the prohibition on door-to-door contact without a prior appointment applies even after an agent or broker has collected a BRC or SOA; notifying enrollees annually that they can opt out of plan business calls; prohibiting the distribution of Scope of Appointment and Business Reply Card forms at educational events; prohibiting sales events to directly follow educational events; requiring 48 hours between the Scope of Appointment and an agent meeting with a beneficiary; limiting Scope of Appointments and Business Reply Cards to a six month timeframe from the submission of a Scope of Appointment (SOA) or Business Reply Card (BRC); requiring website provider directories be searchable by all required elements (for example, name, phone number, address); adding “effect on current coverage” to the Pre-enrollment Checklist (PECL), as well as requiring agents to review the PECL with enrollees; requiring plans to list benefits at the beginning of the Summary of Benefits (SB) and in a specified order; labeling the non-renewal notice as standardized rather than a model, consistent with CMS’s guidance instructions; modifying the TPMO disclaimer to add State Health Insurance Programs (SHIPs) as an option for beneficiaries

to obtain additional help; requiring MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS; requiring agents and brokers to go over a CMS list of required elements with an enrollee prior to enrollment; limiting the requirement to record calls between third-party marketing organizations (TPMOs) and beneficiaries to marketing (sales) and enrollment calls; clarifying the requirement to record calls between TPMOs and beneficiaries such that it is clear that the requirement to record applies only to calls that result in an enrollment and includes virtual connections such as Zoom and FaceTime; and, prohibiting the distribution of data by TPMOs. We are finalizing, in some cases with modifications, the majority of the proposed policies in this final rule. We are not addressing our proposal to prohibit the distribution of data by TPMOs in this final rule but, may address it in a future final rule.

The regulatory changes for Subpart V of Parts 422 and 423 are applicable for the 2024 Contract Year and beyond; thus applying to marketing and communications materials and activities beginning for the 2024 Contract Year; current regulations require the distribution of 2024 materials beginning September 30, 2023.

Sections 1851(h) and 1851(j) of the Act, which address MA, provide CMS the authority to review marketing materials, develop marketing standards, and ensure that marketing materials are accurate and not misleading. These provisions also provide CMS with the authority to prohibit certain marketing activities. Section 1856(b)(1) of the Act authorizes CMS to adopt standards, through rulemaking, standards that are consistent with, implement and carry out the Medicare Advantage statutory provisions. In addition, sections 1876(i)(3)(D), 1857(e)(1) and 1860D-12(b)(3)(D) of the Act provide CMS the authority to adopt additional contract terms for cost plans, MA plans, and Part D plans when necessary and appropriate. Likewise, section 1860D-1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) of the Act for approval of marketing materials and application forms for Part D plan sponsors. Section 1860D-4(l) of the Act applies certain

prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations. In addition, sections 1852(c) and 1860D-4(a) of the Act require organizations to provide certain materials to Medicare beneficiaries concerning MA and Part D plan choices, benefits coverage, and other information to make informed enrollment decisions. These statutory provisions help ensure Medicare beneficiaries are informed, and thus have sufficient knowledge to assist in protecting them when making an election to enroll in an MA (including MAPD) or Part D plan. We believe the changes proposed and adopted in this rulemaking strengthen CMS' ability to ensure MA and Part D marketing to beneficiaries is not misleading, inaccurate, and/or confusing. Additionally, under 42 CFR 417.428, most marketing requirements in subpart V of part 422 apply to section 1876 cost plans as well. (75 FR 19783 through 19785)

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

In accordance with regulations at §§ 422.2261(a) and 423.2261(a), MA organizations and Part D sponsors (MA organizations/Part D sponsors) must submit all marketing materials, all election forms, and certain designated communications materials for CMS review. The HPMS is CMS' system of record for marketing materials.¹²⁸ In the past, §§ 422.2261(a)(3) and 423.2261(a)(3) prohibited third-party and downstream entities from submitting materials directly to CMS, unless specified by CMS. In the January 2021 final rule, we modified §§ 422.2261(a)(3) and 423.2261(a)(3) to provide CMS the flexibility to allow third parties to submit materials directly to CMS in the future (86 FR 5998). CMS made this modification in anticipation of operational changes to HPMS, which occurred in May 2021. Prior to the HPMS changes, third-party materials were submitted into HPMS, but the TPMO was required to send materials to an MA organization or Part D sponsor and have the MA organization or Part D sponsor submit the materials on the TPMO's behalf. These system changes permitted third parties and downstream

¹²⁸73 FR 2257, 78 FR 32257 and 83 FR 659

entities, such as TPMOs, to submit materials directly to CMS following the receipt of prior approval from at least one MA organization or Part D sponsor. In cases where a TPMO document only markets one MA organization/Part D sponsor, there would be no change for the TPMO, meaning they would still send the document in through the MA organization/Part D sponsor who would submit it into HPMS. For TPMOs that develop materials for more than one MA organization/Part D sponsor, the TPMO would submit the material directly to CMS. Based on CMS' operational change, we proposed to require TPMOs, as defined at §§ 422.2260 and 423.2260, to submit their marketing materials developed for multiple MA organizations and Part D sponsors (and their specific plans) to CMS through HPMS. Specifically, we proposed to remove §§ 422.2261(a)(3) and 423.2261(a)(3), which as implemented prohibited TPMOs from submitting materials the TPMO alone developed, and modify §§ 422.2261(a)(2) and 423.2261(a)(2) to require that marketing materials developed by a TPMO for multiple plans must be submitted into HPMS by the TPMO. In addition, submission may only occur after the TPMO receives the prior approval of each of the MA organizations or Part D sponsors on whose behalf the materials were designed and developed by the TPMO.

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. Prior to this change, if the marketing material was sent in by the one "lead" organization, the "non-lead" organizations were automatically included in the marketing piece.

Comment: The vast majority of commenters supported our proposal to require TPMOs to submit marketing materials to CMS through the HPMS. One commenter supported the proposal but was concerned about the burden if all plans did not opt into the marketing piece.

Response: CMS thanks the commenters for supporting our proposal to require TPMOs to submit marketing materials into HPMS. Regarding the concern about plans that may not have opted in, a TPMO may not use the marketing piece for any plan that does not opt into the piece.

Comment: We received a few comments opposing our proposal. Commenters generally stated that the current process is cumbersome and inefficient, requiring a TPMO to receive approval from every plan prior to submission into HPMS. One of the commenters suggested that a single plan serve as the reviewer for multi-marketing plan materials submitted by the TPMO while another commenter suggested CMS return to the former process where one plan submitted on behalf of the TPMO.

Response: We appreciate the comments. Our proposal does not change our current process. Currently, marketing materials are required to be submitted to CMS, with HPMS being the method of submitting materials. The current regulation was written, stating that TPMOs may submit materials into HPMS, in preparation for a major HPMS marketing module change. The marketing module change took place in May 2021, which changed the way third party materials were submitted. We proposed to modify the regulation to make the submission of multi-plan marketing materials in HPMS a requirement, instead of a “may,” which, as previously stated, was in preparation for our systems change.

This 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. With this new process CMS can better hold MA organizations and Part D sponsors responsible for the actions of their first tier, downstream, and related entities and, therefore, we believe that MA organizations and Part D sponsors should know and approve of the materials being used to market their products.

Comment: We received one comment opposing requiring TMPOs to submit materials on behalf of employer group waiver plans (EGWPs).

Response: Currently, our Medicare Communication and Marketing Guidelines (MCMG) do not require EGWPs to submit communication or marketing materials in HPMS, provided the materials are specific to the EGWP(s). The HPMS material submission requirement is waived (for TPMOs and EGWPs) when the materials are only applicable to and used for EGWPs.

After review of the comments and for the reasons outlined in the proposed and our responses to comments, we are 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.

2. Prohibit the use of the Medicare name, CMS logo, and products or information issued by the Federal Government in a misleading way.

CMS proposed to add a new sub-subparagraph (xix) to § 422.2262(a)(1) and a new sub-subparagraph (xviii) to § 423.2262(a)(1) to address the use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card. CMS is aware of concerns from external stakeholders about marketing activities and documents that appear to be from Medicare, CMS, or the Federal Government. Through beneficiary complaints and CMS surveillance activities over the years, we have seen the word “Medicare” in names of store fronts, on notices or postcards where “Medicare” is in large font while disclaimers are miniscule, and in television advertisements where a beneficiary could assume that the advertising is coming from CMS or the Medicare program in general. We have also seen logos that are very similar to the Health and Human Services (HHS) logo, on websites and print materials. These logos have featured circles with writing around the circle and a bird, wings, or other images that appear to be the same image used by the Federal Government. There are also numerous third-party internet sites with “Medicare” in the URL or a logo similar to the HHS

logo, potentially causing a beneficiary to click on a private site when they intend to go to Medicare.gov or are seeking official Medicare information or access. Often, it appears as if the materials urging the beneficiary to “take action” are from Medicare, or that these third parties represent Medicare or the Federal Government. With the increase of third parties in the marketplace, based on CMS’ surveillance and complaints received (especially through 1-800-MEDICARE), we are concerned that an increasing number of beneficiaries are being misled into believing the entity they are contacting is Medicare or the Federal Government. One specific example, provided by a Medicare beneficiary, is a postcard with the beneficiary-named address with “Medicare Notice” in large, bold letters at the top along with “Personal & Confidential” and “Important Medicare Information.” This postcard also had a “Medicare Information” box listing a “Customer ID,” formatted to look like an official Medicare beneficiary number. This misleading postcard appeared to be an official document disseminated by the Federal Government. In our review of complaints received through 1-800 MEDICARE, CMS discovered other examples of beneficiaries who mistakenly believed they were calling Medicare rather than a private MA or Part D plan or its agent or broker, likely based on the receipt of a flyer using the word “Medicare” in a way that conveyed to the beneficiary that they must call the telephone number on the mailer. These complaints illustrate that the use of the Medicare name is at times confusing and misleading to Medicare beneficiaries. CMS can see no value or purpose in a non-governmental entity’s use of the Medicare logo or HHS logo except for the express purpose of sowing confusion and misrepresenting itself as the government.

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. We are therefore concerned that the use of the term “Medicare” in situations like those, as previously described, erroneously leads beneficiaries to believe that Medicare-related communications or advertising are disseminated or

endorsed by Medicare or the Federal Government, when in actuality such communications are being disseminated by the MA organizations/Part D sponsors themselves, or by entities operating on behalf of the MA organizations or Part D sponsors. Although the types of plan communications, previously described, that feature the word “Medicare” typically include disclaimers that state the information presented is not connected to or endorsed by the Federal Government or the Medicare program, these disclaimers are often tiny, difficult to read, and are mixed in with other CMS-required disclaimers as well as plan-developed, non-required, disclaimers. While CMS already prohibits inaccurate or misleading information under §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), we believe it is important to specifically prohibit the misleading use of the Medicare name, CMS logo, and products or information issued by the Federal Government, 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). We are not including the Medicare Part D mark, as CMS gives Part D sponsors contractual permission to use the mark. With these proposals, we intended to firmly and clearly prohibit the improper use of these terms and logos. Therefore, we proposed 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. We acknowledge that reasons exist to use the Medicare card image, which we will permit with authorization from CMS.

Since CMS contracts with MA organizations and Part D sponsors and those contracts incorporate requirements to comply with part 422 and part 423 regulations, CMS holds these organizations accountable for the actions of their first tier, downstream and related entities (FDR), per §§ 422.504(i) and 423.505(i); in addition, CMS requires MA organizations and Part D sponsors to include in their contracts with first tier, downstream and related entities that any services or activities conducted by the first tier, downstream or related entity are performed in accordance with the MA organization’s or Part D sponsor’s obligations under its contract with

CMS. If CMS determines that the Medicare name, CMS logo, or official products like the Medicare card, have been used in a misleading manner by an FDR, CMS would address the issue with the MA organization or Part D sponsor on whose behalf the FDR was operating and hold the sponsoring organization accountable for the misleading information.

Comment: We received numerous comments supporting our proposal limiting the use of the Medicare name, logo, and products. Some commenters supporting our proposal did request that we 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.

Response: We appreciate the support for this proposal. We agree with the commenters that there are instances where the use of the word “Medicare” or the image of the Medicare card are both necessary and not misleading. Situations such as identifying the difference between a MA organization’s or Part D sponsor’s card from the Medicare card, displaying a picture of the Medicare card to remind beneficiaries that they do need to keep the card safe, even though they are in a Medicare Advantage plan, and showing the card so a beneficiary knows where to find their Medicare Beneficiary Identification number serve legitimate and important purposes. To ensure that the Medicare card image is not being used inappropriately, we are requiring organizations, including first tier, downstream, and related entities to receive authorization from CMS prior to the use of the image. This will ensure that the card is only being used in educational ways and not for marketing purposes.

Comment: We received one comment opposing this 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.

Response: Ensuring that beneficiaries can recognize and trust that materials are from Medicare or the federal government is important. Specifically prohibiting 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), will protect beneficiaries. Website names containing “Medicare” such as “medicare.com” may easily be confused with Medicare.gov. Although sites may have a disclaimer stating they are not a governmental agency, the disclaimer may be small, at the bottom of a very long page, or hidden in another page, all of which can make the disclaimer difficult for a beneficiary to notice on the website.

Disclaimers or taglines that are prominently placed, in a font size and color to be readily noticed, and that clearly explain that an entity or website is not affiliated with, endorsed by, or otherwise somehow related to the federal government, CMS, HHS, and/or Medicare are essential. Additional information or factors may contribute to, or alternatively, actually eliminate the potential for use of the Medicare name, CMS logo, and products and information issued by the federal government to be confusing or misleading to enrollees or potential enrollees. 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 this provision we are finalizing. Plans and their TPMOs need to take the necessary steps to ensure that their marketing and communication materials and activities comply.

Based on 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.

3. Prohibiting the use of unsubstantiated statements without supporting data.

In our January 2021 final rule, we prohibited plan use of unsubstantiated statements except those used in taglines and logos in 42 CFR §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii). Prior to the January 2021 final rule, we had prohibited the use of unsubstantiated superlatives and pejoratives, except when used in logos and taglines, through our Medicare Communications

and Marketing Guidelines. In the December 2022 proposed rule, we proposed to further restrict the use of superlatives by prohibiting all superlatives unless substantiating supporting data is also provided with the material and essentially adopt a regulation that builds upon our prior guidance. We proposed this for all superlatives, including those used in logos and taglines. Previously, CMS generally required plans to provide substantiating data to support the use of a superlative. However, that substantiating information was only provided to CMS, resulting in the beneficiary seeing the superlative without any context. Currently, a beneficiary may have no knowledge of how the superlative is determined, potentially misleading the beneficiary to believe a statement that may be partially or mostly true, but is lacking context and important specificity. For example, an MA organization may advertise that it has the *largest* fitness network, which may be accurate if all fitness facilities in their national network are considered. However, when looking at a particular service area, the MA organization advertising the largest fitness network may only have two contracted facilities, but another organization may have eight contracted facilities. The advertisement of the largest fitness network would be mis-leading, potentially enticing a beneficiary to enroll in a plan based on inaccurate information. Permitting the use of superlatives without specific information explaining the basis or context that is relevant to the prospective enrollee is potentially misleading to beneficiaries so we have reconsidered the scope of §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) as previously finalized.

CMS believes it is critical to provide 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. This documentation and/or data can be referenced through footnotes explaining the basis, noting the source (with enough information for a beneficiary to locate), or providing the actual comparison done to determine the superlative. For example, if an organization stated that they have the lowest premiums, the organization must identify the specific MA or Part D plan and their premium and the premiums of other plans in the service area, or reference a study, review, or other

documentation that supports the superlative and with which the beneficiary can make accurate comparisons between plans.

We also proposed to add a requirement that the supportive documentation and/or data be based on current data. Our proposed regulation text requires that the supportive documentation or data must reflect data, reports, studies, or other documentation to have been published either in the existing contract year or the prior contract year. For example, a plan could not make the statement in CY 2022 that they have the largest provider network in an area using 2018 data. Rather, in CY 2022, the statement that a plan has the largest network (of providers or pharmacies) in an area must be supported by documentation and/or data published January 1, 2021 or thereafter. Data and the underlying situations can be dynamic and change over time, therefore, CMS proposed that recent data, meaning the current or the prior contract year data, are the only data that may be used to substantiate superlatives. We believe any data older than the prior contract year may be misleading, given the age of the data and the potential that the data has changed. Based on this, we 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.

Comment: CMS received numerous comments supporting the requirement to use current year or previous year data.

Response: CMS thanks those supporting our proposal. Requiring that a superlative statement be based on data about current or recent circumstances will ensure that beneficiaries can make decisions informed by accurate information that best reflects the plan options at the time the beneficiary is choosing among MA and Part D plans.

Comment: 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.

Response: We thank that commenter for identifying the potential issue and providing a recommended solution. We agree that more precise language is necessary. It may be possible for a study published in 2023 to be based on data from 2018 and using that information would not be consistent with our goals and intent for this rule. Ensuring that superlative statements, which lack nuance, are supported by current and relevant data is at the heart of our goal for the proposed revision to §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii). We are finalizing the proposed change with modifications from our proposal, including using the phrase “that applies to” instead of “has been published.” Information applying to the current or prior contract year means information that is about, from or based on the current or prior contract year.

Comment: One commenter partially supported the proposal, stating that their support was contingent on permitting citations to be used as the documentation.

Response: As proposed, the amendments to paragraphs (a)(1)(ii) required “sources of documentation or data supportive” when using superlatives. CMS considers 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.

Comment: CMS received one 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.

Response: CMS understands the concerns and agrees with the commenter that advertisements describing long-standing positive performance should not be prohibited by the two-year data requirement. It was not our intent to prohibit advertising an organization’s long-standing positive performance, but rather to ensure that the performance advertised is about the

current or previous contract year. If an organization has maintained the high performance for the current and previous contract year, as well as years prior, CMS will permit the advertising of the past two years' worth of data. For example, if an organization's contract has received five Stars (CMS Star ratings) for the past five consecutive years, the organization may advertise that they have received five Stars since X date. 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 a five Star rating since X date or in Y years out of the past five years.

After consideration of the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposal with two minor modifications. First, we 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, we 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.

4. Prohibition on advertising benefits not available in a service area.

In §§ 422.2263(b) and 423.2263(b), we proposed adding a new (8) which prohibits organizations from advertising benefits not available in a service area, unless doing so is unavoidable in a local market. This prohibition is codifying our previous guidance outlined in section 30.1 of the 2016 Medicare Marketing Guidelines (MMG),¹²⁹ providing that marketing activities should be limited to a plan's service area unless doing so was unavoidable, such as advertising in a local newspaper that may be distributed outside a service area. In cases where

¹²⁹<https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2016-Medicare-Marketing-Guidelines-Updated.pdf>

marketing outside a service area was unavoidable, CMS's guidance provided that the plan's service area be disclosed.

Over the past few years, CMS has seen a significant increase in national marketing which promotes benefits such as dental, vision, and money back on a beneficiary's Social Security check. While many of these benefits are available to a large number of beneficiaries, they are not available in all service areas, or to all Medicare beneficiaries in the amounts often advertised. For example, in 2021 there were national advertisements that claimed a beneficiary "could get up to \$144 back" on their Social Security check, which would be accomplished through a reduction in the beneficiary's Medicare Part B premium. A premium reduction of this magnitude would have covered most of the standard 2021 Part B premium of \$148.50. However, during CYs 2021 and 2022, the only states or territories that had plans with a reduction of \$140 or more were California, Florida, and Puerto Rico. Further, the plans offering the \$140 or more premium reduction were not available in all counties in those locations. Since beneficiaries in more than 60 percent of states only had access to plans that offer a Part B premium reduction of \$99.00 or less in CY 2022, advertising on a national or even a regional level that a beneficiary can get up to—or even close to—the full amount is potentially misleading. And although MA plans in over 30 percent of states and territories offered a Part B premium reduction of \$100 or more in CY 2022, those plans were not available in all counties in those locations. These national advertisements publicize that a beneficiary can get up to a certain dollar amount (for example, \$144) even if there are no plans available in the state or location where the advertisement runs that offer any dollar amount close to \$144. CMS believes that if a plan offering "up to" the top dollar amount is advertised as available for enrollment, then such a plan should be available to beneficiaries who are receiving or exposed to the advertisement where they reside. A beneficiary calling, based on an advertisement touting up to \$144 back, would expect that plans would be available that provide a reasonable Part B premium reduction. However, the actual reduction available for many beneficiaries in various locations may be minimal, anywhere from

\$1 to \$25, significantly below the “up to” advertised amount; or in other cases, there may not even be a Part B premium reduction in that particular service area. We believe this practice is a misleading tactic to entice beneficiaries to call the number and potentially enroll or switch them into another plan, regardless of whether the plan offers any Part B premium reduction or a reduction of the scope that is advertised, resulting in a plan choice that may not be well-suited to meet the beneficiary’s health care needs.

A similar issue exists for other MA benefits such as dental, vision, and hearing, as well as Part D benefits, non-formulary medications, and over-the-counter medications. In the past, national advertisements have promoted plans with high dollar amounts for certain benefits, for example, a \$2,500 dental benefit on a national level. While many beneficiaries have access to MA plans with some level of additional dental, vision, and hearing benefits, CMS believes advertising that high dollar amount is misleading when some markets may not have access to a plan with any dental benefit, while others may only have access to a plan with limited dental benefits (for example, \$500).

Based on CMS’ marketing surveillance of recorded calls,¹³⁰ CMS has learned that once the beneficiary places a call to the advertised number, the agent often markets an MA or MA-PD plan that offers a premium reduction at a much lower level than the advertised dollar value or that does not provide a Part B premium reduction at all, or a plan with more limited dental, hearing, or vision than was advertised. Once the agent or broker has the beneficiary on the line, the beneficiary is put in a position of trying to end the call or listening to an agent sell a plan in which he or she was not interested, potentially resulting in the individual enrolling in a plan that does not offer the advertised benefits. Because of the initial call, which was based on unavailable benefits, the beneficiary may end up enrolling in a plan that does not best meet the individual’s health care needs. In this situation, the beneficiary may have benefited by staying in

¹³⁰CMS has retained the recordings of these calls. The calls include sensitive information, and as such, we believe it would be inappropriate and illegal to include them as part of this public record.

the individual's existing plan, and may have stayed in that plan, if not for the advertisement urging the beneficiary to call to "get the money they deserve."

When a plan advertises benefits that are not available to beneficiaries in the service area where the advertisement airs, that type of marketing is misleading. Therefore, we proposed a new paragraph (8) at §§ 422.2263(b) and 423.2263(b) that provides that MA organizations and Part D sponsors may not engage in marketing that advertises benefits that are not available to beneficiaries in the service area where the marketing appears, unless unavoidable in a local market.

Comment: CMS received numerous comments supporting this proposal.

Response: We thank the commenters for their support.

Comment: Some commenters requested clarification on what "unavoidable" means in the context of this proposed new rule.

Response: CMS thanks the commenters for requesting clarification on the term "unavoidable." As proposed and finalized, §§ 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. We discuss examples here of permissible exceptions and will provide examples and additional assistance in our Medicare Communication and Marketing Guidelines.

One example of unavoidable marketing would be a newspaper advertisement in a metropolitan area which is distributed to beneficiaries that live within the metropolitan area, but the beneficiaries do not live within the service area of the plan for which the particular benefits are being marketed. For example, an MA organization advertises dental benefits up to \$3,000 in a Washington, D.C. newspaper. This benefit is only applicable to the plans being sold by the MA organization in Washington, D.C. However, the local distribution of this newspaper encompasses Washington, D.C., parts of Maryland, and parts of Virginia. In this case, the marketing of benefits that are not available to the full scope is unavoidable since the "normal"

distribution of the local newspaper is greater than the service area of the plan, about which the benefits are being advertised.

Another example would be a local television commercial airing in a specific market, but that may be picked up in an adjacent market. For example, Baltimore television channels can be seen in parts of the Washington, D.C. market and vice versa. An MA organization advertising benefits available through plans with service areas that encompass Baltimore on a Baltimore television station would result in unavoidable marketing for those beneficiaries in the Washington, D.C. market who are able to access Baltimore stations.

The exception we are finalizing for unavoidable marketing does not apply for any national marketing, so new paragraph (b)(8) includes an exception only for marketing in local media that covers the service area(s) for the benefits. 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, especially since Medicare Advantage is not available in every county in the United States and its territories.

Comment: Some of the commenters supported the proposal, but also requested that we permit the marketing of benefits if a certain percentage of plans in that marketed area offered the benefits. For example, if 70 percent or more of the plans offered dental, vision, and hearing the marketing could state “most plans offer...”. If 50 percent to 70 percent offered vision, dental, and hearing the marketing piece could say “many plans offer...”.

Response: We appreciate the commenters suggestions. However, we believe limiting 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. Benefits can vary greatly by service area, individual plan, and by type and value of the benefits offered.

A company, especially a TPMO, that advertises that most plans offer dental, vision, and hearing is providing very little specific information relevant to the beneficiary and what plans are available in the beneficiary's service area and the actual benefits offered. There may be no plans in a beneficiary's service area that offer hearing benefits, making this marketing inaccurate for this beneficiary, even though hearing is available in 80 percent of the plans the TPMO offers. In addition, even if vision, dental, and hearing benefits were all available, it is important to provide the value of these benefits that are available to the beneficiaries that are exposed to these advertisements and marketing, so that the beneficiaries have the information that is useful in making an informed decision about their health care. For example, the vision benefit advertised nationally in a generic way could be \$50 per year and the dental benefit may only include cleanings. We have seen vague ads, which we believe are leading or at least have significant potential to lead beneficiaries to believe the benefit available in their area is a more valuable benefit, covering dental covering fillings, root canals, and dentures, when the benefit is actually of lesser value.

To make the advertising of benefits useful for beneficiaries to choose the best plan for their needs, organizations would need to provide a benefit amount associated with the benefits offered. For example, if a TPMO advertised that 85 percent of the plans represented by a TPMO may offer hearing benefits, the plans offering hearing benefits may be limited to one geographic region, while plans in other regions do not offer hearing. Another concern is advertising that plans may have hearing benefits up to \$3,000. In this case there may only be one plan that offers more than \$1,000 in hearing benefits, while all of the other plans offer \$1,000 or less in hearing benefits. To permit the advertising of up to a certain amount, even if it states the beneficiary "may" be eligible could lead a beneficiary to believe the benefits available to them are far greater than the benefits actually available.

Comment: CMS received a few comments opposing this proposal. A commenter stated that plans would have to create multiple materials to address different benefits for each specific

area. The commenter noted this would be especially problematic for regional plans who have multiple products spanning across large areas.

Response: CMS appreciates the comments. We disagree that plans will face significant issues in accurately marketing available benefits. 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. If a plan has four markets and wants to advertise dental up to \$4,000, the plan can use the exact same advertisement for all markets and simply switch out the dollar amount offered to reflect the appropriate amount for the dental benefit in each individual market. Protecting beneficiaries from misleading advertisements promoting benefits for which beneficiaries are ineligible far outweighs the perceived burden of organizations having to create marketing materials that specifically reflect the benefits offered by their plans in specific service areas. In addition, over the past year, CMS has seen a decrease in the number of advertisements promoting specific dollar amounts, especially with respect to the Part B premium buydown and has not received complaints from plans regarding the burden of producing advertisements that more accurately reflect the actual benefits being offered.

CMS recognizes the majority of the advertisements discussed here are tailored to Part C benefits. However, we believe it is necessary to include this proposal in the Part D regulations as well to account for the instances where a Part D plan does or may advertise benefits that are not available in a particular service area. After review of the comments received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing new paragraph (b)(8) in §§ 422.2263 and 423.2263 as proposed.

5. Prohibits marketing unless the names of MA organizations or Part D sponsors being advertised are clearly displayed.

We proposed a new paragraph (9) at §§ 422.2263(b) and 423.2263(b) to prohibit marketing unless the names of the MA organizations or Part D sponsors that offer the benefits being advertised are clearly identified. In cases where the MA organization or Part D sponsor

uses a specific marketing name, as identified in HPMS, that marketing name can be used in place of the MA organization or Part D sponsor name. CMS has seen an increase in the marketing of benefits, through television, websites, and mailers that mention additional benefits such as dental, vision, hearing, as well as low or zero-dollar premiums. These advertisements do not identify which product(s), plan(s), or specific plan(s) benefits are being advertised, but rather speak generically about those items and serve to generate sales leads and obtain beneficiary contact information.

There are specific reasons for advertisements to contain the MA organization's and Part D sponsor's names. We believe including the names in the advertisement will help the beneficiary understand that they are calling a plan, a plan representative (including an independent agent) and not Medicare or another non-profit, neutral agency such as a State Health Insurance Program (SHIP). Adding the names of specific organizations or sponsors provides the necessary information for a prospective enrollee to know if they reach out because of the advertisement they saw, they are contacting an individual connected to a particular MA or Part D plan. In addition, when an advertisement provides a name, a prospective enrollee can do additional research on the plan before reaching out to the plan, including reviewing their Star Ratings and complaint rates. The prospective enrollee could also discuss the plan with relatives or friends, whom they trust to help make health care decisions. All of these factors allow a prospective enrollee to make a more informed decision on whether they want to contact the particular plan's agent to learn more.

Not only does this proposed policy assist beneficiaries, it will also assist CMS and MA organizations and Part D sponsors to ensure the marketing reflects the appropriate MA organizations and Part D sponsors. CMS also proposed (and finalized in section III.I.1) to require, instead of permitting, TPMO developed marketing to be submitted into HPMS. Under both policies, the TPMO must ensure each MA organization or Part D sponsor on whose behalf the materials were created or will be used was reviewed. Under the revisions to

§§ 422.2261(a)(2) and 423.2261(a)(2), as proposed and finalized, once TPMO materials are submitted, each MA organization or Part D sponsor would decide whether they want the TPMO to use that particular marketing material on their behalf. Even though organizations have already reviewed the piece prior to the TPMO submission, we are providing an organization the ability to decide if they want the TPMO to use the piece. If an MA organization or Part D sponsor “opts into” the material, the TPMO may then use it on their behalf and market those organizations. If the MA organization or Part D sponsor “opts out” of the marketing material, then the TPMO would not have permission to market *those specific organizations*. In addition, we do permit TPMOs to add additional MA organizations and Part D sponsors to the HPMS submission. These added organizations also decide if they want to opt in or opt out of each specific marketing piece. All organizations are permitted to change their original opt in or opt out at any time. This may be necessary in case an organization stops contracting with a specific TPMO or the organization has just decided to limit marketing by the TPMO.

By requiring MA organization and Part D sponsor names in marketing materials, both CMS and the organization would then be able to ensure that only those MA organizations and Part D sponsors who opted into the TPMO using the material are being advertised in that material. And CMS oversight and review of marketing materials would be more effective and efficient. If CMS determines a material is misleading, we will then be able to identify the organizations from the advertisement, compare them to the ones that opted in and address the issue with those organizations who opted into the TPMO material. This will allow CMS to quickly notify the MA organization or Part D sponsor of the issues, have the organization resolve the issues, and get the misleading materials out of circulation quickly.

Therefore, we 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, beneficiaries will have knowledge of who they are contacting.

In addition, we 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. We proposed including requirements in this new paragraph (9) to ensure the information is comprehensible and visible. We 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 be only be displayed in the disclaimer or fine print. We use the phrase "fine print" as it is generally defined to mean printed matter in small type or print displayed in an inconspicuous manner. For television, online, or social media-based advertisements, we 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, we proposed that these names must be read at the same speed as the phone number. To implement these new requirements, we proposed new paragraphs (b)(9)(i), (ii), and (iii), respectively. (In the proposed rule, we mistakenly identified these as paragraphs (b)(9)(A), (B), and (C) but use the correct references here.)

Comment: CMS received a number of comments supporting this proposal.

Response: CMS thanks the commenters for their support.

Comment: We received a few comments opposing this proposal. One commenter noted that there would be too much information on the advertisement.

Response: CMS does not believe that a concern that the names of the plan or organization being marketed is "too much information" justifies not finalizing the proposal. Beneficiaries

need to have certain information to make informed decisions. By having the names of organizations or plans being marketed available on the advertisements, beneficiaries will have necessary and appropriate information to decide whether they want to contact the organization, plan, or TPMO, based on the organizations the TPMO represents.

Comment: Another commenter noted that advertisements would need to be pulled if a plan did not opt into the TPMO advertisement.

Response: CMS has 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. The revisions to §§ 422.2261(a)(2) and 423.2261(a)(2) are clear that prior review of the organization is necessary before the TPMO submits the materials. If a TPMO provides the marketing material to organizations and updates the material appropriately based on comments, the TPMO’s material should be opted-in by the organizations, eliminating the need for the piece to be pulled.

After review of the comments received and for the reasons outlined in the proposed rule and our responses to the comments, we are 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.

6. Prohibit the marketing of “savings” not realized.

We proposed to add a new paragraph (10) to §§ 422.2263(b) and 423.2263(b) to address the marketing of “savings” for beneficiaries. As part of our marketing surveillance and reviews, CMS has seen advertisements touting that a beneficiary can save \$9,000 or more on their prescription drugs, or over \$7,000 in health care expenses, if they join a particular Part D plan or MA plan. In the example referring to savings for prescription drugs, advertisements included a small disclaimer stating that the “savings” figure is based on the usual and customary price that

someone without prescription drug insurance would pay. In other examples, MA organizations, Part D sponsors, or TPMOs have marketed dual eligible special needs plans (D-SNPs) that provide a “savings” of over \$7,000. In this instance, the “savings” described in the advertisement refers to the Part B Medicare premium and cost sharing amounts that are covered by Medicaid for full-benefit dually eligible beneficiaries, or are the costs saved through a prescription drug savings program, in which the eligibility for the program is based on income. However, with both of these examples, most beneficiaries are not saving the advertised amount of money because they would never have incurred many of those out-of-pocket expenses. Specifically, a beneficiary who already has prescription drug coverage (such as a current Part D plan or other creditable prescription coverage from before the individual became eligible for Medicare) would not save \$9,000 in out-of-pocket costs by switching to the advertised plan because they already had coverage for their drugs through a different plan. This advertised “savings” is only applicable if the beneficiary currently had no drug coverage, meaning they had to pay the retail cost for all of their drugs out-of-pocket. In the case of significant savings on Part C benefits, some of these advertised savings required dual eligibility, but only included information about this requirement in fine print stating that the individual may need to be income eligible or Medicare and Medicaid eligible in order to receive the advertised savings. However, since dually eligible beneficiaries already have Medicaid coverage or may already be enrolled in a D-SNP, those individuals would not be saving the full \$7,000, because they never paid the full \$7,000 in their previous or current plan. Further, if the beneficiary is eligible for Medicaid to pay certain costs on the beneficiary’s behalf (such as payment of Part B premiums) or is protected from paying cost sharing by § 422.504(g)(1)(iii), the advertised savings are not specific to the advertised plan because the same “savings” would accrue if the individual enrolled in any available D-SNP.

We believe that these commercials and other types of advertising (for example, direct mailers) using these techniques and descriptions 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. To address these concerns, we 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.

Comment: Many commenters supported this proposed change agreeing that the change would reduce the potential for misinformation.

Response: We appreciate the support from these commenters.

Comment: A commenter stated that CMS should not prohibit advertising savings associated with enrolling in Part D coverage. The commenter suggested that CMS instead require appropriate disclaimers where such “savings” are discussed.

Response: The commenter may have misunderstood CMS’s proposed change. CMS did not propose to 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. As proposed and finalized, the amendment to add new paragraph (b)(10) to §§ 422.2263 and 423.2263 specifically prohibits advertising “savings” 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. Advertisements based on comparisons to specific costs that a Medicare beneficiary would or could face—such as accurate comparisons of plan copayments for specific services to original Medicare cost sharing for the same services, are permissible, subject to our marketing rules. CMS believes it is better to prohibit misleading

language in advertising rather than requiring a disclaimer on the advertising indicating how the language is misleading.

After review of the comments received, particularly the extensive support for the proposed change and for the reasons outlined in the proposed rule and our responses to the comments, CMS is finalizing the revision to add a new (10) to §§ 422.2263(b) and 423.2263(b) as proposed.

7. Clarify door to door solicitation.

We proposed adding a new paragraph (A) to §§ 422.2264(a)(2)(i) and 423.2264(a)(2)(i) to add to the current prohibition of unsolicited door-to-door solicitation. Business Reply Cards (BRC) and other types of documents where the beneficiary requests additional information are intended to allow the agent to reach out to the beneficiary via telephone, email, or direct mail. We 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, requesting to market MA or Part D plans to that beneficiary. CMS considers this activity to be unsolicited door-to-door solicitation. Therefore, we proposed adding 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.

Comment: Many commenters supported this proposed change. There were no comments directly opposing this proposed change.

Response: We appreciate the support for this proposed change. Upon reflection during the comment period, we believe that the regulation text would be clearer without the phrase "considered to be," because our position is that the BRC is not an agreement to an unscheduled, in-person meeting initiated by an agent or other individual arriving at a beneficiary's home. Therefore, such contact is unsolicited.

After considering the strong support for this proposed change and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the changes to add a new paragraph (A) to §§ 422.2264(a)(2)(i) and 423.2264(a)(2)(i) largely as proposed but without the phrase “considered to be.”

8. Requirement for an annual opt-out for plan business.

Currently, regulations at §§ 422.2264(b) and 423.2264(b) permit MA organizations and Part D sponsors to contact existing members, and to a limited extent, former members, to discuss plan business. In §§ 422.2264(b) and 423.2264(b), we define plan business to include calling current members to discuss Medicare products. In addition, in §§ 422.2264(b)(2) and 423.2264(b)(2), we currently require that MA organization and Part D sponsors provide beneficiaries an opportunity to opt out of being contacted concerning plan business. However, we have interpreted and implemented this regulation as requiring MA organizations and Part D sponsors to present enrollees with a one-time opt-out opportunity, regardless of how many subsequent contacts an enrollee receives. Therefore, we 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. Over time, beneficiaries may realize that having plans contact them regarding marketing is not necessary. By only 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, our 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.

Under the proposal, we defer to plans on how best to communicate this, so long as it is in writing, as we believe that plans are in the best position to develop appropriate language based on the plan business they conduct. In addition, we are not proposing the specific written format

that plans must utilize when communicating this information during the year, nor specifying when the plan must provide this information during each contract year. MA organizations/Part D sponsors may provide this opt-out notification as a single letter, in a welcome packet, or another method of written communication. Under this proposal, as with the current regulation, the enrollee's decision to opt out of contacts for purposes of plan business will remain in effect until an enrollee chooses to opt in. We solicited comments on whether CMS 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.

Comment: We received numerous comments supporting this proposal. Many commenters stated that receiving calls about other lines of business is akin to unsolicited contact, and makes it harder for beneficiaries to distinguish between important plan information and marketing. A commenter was concerned if our change in requirements would prohibit organizations from contacting beneficiaries about their existing plan coverage.

Response: We appreciate the support for this proposal, as we believe providing an annual, written notice will empower enrollees to make the decisions that are right for them about the extent to which their MA or Part D plan contacts them for plan business. We appreciate the concern about ensuring that plans may continue to contact current enrollees regarding their existing plan and current coverage but this proposal, which we are finalizing, does not prohibit calls and other contact about the enrollee's current plan. Per §§ 422.2264(b) and 423.2264(b), plan business includes discussion about other Medicare products (not the enrollee's current plan) or about other types of insurance or lines of business (for example automotive or home insurance). Plans and agents would still be permitted to call members regarding their current plan.

Comment: We received a few comments opposing this provision. A commenter stated that the opt-out notice was unnecessary and unwanted by beneficiaries because of the overall

amount of communications they already receive regarding their plan, including the ability to opt-out of calls regarding plan business.

Response: CMS believes the 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 member with a yearly notice, reminding them of their ability to opt out.

Comment: 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.

Response: Requiring an opt-out on a yearly basis does not, in itself, preclude an agent from contacting a beneficiary regarding plan business. 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 that they no longer wish to be contacted regarding plan business.

Based on the numerous comments supporting this proposal, we are finalizing as proposed.

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

Our regulations at §§ 422.2264(c) and 423.2264(c) describe what marketing activities are permitted at sales and educational events, as well as any conduct that is prohibited at these events. Currently, MA organizations and Part D sponsors, including the agents and brokers with which they contract, may not market specific MA/Part D plans or benefits at educational events. However, CMS currently permits MA organizations and Part D sponsors participating in educational events to set up future personal marketing appointments and to collect beneficiary contact information, including Business Reply Cards (BRCs), or Scope of Appointment forms (SOA) at educational events. Our regulations also permit marketing events to immediately

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

In 2018, prior to the implementation of §§ 422.2264(c) and 423.2264(c), our sub-regulatory guidance prohibited many of these activities, such as holding marketing events following an educational event, distributing SOA cards, and setting up future individual marketing appointments. In the January 2021 final rule, CMS codified, in large part, this sub-regulatory guidance. Since that time, CMS has expanded its review of plan marketing activities and related information. We have reviewed complaints through 1-800-MEDICARE about confusing and misleading marketing tactics received and have heard from industry groups concerned about the changes in our policy regarding educational events. Since the 2021 final rule, complaints about plan marketing activity have increased and included allegations of unsolicited contact to prospective enrollees. We believe that some of these complaints may be attributed to the collection (and later use) of beneficiary contact information, such as BRCs, or SOA cards at educational events.

We proposed, in §§ 422.2264(c) and 423.2264(c), to reinstate the prohibition on accepting SOA cards or the collection of beneficiary contact information at educational events. Section 1851(j)(1) of the Act prohibits sales and marketing to take place at educational events. Such events are meant to provide information on the basics of Medicare, including information about coverage options through Traditional Medicare, Medigap plans, as well as Part C and Part D. These events are aimed at informing beneficiaries on what Medicare covers and the different options beneficiaries have when they are Medicare-eligible, or are looking at the options should they wish to change the way they receive their Medicare benefits. In other words, these events are meant to provide generic, factual, non-biased information about different coverage options, rather than information designed to persuade beneficiaries to enroll in a particular type of plan (for example, MA-PD or Medigap), or in a plan offered by a specific organization.

Although the collection of beneficiary information through SOAs or BRCs has been permitted at educational events, we now believe that agents should be permitted to receive contact information at educational events, if the beneficiary chooses to provide their information. As discussed in our May 2022 final rule, the number of marketing complaints received by CMS has increased significantly over the past few years. Specifically, a significant portion of these complaints involve unsolicited contact. A likely contributor to these unsolicited contacts is a beneficiary not realizing the contact form they have completed at an educational event gives an agent permission to contact the beneficiary in the future. CMS has also heard from advocacy groups requesting that CMS reinstitute the beneficiary protections from our previous sub-regulatory guidance that were not included in the January 2021 final rule, including limits on distributing SOA and BRCs at educational events.

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. This especially may be the case if the beneficiary believes they should provide this information in exchange for attending the educational event, which could include the provision of a meal and helpful question and answer opportunities. We believe the beneficiary needs to be in charge of and in control of whether or not they want to be contacted, by whom, and in what form. Therefore, to ensure such decisions remain with the beneficiary, we proposed amending the regulations that list the activities that are permissible to include in educational events (§§ 422.2264(c)(1)(ii) and 423.2264(c)(1)(ii)) by removing the

paragraphs that authorize obtaining beneficiary contact information, including Scope of Appointment forms.

The current regulations at §§ 422.2264(c)(1)(ii)(C) and 423.2264(c)(1)(ii)(C) also permit agents to set up future personal marketing appointments at educational events. Similar to SOAs and contact information, we believe that beneficiaries should be in charge of with whom they speak, when they meet with an agent, and what products they want to discuss with that agent. In the case of educational events, the beneficiary generally attends the event to learn about Medicare, not to facilitate a marketing meeting where the beneficiary is encouraged to enroll in a plan. Once an agent speaks with a beneficiary at an educational event, the beneficiary may believe they are being pressured into setting up a marketing appointment. The “on the spot” request at an educational event for the beneficiary to schedule a future meeting does not provide the beneficiary enough time to consider whether they want someone to come to their home and market a plan to them for the purpose of enrollment. We believe that an educational event should be solely for education and not for lead generation or future marketing opportunities for agents. Therefore, we also proposed 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.

Comment: We received a substantial number of comments supporting the proposal to prohibit the collection of SOAs and BRCs at educational events.

Response: CMS thanks the commenters for their support.

Comment: We also received a substantial number of comments opposing this proposal. Some commenters stated that not being able to collect SOAs and BRCs at educational events will result in agents not holding these events at all, and that such a result is a detriment to beneficiaries.

Response: We appreciate the comments. However, we disagree that the prohibition of collecting SOAs and BRCs will cause agents to no longer hold educational events. We note that

prior to 2018, CMS prohibited the collection of SOAs and BRCs at educational events and these events still took place. We also note that many educational events are held by individuals and entities other than agents or plans. Educational events are regularly sponsored by individuals and groups that are not affiliated with any specific MA organization or Part D sponsor, such as events and forums sponsored by State Health Insurance Assistance programs and other local and community-based groups.

Comment: A few comments stated that this 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 these events. One of these commenters stated that beneficiaries go to educational events to meet with agents.

Response: Thank you for your comments. However, CMS disagrees that it will place an undue burden on beneficiaries to reach out to an agent after an educational event, rather than the agent reaching out to the beneficiary. If a beneficiary takes the time to travel to an educational event, it should not be burdensome for the beneficiary to later contact the agent after attending the event. As for the statement that beneficiaries go to the educational event to meet with agents, CMS also disagrees that this is the only or primary purpose for beneficiaries to attend these events. If a beneficiary's goal is to meet with an agent, he or she can simply call an agent and set up an appointment without going to an educational event. We believe beneficiaries are going to educational events to learn about all parts of Medicare, not just to meet with agents.

However, we do not want to unnecessarily burden beneficiaries. Our proposal is to ensure the beneficiary is making the decision to reach out to an agent. Given the comments, we are modifying this proposal to permit BRCs to be made available and received by agents at educational events but are still prohibiting the collection of SOAs at educational events.

Comment: One commenter stated that this will create challenges in connecting with beneficiaries.

Response: As stated previously, we believe the choice to reach out and potentially meet with an agent should be up to the beneficiary. The proposal, which we are finalizing with some modifications, to prohibit scheduling or setting up personal future marketing appointments and obtaining beneficiary contact information, including SOA forms, will require agents to wait until a beneficiary reaches out to them, which may present challenges for the agent. This change is aimed at protecting and giving the choice to the beneficiary, not at easing the path for agents to more readily reach out to beneficiaries, who may not wish to receive such outreach.

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 we believe are in the best interest of the program and of beneficiaries. First, we 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 accomplished 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, we 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.

10. Prohibiting sales events to directly follow educational events.

CMS is also concerned about marketing events directly following an educational event. Educational events are meant to provide information on how Medicare works, including material on the options of Original Medicare, Medigap plans, Part C, and Part D, and are not meant to persuade beneficiaries to enroll in a plan. Beneficiaries attending an educational event directly followed by a marketing event may believe that they are being pressured, at the conclusion of the

educational event, into staying for the marketing event. For example, an agent may hold an educational event providing free meals and desserts, and then directly follow that educational event with a marketing event. Beneficiaries may believe that they are being pressured into staying for the marketing event because of the free meal they received at the preceding educational event. Although our current regulations require there be an opportunity for a beneficiary to leave the educational event prior to the start of the marketing event, we do not regulate how much time must elapse between an educational and a marketing event, nor do we prescribe what the agent can or cannot say at the educational event about the marketing event that will follow. Beneficiaries may believe that there is an obligation to stay for a variety of reasons, including not having enough time to gather their belongings or feeling awkward leaving when others are staying. The belief of an obligation may add pressure for a beneficiary to stay and possibly enroll in an MA or Part D plan, even though they only came to the event to be educated about Medicare and the options available to them. Furthermore, attending a marketing event right after an educational event may raise the risk of beneficiaries being confused that the benefits of an MA or Part D plan in general are actually unique to the specific plan options that are being marketed. For example, a factual and impartial statement like, “It is important to consider your out-of-pocket costs and which drugs you take when deciding on your enrollment options” in the educational event could be followed up in the marketing event that uses the same phrasing and terms in describing a specific plan’s benefits. The beneficiary might conflate these issues if the educational and marketing meetings are held so close in time. For example, the beneficiary may believe that the plan being touted at the marketing event is the best, or even only plan available, taking into account the individual’s costs and drug needs.

In the past, CMS permitted marketing events to immediately follow educational events because at the time we were concerned if these events were separated by time and location, beneficiaries might have to travel to separate educational and marketing events at different times, and potentially different locations. Over the past few years, CMS has witnessed a significant

increase in the use of technology replacing the need for individuals to physically travel to locations to attend educational or marketing events and receive information. The COVID-19 pandemic resulted in fewer face-to-face communications and more technology-based marketing, such as Zoom calls and live education events on the internet and has lessened travel to physical locations. The use of technology may have in these instances provided more options for some beneficiaries to be educated about Medicare. We note that because of the policy to require MA organizations to evaluate the need for and provide digital literacy education to their enrollees addressed elsewhere in this rule, we expect digital literacy among enrollees to improve as well. As a result, we believe that the need for sales events to immediately follow educational events because of travel considerations has become less critical.

By separating educational events from marketing events, beneficiaries are afforded the time to consider all their questions and options before making any decisions about their health care and without any pressure to decide on the spot with the agent present. By mandating a specific time between an educational event and a marketing event, CMS believes it is allowing beneficiaries needed time to carefully consider their health care coverage options and whether or not they want to reach out to the agent and learn more about the particular plan(s) the agent is selling. CMS believes this proposal to separate marketing from educational events will alleviate the pressure a beneficiary may believe that they are being pressured to stay for a marketing event after an educational event, and will protect beneficiaries from potential undue pressures to enroll in a plan that does not best meet their health care needs. Based on this, we proposed to prohibit marketing events from taking place within 12 hours of an educational event in the same location. We proposed changes to §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) to read, “Marketing events are prohibited from taking place within 12 (twelve) hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.” We believe a 12-hour window is important to ensure beneficiaries are not pressured into attending a marketing event. This will usually give beneficiaries until the next calendar day, providing

sufficient time to consider the impartial and factual information provided at the educational event. We are concerned that a short window, such as 10–15 minutes, will not provide beneficiaries with enough time to finish conversations, pack their belongings, and leave the facility prior to the marketing event starting. If a beneficiary is unable to leave during the break, we are concerned that the beneficiary may be “guided” to the sales event or pressured into attending by being told the event won’t last long or that there will be no pressure to join, or will otherwise believe that is an obligation to go to the sales event. CMS believes the best way to protect beneficiaries from being pressured into attendance would be for the sales event to be at a different time, with a sufficient amount of time between the two events. We also believe it is necessary to limit this new requirement to when the marketing event is in the same location as the educational event. This ensures that an agent or broker can hold a marketing event the same day as an educational event, provided the marketing event is in a different location. If an agent wishes to have a sales event three miles from an educational event, we do not want to limit the ability of the agent or broker to do so. Therefore, we proposed to revise paragraph (c)(2)(1)(1) of §§ 422.2264 and 423.2264 to prohibit marketing events from taking place within 12 hours of an educational event, at the same location.

Comment: We received numerous comments supporting the proposal to clearly separate educational events from marketing events. Some of these commenters specifically addressed the need for prospective enrollees to clearly recognize the different purposes of each event, and a time gap or venue change, along with the accompanying lack of pressure to immediately attend a marketing event, would help with that goal. A few commenters reiterated that educational events should only be for education and not for lead generation.

Response: We appreciate the support and agree that educational events should only be educational in nature and not for lead generation purposes.

Comment: Approximately half of the comments we received opposed this provision. We received a number of comments stating that agents are not hurting seniors, comments that this

proposal will result in friction for beneficiaries, comments that this requirement will not add any additional protection, comments that the proposal will degrade the consumer experience, and comments that the proposed solution is both heavy handed and unworkable.

Response: We acknowledge that some commenters generally oppose this proposal. However, these commenters did not provide CMS with evidence indicating that reduction in marketing event attendance will likely occur if this proposal is implemented, or occurred when our prior guidance in place before 2018 prohibited marketing events from directly following educational events. With the increase of online events and other tools for TPMOs to inform and market plans to prospective enrollees, we believe that those prospective enrollees that attend in-person sessions will be sufficiently motivated to either leave a completed BRC with agents at educational events, or move to another venue or return to a marketing event in the same location soon thereafter.

Comment: A few commenters stated that educational events would not be held, resulting in beneficiaries being less informed overall and increasing the likelihood of a beneficiary enrolling in a plan that does not meet their help care needs.

Response: We appreciate the concern about the decrease in educational events. However, we disagree that beneficiaries will not receive sufficient detail on their options. Plans and agents can incorporate sufficient information about Traditional Medicare, Parts C and D, as well as Medigap options during their marketing presentations. CMS does not prohibit educational information being presented at marketing events but marketing events are (or should be) accurately identified as marketing, so that beneficiaries can make informed decisions about whether to attend and to understand the goal of such events from the presenters: to sell the beneficiary something. Educational events must remain as advertised and as permitted by §§ 422.2264 and 422.2263; they must be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program. The goals of the marketing and communications regulations are undermined when

there is not a clear distinction between an educational event and a marketing event, particularly when they are held in the same location on the same day. Section 1851(j)(1)(D) of the Act directs that sales and marketing are prohibited from occurring at educational events; ensuring that these different types of events remain separate is part of CMS's responsibilities and obligations under the Medicare statute.

Comment: Several commenters opposed this provision stating that transportation issues, especially for dually eligible beneficiaries, make this challenging. These commenters suggested that dually eligible individuals frequently lack access to transportation, making it critical to have access to information and resources in just one interaction. Some expressed health equity concerns based on those with transportation issues having to go to separate locations to attend an educational event and a marketing event.

Response: We appreciate the concern regarding transportation, especially for beneficiaries that are low-income, have disabilities, or are part of underserved communities. The revisions to §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i), as proposed and finalized here, do not prohibit educational events or prohibit marketing events from including educational content and materials. This final rule establishes parameters to clearly separate educational events and marketing events to ensure that beneficiaries are not pressured into attending a marketing/sales event which directly follows an educational event. Commenters are concerned about vulnerable populations and CMS is concerned also. Protecting dually eligible individuals and other vulnerable groups is exactly why we are requiring a break between an educational event and a marketing event. We want to ensure beneficiaries are ready to make a health care decision, rather than being pressured into a decision. If a beneficiary attends an educational event, requests to hear more about specific products, but has no transportation to a sales event, CMS believes the agent will reach out and meet with the beneficiary or provide the beneficiary with the agent's contact information to set up another meeting. We do not believe a beneficiary's transportation issues will prevent an agent from finding a way to connect with the beneficiary,

either telephonically or in person. The number of people ages 65+ who own a smartphone has increased dramatically over the past few years. In 2018, 46% of those 65+ owned a smartphone. This number has increased to 61% in 2021, an increase of almost 25% in four years.¹³¹

Comment: Several commenters stated that in-person conversations are the most effective way to share information, that beneficiaries prefer in-person meetings and in person meetings result in fewer disenrollments, fewer complaints, and higher customer satisfaction.

Response: CMS agrees that in-person meetings can be effective for explaining and discussing information about a beneficiary's health needs and various options for Medicare coverage. In addition, we agree that beneficiaries may prefer in person meetings. The changes proposed and being finalized here about when and where a marketing event can take place in relation to an educational event do not prohibit in-person meetings. This revision will prohibit marketing events from being held in the same location within 12 hours of an educational event. We actually strongly support agents meeting with beneficiaries, believing that more information, better communication, and a better understanding may occur in person. We believe if the beneficiary prefers an in-person interaction, he or she will choose to attend the marketing event or will meet with an agent one-on-one.

Comment: Lastly, it was noted that beneficiaries should be able to make their own decisions on when to attend events.

Response: We agree that beneficiaries should be in control of when and how they meet or engage with MA organizations, Part D sponsors or agents who are trying to market to the beneficiary and sell a particular coverage option (or options) to a beneficiary. We disagree that this provision prohibits beneficiaries from making their own decisions on when to attend events. This provision is not prohibiting attendance at events, rather it is prohibiting when events can occur. If a beneficiary wants to attend both an educational event and a marketing event, they are welcome to attend both.

¹³¹<https://www.statista.com/statistics/489255/percentage-of-us-smartphone-owners-by-age-group/>

After considering the comments, and for the reasons outlined in the proposed rule and the final rule, we are finalizing these provisions as proposed.

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

Sections 1851(j)(2)(A) and 1860D-4(l)(2) of the Act require an advance agreement with a prospective enrollee on the scope of the marketing appointment, which must be documented. Our regulations at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) reiterate this requirement, designating this requirement as a Scope of Appointment (SOA). Both the statute and the current regulations require an advance agreement between the beneficiary and the agent. Previously, we interpreted this standard of agreement in advance in our marketing (MCMG) guidance as meaning as 48 hours prior the appointment when practicable. We proposed codifying our previous marketing (MCMG) guidance by prohibiting personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary. However, we did not propose to include “when practicable” in the proposed regulation because we believe the phrase “when practicable” nullifies the purpose of the 48-hour timeframe, given the many reasons that might be cited for why waiting the full 48 hours is not “practicable,” such as the beneficiary living an hour away, the beneficiary wanting to discuss the products immediately following the signing of the SOA, the beneficiary may believe that they are being pressured by the agent to discuss the product immediately, or the beneficiary needs to arrange to have the person that helps them with health care decisions available at the meeting. The reasons for why a meeting must occur within the 48-hour timeframe are numerous and subjective, meaning what is practicable for one person may not be practicable for another, thus we are concerned about our ability to enforce the regulation if we include “when practicable” in requiring advance agreement at least 48 hours before the meeting. In addition, given today’s technology and the fact that we permit SOAs to be completed via telephone, electronically, or in paper form, obtaining a SOA 48 hours prior to the appointment should not present a significant

burden for either beneficiaries or the plan representatives and agents that engage in these meetings. Therefore, we proposed to add “At least 48 hours” before the word “Prior” to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to read, “At least 48 hours prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).”

Comment: We received a significant number of comments on our proposal to require 48 hours between an SOA and a meeting with a beneficiary. About twenty percent of the comments supported this proposal.

Response: We appreciate the support; however, based on the reasons discussed this section of this rule, we are modifying the proposal as described in this section.

Comment: We received a substantial number of comments opposing our proposal. Some of the commenters stated that that the 48-hour waiting period will have no real positive effect on beneficiaries as there is no need for a waiting period when one takes the substantial step to request a detailed discussion of programs and benefits at a certain time and place, it is detrimental to beneficiaries, and beneficiaries are not required to wait 48 hours for such things as purchasing a car. A commenter stated that CMS lacks authority to require a specific period of time between the SOA agreement and the meeting with a beneficiary because section 1851 of the Act only requires an “advance agreement,” not agreement a specific time period in advance.

Response: We appreciate these comments. We disagree that the Secretary, in promulgating rules and requirements under Section 1851 of the Act, does not have the authority to interpret and define what timeframe may be applied to an advanced agreement. The 48-hour timeframe was a longstanding rule before 2018, both in Subpart V of Part 422 and the MCMG. This proposal was, in effect, a restoration of that requirement. We also disagree that the rule is detrimental for the majority of beneficiaries. We also do not agree that the timeframe will have no real effect. Giving beneficiaries time to consider their options and whether they wish to meet with an agent is often beneficial, providing beneficiaries, especially vulnerable beneficiaries,

time to speak with caregivers and others who they may rely upon for help or advice, or just provide the beneficiary additional time to consider their options.

CMS, under its delegated authority from the Secretary, is authorized to set limitations and standards for the marketing by plans. Section 1851(h) of the Act requires compliance by plans with fair marketing standards adopted by the Secretary, which must include that plans engage in activities described in section 1851(j)(2) “in accordance with the limitations established under that subsection. Section 1851(j)(2)(A) of the Act requires that the Secretary establish certain limitations on marketing activating “with respect to *at least*...[the] scope of any appointment [for marketing a plan]” (emphasis added) and the limitations adopted require an advance agreement. The proposal to amend §§ 422.2264(c)(3)(i) and 423.2263(c)(3)(i) to establish how far in advance a SOA must be set is within the scope of CMS’s authority as the statute sets forth minimum requirements and authorizes additional limitations as well as standards to implement and interpret the specific limitations set forth in subsection (j)(2)(A).

Comment: We received a significant number of comments noting 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. A number of commenters were also concerned about the impact of our proposed policy on beneficiaries who may face transportation barriers, or those that travel long distances to meet with an agent. Based on the previously stated reasons, some of these commenters opposed the provision and some requested exceptions. A commenter pointed out that the reasons listed by CMS in the proposed rule for having a meeting sooner than 48 hours after the SOA is set indicated how the 48- hour requirement, especially with no exceptions, would interfere with the real-world planning beneficiaries need to do.

Response: We agree with the commenters that for beneficiaries who travel long distances or who have transportation issues, and those that are nearing the end of a valid election period, a shorter period between when the SOA is set and the personal marketing meeting occurs may be appropriate to ensure beneficiaries get the assistance they need. Our proposal was meant to

provide an opportunity for beneficiaries to consider their options, but not to inhibit enrollment by beneficiaries who choose to enroll through a particular agent. We did not intend, nor do we want, a beneficiary to miss the opportunity to enroll in a plan because of a required 48-hour waiting period.

Based on comments, we are convinced that a categorical prohibition on having a personal meeting less than 48 hours after the SOA is set is too strict and that exceptions are necessary. Therefore, we are finalizing the revisions to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) with modifications from our proposal to provide two exceptions to the 48-hour requirement. The first exception is for beneficiaries who are approaching the end of a valid enrollment period. This could be the end of the AEP, the OEP, an SEP or the ICEP. For these beneficiaries, we will not apply the 48-hour rule if the SOA is completed during the last four days of the election period. For example, the AEP ends on December 7th of each year so if an SOA is completed on or after December 3rd, the personal marketing appointment can occur during the period between December 3rd and December 7th. If an election period ends on the 31st of the month, the SOA must have been completed no earlier than the 27th of that month.

The other exception we will be for walk-ins. Beneficiaries who walk into an agent's office, a kiosk, a plan's office or any other walk in will not be subject to the 48-hour rule. This exception will assist beneficiaries who have transportation issues and those that have traveled long distances to see an agent. Because this exception is tied to an unscheduled in-person meeting initiated by a beneficiary, we are finalizing an additional change to use the phrase "personal marketing appointment or meeting" in paragraph (c)(3)(i) of §§ 422.2264 and 423.2264.

After review of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are revising §§ 422.2264(c)(3)(i) and 423.2264(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 initiates an in-person meeting.

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

Regulations at §§ 422.2264(c)(3)(iii) and 423.2264(c)(3)(iii) prohibit an MA organization/Part D sponsor, including their agents and brokers and other first tier and downstream entities, from marketing a health care product during a personal marketing appointment beyond the scope agreed upon by the beneficiary. Sections §§ 422.2274(g)(1) and 423.2274(g)(1) require that MA organizations/Part D sponsors ensure TPMOs (which includes agents and brokers) acting on their behalf adhere to any requirements that apply to the plan itself. Therefore, the requirement for noting the scope of a personal marketing appointment (SOA) is applicable to TPMOs. Currently, CMS requires permission by the beneficiary to be granted and completed in the SOA, concerning the products that will be discussed, prior to the marketing discussion. The existing regulations do not stipulate a timeframe in which the beneficiary may be contacted after an SOA is completed or an expiration date after which the SOA is invalid.

CMS also is aware that MA organizations, Part D sponsors and TPMOs encourage beneficiaries to fill out business reply cards (BRC) or similar mechanisms so the MA organization/Part D sponsor or TPMO has permission to contact the beneficiary at a later date. BRCs are different from SOAs in that the SOA must list all the products to be discussed at the appointment on the document, while many times the BRC is simply a process for obtaining contact information for a beneficiary (that is, name, phone number, address, email). While SOAs are required by statute to identify the types of products that will be discussed, BRCs are not required to specify the products expected to be discussed. Because BRCs like SOAs, often are open-ended and without expiration, they allow an MA organization, Part D sponsor or TPMO

to contact a beneficiary at any point in the future. For example, a beneficiary could fill out a BRC in October of one year and be contacted by the MA organization/Part D sponsor or TPMO 24 months later, well beyond the timeframe a beneficiary might reasonably expect to be contacted about their plan choices when they first filled out the card.

CMS proposed to modify the current regulations at §§ 422.2264(c)(3)(iii)(A), 422.2264(c)(3)(iii)(B), 423.2264(c)(3)(iii)(A) and 423.2264(c)(3)(iii)(B) to limit the 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 organizations/Part D sponsors are requesting information at that present time. Since the purpose of the SOA or BRC is for beneficiaries to discuss plan products applicable for the present or following contract year, having the SOA or BRC expire after 6 months satisfies that purpose, and would prevent agents from using it in perpetuity and thus avoiding the statutory and regulatory prohibitions on unsolicited contact and cold calling. If a beneficiary wants the agent tied to the SOA or BRC to continue contacting them beyond 6 months, the agent may secure and document that permission through a new SOA, BRC, or similar mechanism.

Comment: We received numerous comments about limiting how long a Scope of Appointment, Business Reply Card, or other contact mechanism remains valid. Almost 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 or 12 months to account for the next Annual Enrollment Period.

Response: We appreciate all of the supportive comments and have considered extending the six-month timeframe to either nine or 12 months, and the timing of when SOA, BRC, or other cards could be received and how that receipt date would affect the ability of an agent to

reach out to beneficiaries. After that review, we determined that a 12-month timeframe is the appropriate timeframe for the validity of these documents. For example, a beneficiary in original Medicare might miss the individual's chance to enroll in an MA plan during the AEP and might begin to consider enrolling in an MA plan in January. Or the beneficiary might decide against enrolling in one of the plans available during an AEP, but wish to re-evaluate that decision in the next AEP. This beneficiary might fill out an BRC in January and be contacted by an agent, but under our proposed policy, this individual would not be able to be contacted by the agent again, when the next AEP begins in October, because 10 months would have transpired between the time he or she filled out the BRC and the start of the AEP. In addition, using a 12-month limit will facilitate a beneficiary giving permission annually to be reminded about the next AEP and the opportunity to evaluate (or reevaluate) MA and Part D plan options.

Comment: A few commenters opposed limiting how long a SOA, BRC, or other contact card remained valid. These commenters generally did not provide a rationale for their opposition.

Response: CMS continues to believe that SOAs, BRCs, and other contact cards should not be open-ended and adopting a time limit on how long these materials may be used to contact a beneficiary is necessary and appropriate to protect beneficiaries from unwanted or unsolicited contact in the future. We believe that a 12-month limit reflects when a reasonable person would consent to or expect to be contacted, especially given how for most beneficiaries, the AEP is when enrollment decisions are made.

After considering the comments, and for the reasons outlined in the final rule, we are modifying the proposal to extend the timeframe from six months to 12 months.

13. Searchable provider directory.

In accordance with § 422.2265(b)(4), MA organizations are required to have a searchable provider directory on their website. The current regulations do not identify the elements by which the provider directory can be searched, leaving that up to each organization. We proposed

to modify § 422.2265(b)(4) by requiring the organization's provider directory be searchable by every element, such as name, location, and specialty, required in CMS' model provider directory. We believe this proposal is necessary to assist beneficiaries in finding particular providers. For example, if an organization only provides a beneficiary with the ability to search by location, the beneficiary would have significant difficulties finding a particular specialty or a particular provider. In section III.A.3. of this final rule, we are adding 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 directory be searchable by this new element. By requiring website provider directories be searchable by every element, our proposal would ensure that a beneficiary would be able to locate specific provider specialties, as well as providers by names, addresses, or other elements the organization has listed in the online provider directory.

Comment: We received a few comments that supported this proposed change. Most of those comments that discussed this change specifically also commented on the need for improved accuracy of provider directory information overall.

Response: We appreciate the support for this proposed change, which we continue to believe will assist beneficiaries. While provider directory accuracy is outside the scope of this proposed change, CMS remains committed to working towards greater accuracy in provider directories.

Comment: One commenter opposed this proposed change, but only for the element of "languages spoken." The commenter stated that this change would add to the burden providers already face in communicating changes in their information reflected in a provider directory. The commenter recommended that CMS delay implementation of this requirement until a national provider information data system is made available.

Response: We do not agree that the addition of this element places significant additional burden on providers as it will require the providers to spend a minimal amount of time to

communicate the new contents specified in this rule to each MA organization with which the provider contracts. Providers are already required to provide information to MA organizations and Part D sponsors, under their contracts with the plans. This proposal does not require the provider to provide more information, rather it is to require MA organizations and Part D sponsors to make the provider directory searchable by all elements. This proposal to require the MA plan's website include a provider directory that is searchable by every data element required in the model provider directory will primarily require MA organizations to build or revise their existing website software to enable searches by more fields.

After considering the comments, and for the reasons outlined in the proposed rule and the final rule, we are finalizing this provision as proposed.

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

CMS proposed to modify the pre-enrollment checklist (PECL) requirements at §§ 422.2267(e)(4) and 423.2267(e)(4). First, we proposed to add new paragraphs at §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), to add "Effect on current coverage" to the list of references currently provided within §§ 422.2267(e)(4)(i)–(vii) and 423.2267(e)(4)(i)–(vii). Second, we proposed to update §§ 422.2267(e)(4) and 423.2267(e)(4) to require that plans review the PECL with the prospective enrollee during telephonic enrollments.

The PECL contains important information prospective enrollees need to know prior to enrolling in an MA or Part D plan. It ensures beneficiaries understand important documents and what information is in such documents, such as the Evidence of Coverage, which provides all costs, benefits, and plan coverage. The PECL also includes information designed to help beneficiaries, such as a reminder to make sure their doctors, pharmacies, and prescriptions are either in the plan's network or covered in their formulary. Finally, the existing PECL reminds beneficiaries of certain plan rules, formularies, and that out-of-network services are not covered

except for emergency and urgently needed care, and that benefits and costs may change on January 1 of each year.

In §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), we proposed to add “Effect on current coverage” to the list of information that must be referenced as part of the PECL. During most of 2021 and all of 2022, CMS engaged in an in-depth review of 1-800-MEDICARE complaints. Our reviews revealed numerous beneficiary complaints that they were not aware their current coverage, such as an existing MA plan, a Medigap plan, or their Tri-care plan, would end once they enrolled in an MA plan. Thus, CMS proposed to add “effect on current coverage” to the list of information that plans must provide to prospective enrollees in the PECL, as we believe it will provide additional education to beneficiaries on the implications of choosing an MA or Part D plan and ensure beneficiaries are fully aware that this selection will cause their existing coverage to end.

In §§ 422.2267(e)(4) and 423.2267(e)(4), we also proposed that the PECL be reviewed with the prospective enrollee during telephonic enrollments as well as provided when hard-copy enrollment forms are provided. As previously discussed, the PECL provides information necessary for beneficiaries to understand the details of the plan for which they are enrolling. Although the PECL must be provided with an enrollment form, CMS’ review of telephonic enrollments revealed that the neither the PECL nor its substance was being conveyed to beneficiaries during most telephonic enrollments. Specifically, complaints received by 1-800-MEDICARE included beneficiaries who called 1-800-MEDICARE to inform the Agency via the toll-free line that agents failed to inform the beneficiary that the individual’s doctors were not in the MA plan’s network, were inaccurately told that there would be no costs, or were inappropriately told that their existing coverage would not be affected by enrolling into a new MA or Part D plan. During CMS’ review of telephonic enrollment audio recordings between beneficiaries and agents, it was clear that some beneficiaries were confused when they were told that their current coverage would be ending. It also was clear that some were misled by the

agent and were told that their existing benefits would not change, and others were never informed by the agent that enrollment into an MA or Part D plan would cancel the beneficiary's current coverage. There also were cases where the agent failed to go over the beneficiary's current providers or Part D drugs. In addition, few, if any, of the calls with agents we reviewed included explanations that all of the benefits and cost sharing for the plan could be found in the plan's Evidence of Coverage.

By requiring the PECL to be reviewed with prospective enrollees as part of telephonic enrollments, we intend to ensure that beneficiaries are better informed about the details surrounding the plan for which they are enrolling. Under this proposal, MA organizations and Part D sponsors would decide whether they would require their contracted agents and brokers to read the PECL in its entirety or to require that each item contained on the PECL be discussed. It is CMS's expectation that the agent ensures the beneficiary understands the items in the PECL. Agents may confirm this understanding by receiving an affirmative answer to whether the prospective enrollee understands the information provided, as well as asking the prospective enrollee if she or he has any questions. CMS believes that an actual review of the PECL elements with prospective enrollees will decrease inaccurate information and misunderstandings, resulting in fewer 1-800-MEDICARE complaints and higher beneficiary satisfaction.

Therefore, CMS 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.

Comment: We 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 enrollee on telephonic enrollments.

Response: We appreciate the support for this proposed change.

Comment: Some commenters suggested that CMS provide model language to the PECL to be used when confirming effect on current coverage with potential enrollees.

Response: CMS 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. Please note that the PECL is a standardized material that plans must use as issued by CMS (except for filling in designated blanks) and that the model language added to the PECL could be customized so long as the new regulatory requirement that the contents of the PECL be reviewed with the potential enrollee is met.

After considering the comments, and for the reasons outlined in the proposed rule and the final rule, we are finalizing these provisions as proposed.

15. Summary of Benefits (SB) medical benefits.

CMS also proposed a change to § 422.2267(e)(5)(ii)(A) to require that the Summary of Benefits (SB) list medical benefits on the top half of the first page and in the order currently listed in §§ 422.2267(e)(5)(ii)(A)(1) through 422.2267(e)(5)(ii)(A)(10). Currently, § 422.2267(c)(2) states that model materials, like the SB, must follow CMS' order of content when specified. This existing regulation permits CMS to specify the order of content presented in MA required model materials. CMS has already specified the order of information on medical benefits in the SB instructions, mirroring the regulatory list of medical benefits provided at § 422.2267(e)(5)(ii)(A)(1) through (10). By requiring all plans to list certain benefits in the same location and in a specified order, beneficiaries will be able to more easily compare benefits across different plans and in a more standardized way. The ability for beneficiaries to review and compare benefits across different MA plans will assist beneficiaries in making a more informed health care choice.

Comment: CMS received a number of comments regarding this proposal. All, but one of the commenters supported this proposal.

Response: We thank the commenters for their support. Codifying this specific requirement will provide it with more strength, clarity and transparency versus only including it in instructions to the SB model document. Furthermore, we believe it is important to ensure that the substance of the SB begins with the medical benefits contained in § 422.2267(e)(5)(ii)(A)(1) through (10).

Comment: One commenter did not support the proposal, stating that their organization often provides a cover page or other information prior to listing the benefits.

Response: We appreciate that comment, and want to further clarify the changes to § 422.2267(e)(5)(ii)(A) that we proposed and are finalizing. As revised in this rule, § 422.2267(e)(5)(ii)(A) requires that the information on medical benefits be listed in the top half of the first page of the SB and be in the same order as the information is listed in paragraphs (e)(5)(ii)(A)(1) through (10). This means that the benefits listed in this regulation must be the first set of benefits listed in an MA plan's SB document. Cover pages and other information, provided these do not include benefits, may be above the required medical benefits chart. CMS will provide additional information in our MCMG and/or our SB model material to clarify this.

After considering the comments, and for the reasons outlined in the proposed rule and the final rule, we are finalizing this provision as proposed.

16. Non-renewal Notice.

We proposed a change to 42 CFR §§ 422.2267(e)(10) and 423.2267(e)(13), which provides that the non-renewal notice is a model communications material through which plans must provide the information required under §§ 422.506 and 423.507, respectively. Per §§ 422.2267(c) and 423.2267(c), model materials and content are those required materials and content created by CMS as an example of how to convey information to beneficiaries. CMS provides model materials in the form of an example document and/or a list of required content. Modifications to model materials, including the non-renewal notice, can be made at the MA organization's/Part D sponsor's discretion within certain limits outlined in §§ 422.2267(c) and

423.2267(c). Although our regulations list the non-renewal notice as a model notice, we have always implemented it as a standardized notice; plans are not permitted to make any changes to standardized materials, except where noted. To ensure accuracy and consistency, we 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 material. This is necessary to ensure that the vital information contained in the non-renewal notice about a beneficiary’s alternative health care options and the timing for the beneficiary to make an enrollment decision is conveyed in a way that CMS has determined is accurate and understandable. Beneficiaries receiving the non-renewal notice are provided a Special Enrollment Period (SEP) (as per § 422.62(b)(1)) with deadlines to make new health plan choices. This notice provides beneficiaries with information about the SEP, as well as information regarding other plans that may be available to them. As a model notice, currently, MA organizations/Part D sponsors can place information about SEPs and other plan options anywhere in the document. As a result, MA organizations/Part D sponsors have the ability to highlight their own plan options, instead of providing equal prominence to all health plan options including those offered by competitor organizations. Our proposal would eliminate that possibility.

Comment: We had general support from commenters for this provision, but no specific comments regarding this provision.

Response: We thank the commenters for their general support.

We are finalizing this provision as proposed.

17. Adding “SHIP” to the Third Party Marketing Organization (TPMO) TPMO disclaimer and disclosing the names of all entities the TPMO represents.

In the May 2022 final rule, CMS implemented a Third Party Marketing Organization (TPMO) disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41). The required disclaimer states, “We do not offer every plan available in your area. Any information we provide is limited to

those plans we do offer in your area. Please contact Medicare.gov or 1-800-MEDICARE to get information on all of your options.” We currently require TPMOs that represent more than one MA or Part D plan in a given service area, but do not represent all plans, to verbally convey the disclaimer within the first minute of a sales call, electronically convey the disclaimer when communicating with a beneficiary via email or online chat, or prominently display the disclaimer on their website, and to include the disclaimer on all marketing materials. We proposed to modify this disclaimer to add State Health Insurance Programs (SHIPs) as a source of information for beneficiaries. We also proposed an additional disclaimer requirement, which would require all TPMOs to list names of the MA organizations or Part D sponsors with which they contract in the applicable service area.

Although TPMOs may contract with one or more MA organizations and Part D sponsors, they do not necessarily contract with all available options in a service area. When a beneficiary contacts a TPMO that does not contract with all MA organizations or Part D sponsors in a particular service area, the beneficiary may not know that the TPMO does not sell or represent all of the available options. To ensure beneficiaries in this situation are aware that other enrollment options exist, the disclaimers at §§ 422.2267(e)(41) and 423.2267(e)(41) currently require TPMOs to notify the beneficiary that a complete list of available plans can be obtained from 1-800-MEDICARE or Medicare.gov. We proposed to add that TPMOs also notify beneficiaries that they may contact their local SHIP for more information on available options because SHIPs are a resource to obtain unbiased information on all available health and drug plan options. We believe adding SHIPs to this disclaimer provides beneficiaries with another important and unbiased resource for assistance.

In addition, CMS proposed that TPMOs disclose the names of the MA organizations or Part D sponsors with which they contract when speaking with a beneficiary. This ensures that beneficiaries are aware of all of their choices when communicating with a TPMO. In CMS’s review of hundreds of sales, marketing, and enrollment audio calls, CMS found over 80 percent

of the calls only discussed one plan option from one MA organization. The audio reviews CMS conducted also showed that agents rarely, if ever, informed the beneficiary that there were multiple plans available in the service area. Although the agent may have researched other plans on behalf of the beneficiary they were assisting, the agent rarely communicated information about those plan options to the beneficiary, and thus the beneficiary may not have known about their other options to make an informed decision about the plan that best meets their needs.

CMS proposed to revise the existing TPMO disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41) to require TPMOs that do not contract with every available MA organization or Part D sponsor in a service area to include a list of the MA organizations or Part D sponsors with which they do contract in the beneficiary's service area. In addition, because the existing TPMO disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41) does not apply to TPMOs that contract with every MA organization or Part D sponsor in a given service area, CMS also proposed to revise §§ 422.2267(e)(41) and 423.2267(e)(41) to include a new disclaimer for TPMOs that do contract with every MA organization or Part D sponsor in the service area. This new disclaimer would need to be provided within the first minute of the call, the same as what is required for TPMOs that do not contract with MA organization or Part D sponsor in a service area. As with the existing TPMO disclaimer, this new disclaimer would need to be electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means, prominently displayed on the TPMO's website, and included in any TPMO marketing materials, including print materials and television advertising.

The first disclaimer, proposed for TPMOs that do not sell for all MA organizations or Part D sponsors in a service area, would read, "We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are plans offered by [insert list of MA organizations here]. Please contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program to get information on all of your options." The second disclaimer, proposed for those TPMOs that sell for all MA organizations

or Part D sponsors in a service area, would read, “We offer the following plans in your area [insert list of MA organizations]. You can always contact Medicare.gov, 1–800–MEDICARE, or your local State Health Insurance Program (SHIP) for help with plan choices.”

We received comments on this proposal and respond to them as follows:

Comment: We received a number of comments regarding the addition of SHIP to the TPMO disclaimer. Most of these comments supported this addition.

Response: We thank the commenters who supported the addition of SHIP to the TPMO disclaimer. We continue to believe that beneficiaries should be notified of the availability of their local SHIP as a resource for assistance.

Comment: Some of the commenters opposed adding SHIPs to the TPMO disclaimer. The comments focused on SHIPs having limited budgets, SHIPs not being trained as well as agents, and beneficiaries enrolling through SHIPs can be harmful. One commenter stated that they had to clean up information provided by SHIPs, SHIPs don't face the same level of repercussions as agents, and stated that they did not want to give their business to SHIPs.

Response: We appreciate the comments. We understand budget constraints may limit the constraints of some SHIPs. However, adding SHIPs to the disclaimer ensures that beneficiaries are notified about another neutral party to whom they can direct questions and receive guidance regarding their health care choices. As for SHIP counselor knowledge, we trust that counselors are ensuring they have up to date information. SHIPs receive a significant amount of training and are subject to monitoring by the HHS Administration for Community Living (ACL) to ensure that they have access to information prepared or reviewed by CMS. Furthermore, ACL requires SHIPs to attend federal training sessions and to provide extensive training to staff who provide information, assistance and counseling to beneficiaries; ACL, both directly and through its technical assistance consultant contractor, reviews training materials used by the SHIPs. Therefore, we believe SHIPs, as well as 1-800-Medicare, are important sources for beneficiaries to receive unbiased information regarding all of their choices.

Comment: CMS received numerous comments regarding the requirement of TPMOs to mention all of the organizations they represent in the TPMO disclaimer that is required to be read within the first minute of a call. Many of these commenters supported this requirement.

Response: We thank the commenters for supporting this proposal.

Comment: CMS received a number of comments opposing the proposal to require plan names be included within the TPMO disclaimer. Commenters stated the disclaimer would be long, given the average number of plans offered was 39 in Contract Year 2022, while one county had 82 plans offered. Reading so many plan names would likely confuse, distract, or result in the beneficiary failing to pay attention to the agent. A few commenters suggested that TPMOs may decrease the number of plans they sell for in order to meet the disclaimer requirement, resulting in less choices for beneficiaries, especially smaller plans since TPMOs would most likely contract only with larger organizations. Commenters also stated that adding to the disclaimer would result in their inability to read the disclaimer in its entirety within the first minute of the call.

Response: We appreciate the comments and understand the effects of listing all plan names in the disclaimer. Including this information 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 (including an agent). Because CMS's review of audio recordings during our surveillance activities identified that beneficiaries are generally told of one only plan, even if the agent represents multiple plans, we are concerned that beneficiaries do not have the information available to knowingly select the best plan option for them. Our goal is for the beneficiary to know and understand that the individual has choices. The full scope of potential plan options outlined in the comments reinforces our belief that beneficiaries should be notified of what is available. However, we agree that providing extensive information or reading a long list to a beneficiary is not likely to achieve the goals we have for the proposed amendments to the disclaimer about other plan options. Therefore, we are not finalizing a requirement for TPMOs

to list all of the sponsoring organizations (or MA and Part D plans) represented by the TPMO; instead we are finalizing revisions to the disclaimer required by §§ 422.2267(e)(41) and 423.2267(e)(41) that require the TPMO to identify only the number of organizations and the total number of products available to the beneficiary where they reside. For example, if TPMO A represents ten organizations, three of which have a service area that includes beneficiary B's residence and those three organizations have a total of eight products (HMO, DSNP, PPO, etc.) available, the TPMO will be required to tell the beneficiary that information as part of the standardized disclaimer that we are finalizing.

Comment: A couple of commenters suggested CMS review more data prior to making changes to the disclaimer. One commenter suggested holding a focus group with beneficiaries to gather information on their experiences with TPMOs while another suggested CMS review complaint data to determine if CMS' previous changes have had any impact.

Response: CMS appreciates these comments. We have and will continue to monitor complaints for trends and will consider focus groups to assist with marketing concerns. As discussed in the proposed rule, we developed our proposal based on our review of hundreds of sales, marketing, and enrollment audio calls over the past year. CMS found over 80% of the calls only discussed one plan option from one MA organization. In the calls that we reviewed, agents rarely informed the beneficiary that there were multiple plans available where the beneficiary resided. We believe that this information is adequate to conclude that a requirement for TPMOs to provide additional information is appropriate.

Comment: One commenter who opposed adding the names to the disclaimer suggested a slight modification to the existing disclaimer. This commenter stated that the correct terminology for TPMOs would be "represents" rather than "sells" for plan.

Response: We appreciate that comment and will modify the language for clarity purposes.

After consideration of the comments received and for the reasons outlined in the proposed rule and this final rule, we are finalizing the first disclaimer as proposed by adding the addition of SHIP to the disclaimer. We are also 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.”

18. Comprehensive Medication Review and Safe Disposal

We proposed 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. We received no comments on this proposed technical change and, for the reasons outlined in the proposed rule, we are finalizing the addition of new paragraphs § 423.2267(e)(43) and (e)(44) as proposed.

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

Based on our review of beneficiary complaints and audio calls between agents and beneficiaries, we are concerned about the level of oversight that MA organizations and Part D sponsors maintain over their contracted agents and brokers. In our review of complaints and our

discussions with MA organizations and Part D sponsors, we have determined that MA organizations and Part D sponsors appear to be reactive instead of proactive in addressing inappropriate agent and broker behavior. CMS has received complaints through 1-800-MEDICARE as well as other CMS staff. Once a complaint is received, the complaint is shared with the applicable MA organization or Part D sponsor to review, investigate, and take appropriate action. However, this method of oversight is reactive, and requires organizations and sponsors to respond to issues that CMS is already aware of. As a result, we are concerned that inappropriate behavior by agents and brokers is not being sufficiently curtailed and corrected by MA organizations and Part D sponsors. In §§ 422.2272 and 423.2272, we proposed requiring sponsoring organizations have an agent and broker monitoring and oversight plan that ensures agents and brokers are adhering to CMS requirements and that the MA organization or Part D sponsor is actively monitoring and reporting those agents and brokers to CMS who are not compliant with CMS requirements.

We believe a thorough oversight and monitoring plan will assist in identifying and stopping poor performing agents and brokers more quickly, whether they are independent, captive, or employed agents or brokers. To that end, CMS requires MA organizations and Part D sponsors to oversee the agents and brokers with whom they contract (§§ 422.2274(c) and 423.2274(c)). At a minimum, a proper oversight program would include the review of internal grievances and 1-800-MEDICARE complaints, reviewing a random samplings of past audio sales/marketing/enrollment calls, listening to sales/marketing/enrollment calls in real-time, secretly shopping in-person education and sales events, and secretly shopping web-based education and sales events. These types of activities would improve the plans' overall marketing and sales activities. MA organizations and Part D sponsors should be able to identify areas where agents and brokers have not been adequately trained, agents and brokers who may not fully understand the product offerings they sell, and agents and brokers who improperly market to beneficiaries. MA organizations and Part D sponsors can then quickly act, with such activities

as tailored training or disciplinary measures, based on the specific issues for each agent or broker. We also proposed that MA organizations and Part D sponsors be required to report specific agent or broker non-compliance to CMS. Such oversight and monitoring plans would assist plans and sponsors in gauging the scope of marketing issues, and help plans and sponsors in developing methods to stop inappropriate agent and broker activity. Therefore, we 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.”

Comment: 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, a number of commenters did request clarification on what non-compliance needs to be reported to CMS. Suggestions included egregious issues and repeated issues.

Response: CMS appreciates the support. We agree that additional information on what non-compliance needs to be reported is warranted. We are not expecting organizations to report minor, insignificant issues such as failing to go over one element in a required list of 18 elements. However, if an agent continually fails to address a significant number of elements, especially after being notified of issues, or the agent’s conduct could have beneficiary impact (for example, potential beneficiary harm), the regulation we proposed and are finalizing requires plans to report that particular type of non-compliance. We will provide additional information in our Medicare Communications and Marketing Guidelines, including examples in the future.

Comment: We received a few comments opposing the oversight and reporting requirement. One commenter stated that TPMOs already have a robust oversight plan.

Response: We appreciate and are pleased that the commenter believes TPMOs have robust oversight plans. However, a TPMO having an oversight plan does not replace an MA organization or Part D sponsor having an oversight plan that ensures that the MA organization or

Part D sponsor effectively manages TPMO performance and ensures compliance by TPMOs with Part 422 and Part 423 requirements. In many cases, organizations also have their own agents and brokers and may contract with independent agents and brokers, as well as contracting with TPMOs. As CMS holds organizations responsible for the activities of their contracted TPMOs, the organizations need to properly oversee all of its agents and brokers, even if the TPMO or agent has their own oversight plan.

Comment: One commenter stated that the oversight plan is already required as part of their organization's compliance plan maintained under the Part 422 or Part 423 regulations. A few commenters stated that this proposal would cause additional burden on plans, especially small and medium sized plans.

Response: We only received one comment stating that this proposal is already incorporated into an MA organization or Part D sponsor's existing compliance plan. For those organizations who have put an agent and broker oversight plan in their compliance plan, this proposal should not have a significant effect. These organizations, however, will still need to provide the plan to CMS, upon request, and will also need to report any non-compliance to CMS. For MA organizations and part D sponsors that have not already established an oversight plan of this type for monitoring and ensuring compliance by their TPMOs, we believe that this is an important step toward achieving compliance by TPMOs with CMS requirements.

Organizations are required to ensure all first tier, downstream, and related entities adhere to all statutory and regulatory requirements. In order to ensure compliance, plans should be monitoring and overseeing agents and brokers. This proposal is requiring actions that plans should already be taking. For organizations that do not have an oversight plan in place there will be additional work; however, CMS believes that work is necessary in order to protect beneficiaries from inappropriate marketing by non-compliant agents and brokers.

After consideration of the comments received and for the reasons outlined in the proposed rule and this final rule, we are finalizing as proposed.

20. CMS list of required elements prior to enrollment.

CMS proposed to adopt, at a new paragraph (c)(12) of §§ 422.2274 and 423.2274, additional standards for agents and brokers in their marketing of MA and Part D plans to beneficiaries to require that sponsoring organizations ensure that agents and brokers discuss specific topics and information with beneficiaries prior to enrollment. We believe that adopting these standards is consistent with and achieves a similar goal as the statutory requirement in section 1851(j)(2)(D) of the Act that compensation to agents and brokers create incentives for agents and brokers to enroll beneficiaries in the plan that best meets their health care needs. The provisions in section 1851(h)(4)(D) and (j)(2) regarding the marketing of MA plans apply as well to the marketing of Part D plans per section 1860D-4(l) of the Act. For an agent or broker to ensure the beneficiary is in a plan that best meets their needs, the agent or broker needs to obtain enough information to determine the health care needs of the beneficiary. If the agent or broker fails to have sufficient information to ensure that he or she is enrolling the beneficiary in a plan that best meets the beneficiary's health care needs, yet is still compensated for enrolling the beneficiary in a plan, we believe that section 1851(j)(2)(D) of the Act is undermined. CMS is concerned that agents and brokers too often fail to adequately determine the kind of health plan a beneficiary wishes to enroll in, such as a plan that offers a lower premium and higher copays, one that has specific providers in their network, or one that provides coverage for a certain durable medical equipment. Therefore, in §§ 422.2274(c) and 423.2274(c), we proposed that all agents and brokers (employed, captive, and independent agents) go through a CMS-developed list of items that must be discussed during the marketing and sale of an MA plan or Part D plan.

CMS has listened to hundreds of marketing and enrollment audio calls. In the majority of these calls (over 80 percent), agents and brokers failed to ask pertinent questions to help a beneficiary enroll in a plan that best meets the individual's needs. CMS listened to calls where the agent or broker only asked about primary care providers and/or prescription drugs. There were also calls that CMS listened to where the agent or broker only discussed "extra benefits"

such as dental and vision. During many of the calls CMS reviewed, the agent or broker failed to ask important questions, such as whether there was a specialist that the beneficiary wished to see (or currently sees) and whether that specialist was in the plan's network, whether the beneficiary would prefer lower copays and a higher premium or vice versa, which hospitals the beneficiary preferred, or whether the beneficiary wanted dental and hearing benefits. Some calls were under twenty (20) minutes in length. This short time period led CMS to question whether an agent or broker could have realistically obtained the necessary information from the beneficiary in order to adequately determine their needs and wants, review available options, and complete the enrollment.

To properly assist a beneficiary in choosing a Medicare health and/or drug plan, the agent or broker must have sufficient information about the beneficiary's needs and goals. We do not believe a beneficiary can be enrolled in a plan that best meets the individual's needs when, for example, an agent or broker fails to ask the beneficiary about their current providers or medications, including specialists and preferred hospitals or other facilities. To ensure a beneficiary's needs are reviewed, CMS proposed to add a new (12) to §§ 422.2274(c) and 423.2274(c), requiring an MA organization or Part D sponsor ensure that the agent's/broker's 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. We explained in the proposed rule that CMS would provide in sub-regulatory guidance more detailed questions and areas to be covered based on these general topics.

If agents and brokers are required to ask beneficiaries certain questions, or cover certain topics, prior to beginning the enrollment process, we expect that beneficiaries will be more knowledgeable about the plans that are available to them and whether those plans fit their needs;

this would, in turn, better enable beneficiaries to make an informed choice about their Medicare benefits and how to receive them. We did not propose that agents or brokers would be required to read standardized questions or statements regarding the topics discussed here. Rather, we proposed to require that certain required topics are addressed, prior to the enrollment, specifically topics about providers and whether a beneficiary's current or preferred providers or pharmacies are in-network, costs and premiums for prescription drug coverage and health care coverage, benefits, and the beneficiary's specific health care needs and current medications.

Comment: We received numerous comments supporting this proposal.

Response: We thank the commenters for their support.

Comment: We received two comments opposing this provision. These commenters stated that agents are already required to go over the Pre-Enrollment Checklist.

Response: We appreciate the comments, but the Pre-Enrollment Checklist does not contain the level of detail required to ensure an agent receives all of the information necessary to assist a beneficiary in making a decision that is best for their health care needs. Therefore, we continue to believe that requiring questions from the agent or broker to the beneficiary and a discussion of specific topics is appropriate.

After consideration of the comments received and for the reasons outlined in the proposed rule and this final rule, we are finalizing the addition of a new paragraph (c)(12) to §§ 422.2274 and 423.2274.

21. Limit TPMO call recording to sales, marketing, and enrollment.

Currently, §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) require TPMOs to record all calls with beneficiaries. This requirement helps ensure that TPMOs, including agents and brokers, are appropriately marketing to beneficiaries by ensuring adequate records are available for oversight and monitoring. This requirement for recording all calls with beneficiaries was proposed in a January 2022 proposed rule, and finalized in the May 2022 final rule (CMS 4192-F). The requirement to record all calls was pre-dated by CMS's requirement to record enrollment calls.

As indicated in § 1851 (c)(2)(A) of the Social Security Act, a person with Medicare enrolls in an MA plan or Part D plan by filing an appropriate election form with the organization. CMS has established models for this election form, providing different formats depending on the type of MA or Part D plan as well as the format of the election itself (paper, electronic, telephonic, etc.). The telephonic model includes language establishing the enrollee's agreement to abide by the rules of the plan into which they are enrolling as well as recording this agreement. That recording (that is, the physical recording of the telephone conversation) is the record of the enrollee's request to enroll. As such, CMS has required recording of telephonic enrollment since the incipience of the telephonic enrollment process as a requirement of the encompassing enrollment process. This requirement is reflected in § 422.60(c)(2) which states that an MA plan must file and retain elections forms for the period specified in CMS's instructions and § 422.504(e) requires MA plans to provide access to enrollment and disenrollment records for the current contract period and 10 prior periods. Similar requirements apply to Part D sponsors at §§ 423.136 and 423.505(e).

As previously stated, CMS's experience in reviewing beneficiary complaints and listening to recorded calls between agents and brokers and beneficiaries revealed many instances where agents and brokers failed to provide enough information, and, most concerning, provided inaccurate information about plan benefits. In some cases, the agents and brokers led beneficiaries to believe the beneficiaries were calling Medicare rather than an insurance agent. We received few pertinent comments to this proposal in the January 2022 proposed rule prior to the requirement being finalized at §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii). However, following the May 2022 final rule, CMS heard from trade organizations and plans, as well as individual agents, regarding the obligation to record all calls. Many of these post-final rule questions and comments centered around whether "smaller" agent companies had to record conversations. Some of the comments received after the final rule requested clarification on whether all calls really needed to be recorded.

In the December 2022 proposed rule, CMS did not propose to change the requirement that TPMOs, including agents and brokers, regardless of their size, must record calls. However, we proposed to limit calls that must be recorded from all calls to only those calls regarding sales, marketing, and enrollment by amending §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii). We explained in the proposed rule a concern that current requirement is too broad because calls placed to merely set up an in-person meeting, or to confirm a beneficiary received a plan welcome packet, or calls to provide a beneficiary the opportunity to ask non-marketing questions, such as when the plan will be effective, must all be recorded. We believe requiring the recording of these types of calls is an unnecessary burden and not aligned with our goal to obtain call recordings to ensure the marketing, sales, and enrollment activities conducted by agents, brokers and TPMOs meet the applicable regulatory requirements. Therefore, we proposed to modify §§ 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. We explained that the definition of marketing in §§ 422.2260 and 423.2260 would apply to the use of the term in new paragraph (g)(2)(ii) and that we intended the words “sales” and “enrollment” to include the plain meaning of those terms.

Comment: CMS received numerous comments supporting this proposal.

Response: CMS thanks the commenters for their support.

Comment: One commenter was concerned that they would have to go back and delete all non-marketing, sales, and enrollment calls.

Response: This provision does not require adjustments to be made to recordings of past calls. The commenter will not need to delete non-marketing, sales, or enrollment calls.

Comment: CMS received a few comments opposing the requirement to record calls in any case. Commenters focused on two main points: that beneficiaries may not want to be recorded, but the TPMO has no choice and that marketing issues and potential non-compliance are tied to large call centers and not independent agents or smaller offices.

Response: We appreciate the comments about call recordings. However, our proposal addressed limiting the recording requirements, not eliminating CMS' recording requirements, including the longstanding requirement to record enrollments. Beneficiaries have the right to refuse to be recorded and have alternative methods to enroll, such as in-person or online. Finally, as previously discussed, CMS's reviews of telephone call between agents and beneficiaries strongly indicate that call centers, independent agents, and smaller offices face similar compliance challenges and training needs. Furthermore, all agents must be trained, tested, and licensed in the same manner regardless of location or operational size.

After consideration of the comments and for the reasons outlined in the proposed rule, we are finalizing the amendments to §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) as proposed.

22. Require web-based technology meetings to be recorded.

In addition to modifying §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to only require marketing, sales, and enrollment calls to be recorded, we also proposed to add language to clarify that web-based technology is included in the call recording requirements. Since the May 2022 final rule, we have received questions asking whether technology-based meetings (for example, Zoom meetings between an agent and a beneficiary) need to be recorded. CMS considers meetings taking place on Zoom, Facetime, Skype, or other technology-based platforms to be the same as telephonic calls that present the same concerns about inappropriate marketing as has been found during telephonic calls. Technology is changing the way people interact, and Medicare beneficiaries aging into the program are more likely to have experience with newer technologies and may be more comfortable using such technology. In addition, during the COVID-19 pandemic, many beneficiaries learned to use different technologies to keep in touch with people and to conduct business. Moreover, because of the pandemic, many agents and brokers have moved to using these newer technologies, holding both sales and educational meetings using web-based technologies. And unlike in-person or online documentation, the practical effect of using technology like Zoom, Facetime, or Skype is similar to a telephone call.

We 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.”

Comment: We received some comments supporting this proposed change.

Response: We appreciate the support.

Comment: A commenter opposed the proposed change stating that the change as written did not provide the beneficiary with the choice to not be recorded. The commenter pointed out that if the recording would be preserved for ten years, the beneficiary should have a say as to whether they wanted to be recorded.

Response: The requirement to record calls does not prevent a beneficiary from declining to have the call recorded. CMS has always expected that if a beneficiary declines to be recorded, the call must end. The TPMO may engage with the beneficiary through an in-person meeting.

Comment: One commenter stated that they opposed the requirement to record calls between beneficiaries and TPMOs. They indicated that they did not want their personal information disclosed, recorded during the phone call and then stored.

Response: We appreciate this individual’s desire to not have their information recorded on a phone call between a beneficiary and a TPMO, regardless whether the objection to the recording is from a beneficiary or a TPMO. If the commenter was a beneficiary, there are other enrollment mechanisms outside of phone calls that beneficiaries can use to enroll in a plan.

Comment: One commenter indicated that they opposed the requirement to record calls between TPMOs and beneficiaries as it is an undue burden on independent agents. Some commenters indicated that they opposed the requirement to record calls altogether, regardless of CMS limiting the scope of the recording requirement to certain types of calls. One of these commenters indicated that there should be separate rules for independent agents and large call centers.

Response: The requirement to record all calls is outside the scope of this regulation. The commenter also requested CMS distinguish between independent agents and large call centers with regard to the requirement. CMS did not address the definition of TPMO in the proposed rule and we decline to adopt a change of this scope in the regulation without a fuller opportunity for the public to understand and comment on it. In addition, CMS has anecdotal experience that marketing misrepresentation issues have occurred during calls with independent agents, as well as with the TPMO call centers. Finally, the premise that this requirement is an undue burden is based on the idea that independent agents do not have the capability to record calls and maintain the recordings of those calls and we fundamentally disagree. Independent agents have long been engaging in telephonic enrollment as detailed in the Medicare Managed Care Enrollment Manual and the Medicare Part D Enrollment Manual. Telephonic enrollment entails capturing enrollment requests over the phone. MA and Part D enrollment require the plan to maintain a copy of the enrollment request. In the medium of a telephonic enrollment this would be impossible without the ability to record the telephonic conversation that comprised the telephonic enrollment. As such, independent agents should already have the capability available to capture telephonic conversations with the beneficiaries whom they serve.

After considering the comments on the inclusion of web-based technology meetings, and for the reasons outlined in the proposed rule, we are finalizing this change largely as proposed but with the clarification that the requirement applies only to the audio portion of web-based calls.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit

Program Policies

K. Clinical Trial-Related Provisions (§ 422.109)

MA plans must cover Medicare Part A and Part B benefits, excluding hospice, kidney acquisitions for transplant, and certain changes in benefits due to a National Coverage Determination (NCD) or a legislative change. We proposed to adopt regulations regarding MA coverage of clinical trials covered by Medicare to ensure clarity on these coverage rules for MA plans. These coverage rules implement section 1852 of the Act and are within our rulemaking authority for the MA program. These proposals generally codify guidance currently specified in section 10.7 of Chapter 4 of the Medicare Managed Care Manual for clinical trials covered under National Coverage Determination (NCD) 310.1; A and B investigational device trials (A-B IDE); and National Coverage Determinations with coverage with evidence development (NCD-CED). We received several comments supporting our proposals in general. We address comments on specific proposals in the appropriate sections of this rule.

1. Clinical Trials Under National Coverage Determination 310.1

Clinical trials may include some items and services that would not be covered by Medicare, absent the trial. For clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD) (NCD manual, Pub. 100-03, Part 4, section 310), long-standing CMS policy has been that traditional Medicare (that is, the Medicare FFS program) covers the routine costs of qualifying clinical trials for all Medicare enrollees who volunteer to participate in the approved trial, including those enrolled in MA plans. CMS has discussed this policy in several Advance Notices and Rate Announcements, including the advance notices of methodological changes in Part C payments issued for 2004, 2007, 2008, 2009, 2011, 2017, and 2019, and in the announcements of capitation rates and payment policies for Part C in 2009, 2011, 2012, and 2017. NCD 310.1 is the current statement of the Medicare coverage of routine

costs associated with clinical trial participation. As specified in the NCD, routine costs associated with a clinical trial include:

- Items or services that are typically provided by Medicare absent a clinical trial (for example, conventional care);
- Items or services required solely for the provision of the investigational item or service (for example, administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

Although MA plans must follow all NCDs, section 1852(a)(5) of the Act, which CMS has implemented in § 422.109(b), provides that if an NCD or new legislative benefit introduced in the middle of a plan year is considered a significant cost as determined by the Office of the Actuary, MA plans are not responsible for coverage until the cost to provide the new benefit is calculated into the plan's payment rate. CMS has previously determined, as discussed in the CY 2019 Advance Notice,¹³² that the multiple clinical trials covered under NCD 310.1 trigger the significant cost threshold. Therefore, Traditional Medicare has covered the Medicare-covered routine costs of clinical trials that are covered under NCD 310.1 for MA enrollees. To ensure continued clarity and transparency for this longstanding policy, discussed in section 10.7.1 of Chapter 4 of the Medicare Managed Care Manual, we proposed to codify this policy by adding new § 422.109(e). In § 422.109(e)(1), we proposed to codify that traditional Medicare is responsible for coverage of routine costs of qualifying clinical trials for MA enrollees for clinical trials covered under the Clinical Trials National Coverage Determination 310.1 and all

¹³²The Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter discusses the clinical trial coverage policy for the MA program on pages 23-23 and is available at this link: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Advance2019Part2.pdf>.

reasonable and necessary items and services used to diagnose and treat complications from participating in clinical trials.

Deductibles and MA responsibility for differences in cost-sharing

Traditional Medicare pays for all routine costs of clinical trials for MA enrollees and, as explained in the CY 2011 Rate Announcement,¹³³ MA enrollees do not pay the traditional Medicare Part A and B deductibles when Traditional Medicare pays the Medicare-covered costs associated with the clinical trial.¹³⁴ In § 422.109(e)(2), we proposed to codify this policy that MA enrollees participating in clinical trials are not subject to Part A and B deductibles.

MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services. We proposed to codify this requirement for MA plans to pay the difference between traditional Medicare and plan's cost sharing in § 422.109(e)(3). We also proposed in § 422.109(e)(4) to codify that the enrollee's in-network cost-sharing portion must be included in the plan's maximum out-of-pocket (MOOP) calculation. As the clinical trial costs within the scope of NCD 310.1 are covered by Part A and/or Part B, these are basic benefits within the scope of the MOOP requirements in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), but for clarity we proposed to codify at § 422.109(e)(4) the requirement that the enrollee's in-network cost-sharing must be included in the plan's MOOP calculation. In requiring MA organizations to provide in-network cost sharing for clinical trial services, CMS is requiring that MA plan enrollees have coverage for clinical trial services that is consistent with coverage they have for all other Medicare Part A and Part B services. In paragraph (e)(5), consistent with our guidance in section 10.7.1 of Chapter 4 of the

¹³³The Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter addresses this in a response to a comment on page 20-21 and is available at the following link: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2011.pdf>.

¹³⁴In addition, the See page 31 of the MA Payment Guide for Out of Network Payments, page 31, addresses this topic. The guide is available at the following link: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/downloads/oonpayments.pdf>.

Medicare Managed Care Manual, we proposed that MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial under NCD 310.1. This protection is necessary in order to ensure that MA enrollees have access to and coverage of clinical trials within the scope of NCD 310.1 to the same extent as Medicare beneficiaries enrolled in the traditional Medicare program. While MA plans are responsible for covering any differences in cost-sharing between traditional Medicare and MA plan in-network costs for services in the same category, traditional Medicare, through the MACs, is responsible for all other costs included in clinical trials within the scope of NCD 310.1. Finally, in accordance with § 422.109(c)(2), CMS requires MA organizations to provide coverage for: 1) services to diagnose conditions covered by clinical trial services; 2) most services furnished as follow-up care to clinical trial services; and 3) services already covered by the MA organization. Because § 422.109(c) adequately addresses how MA organizations are required to cover certain benefits and costs even when the traditional Medicare program pays for changes in benefits as a result of an NCD or legislative change, we do not believe that additional regulation text is necessary to apply those rules in the context of NCD 310.1.

Comment: A commenter supported the proposal to codify clinical trial-related policies under NCD 310.1 and stated it believes there is sufficient information on expectations of MA organizations with respect to clinical trial coverage. The commenter also suggested that CMS continue to provide MA organizations with information about coverage responsibilities for Medicare-covered trials to include information in the final decision memo for the NCD regarding significant cost as well as information on policy implications for Part D, dually eligible, and Medicaid.

Response: We thank the commenter for its support of our proposal. We note that, for clinical trials that are outside the scope of NCD 310.1 and are conducted under a separate NDC, coverage of items and services under that separate NCD is addressed by the existing regulation at

§ 422.109(a) through (d). We also appreciate the commenter's suggestion that significant cost information be included with the decision memo for the NCD and will work with our colleagues in Traditional Medicare about including this information in future decision memos. With respect to information about other programs, unless the NCD has specific information relevant to other programs, we believe that each program can best explain through its guidance for the program any issues in implementation or coverage.

Comment: A 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. The commenter expressed concern that the enrollee or the MA organization would have no control over whether the enrollee would, for example, receive a placebo, or the treatment being tested in the trial which could put the enrollee's health and quality of care at risk while also undermining the MA organization's care coordination efforts for the enrollee.

Response: Under the current policy that we proposed to codify, Traditional Medicare pays for MA enrollees for clinical trials under 310.1. 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 organizations may, however, require prior authorization for A and B-IDE trials and NCD-CEDs. Although MA organizations may not require prior authorization for clinical trials under 310.1, enrollees, if they choose, may notify plans of their participation in clinical trials and MA organizations may help facilitate communication with the trial leaders and enrollee. MA enrollees in clinical trials also receive the same protections as those in Traditional Medicare, including informed consent requirements and discussion of the trial's features, such as, whether a placebo will be used.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 422.109(e) as proposed with a minor modification to the heading for paragraph (e) to clarify the scope of the paragraph is limited to NCD 310.1.

2. A-B Investigational Device Exemption Trials

The regulation at § 405.211 specifies Medicare coverage of Category A and B investigational device exemption (IDE) studies. Providers of device trials must submit evidence of an FDA approved IDE for the devices studied, as part of their application to CMS for approval of a trial. Once a trial has been approved by CMS, it is listed on the CMS website. In addition to including assessment of devices, IDE trials differ from clinical trials under NCD 310.1, as they are not covered as a result of an NCD nor are they subject to a significant cost assessment. As a result, MA organizations are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered under traditional Medicare. This is part of the MA organization's obligation to cover the items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B for their enrollees under section 1852 of the Act.

MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. An MA plan is also responsible for coverage of CMS-approved Category B devices. While CMS will cover routine care items and services, it will not approve coverage of Category A devices themselves because they are considered experimental and excluded from coverage under § 405.211(a). As with other benefits for which it is responsible for coverage, an MA plan may apply utilization management, including prior authorization, consistent with § 422.4(a)(1)(ii).

Section 10.7.2 of Chapter 4 of the Medicare Managed Care Manual addresses this policy. In order to clarify this scope of required coverage for MA plans and avoid any inadvertent confusion between the coverage requirements associated with clinical trials under NCD 310.1, we proposed to add § 422.109(f) to specify MA plan coverage of the routine items and services, including the Category B IDE device and related items and services in the context of a Category A and B IDE studies, that are covered by Medicare under §§ 405.211(a) and (b).

Comment: A couple of commenters expressed support for the clinical trial-related proposals, but requested that it was especially necessary in the case of B-IDE coverage to have some mechanism to indicate an enrollees' MA status. The commenters stated that inability for MA plans and providers to distinguish MA enrollees from other enrollees in commercial plans can lead to confusion and delays in coverage.

Response: Per § 422.111(i), MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the MA plan. Such cards indicate that the enrollee is in an MA plan and must meet, at a minimum, the content requirements at § 422.2267(e)(30). The minimum required information includes the MA plan's website, customer service number, and contract/PBP number; the cards should also include information on how to contact the plan if there are questions about coverage. Providers also have access to the HIPAA Eligibility Transaction System (HETS), which permits providers to view Medicare eligibility and coverage. We believe compliance with these regulations and use of the HETS website are sufficient to allow providers and plans to determine plan coverage for B-IDE.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 422.109(f) without modification.

3. National Coverage Determinations with Coverage with Evidence Development

As with other Part A and B benefits (aside from hospice and the cost of kidney acquisition for transplant), MA plans must cover items and services covered by Medicare under NCDs. This is true for NCDs that also have a trial or registry component that is required as part of the coverage, which is explained in section 10.7.3 of Chapter 4 of the Medicare Managed Care Manual. This is referred to as "coverage with evidence development" (CED), as authorized under section 1862(a)(1)(E) of the Act. CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of CMS approved clinical studies

or with the collection of additional clinical data (for example, registry). A list of NCD-CEDs with the coverage protocol for each is available at:

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development>

As in the proposed rule, we are merely reiterating here that MA plans must cover NCDs with CED and CMS has not proposed or finalized a change in coverage requirements or policy for MA plans on this topic. We solicited comment whether additional regulations are needed to address NCDs with CED; we believe that § 422.101(b) is sufficient that these NCDs are within the scope of the traditional Medicare benefits that MA plans must cover and that additional regulations are unnecessary. MA plans may apply utilization management, including prior authorization, to the Medicare benefits covered under these NCDs, consistent with § 422.4(a)(1)(ii) of the MA program regulations.

Significant Cost

In cases of a new NCD or legislative change in benefits, CMS determines, consistent with § 422.109(b), whether the benefit or service is a significant cost to MA plans. As in the December 2022 proposed rule, CMS is including this discussion to make clear that significant cost requirements apply to all new NCDs, that is, that the significant cost assessment includes NCDs with CED. The thresholds for significant cost are specified in §§ 422.109(a)(1) and (a)(2). The assessment generally applies to each NCD or legislative change in benefits that occurs after the rate announcement for a contract year such that the change in costs was not incorporated into the capitation rates for the contract year. Costs are estimated for a particular NCD or legislative change in benefits so the thresholds specified in §§ 422.109(a)(1) and (a)(2) apply to each NCD or legislative change in benefits rather than to the aggregate number of such changes over the course of a contract year.

Comment: A commenter stated it did not believe regulations beyond those proposed were necessary for NCD-CED policies and that it believes that the agency is taking appropriate steps to ensure that NCD-CEDs generate meaningful clinical data.

Response: We thank the commenter for its input on this proposal.

Comment: A commenter was concerned that with respect to NCD-CEDs, our proposal would shift costs from Medicare Advantage to Traditional Medicare. The commenter was also concerned that the NCD-CED proposal could permit obstacles to emerging care for especially patients with rare diseases because of utilization management policies permitted under the Medicare Advantage program.

Response: Currently, Traditional Medicare covers clinical trials under 310.1 for MA enrollees while MA plans are responsible for covering NCD-CED and A-B IDE trials. Because MAOs already cover NCD-CEDs there will be no cost-shifting from the Medicare Advantage program to Traditional Medicare. As with any benefit for which it is responsible, an MA plan may require utilization management, including prior authorization, subject to the requirements in Part C of the Medicare statute and MA regulations in 42 CFR Part 422. We direct readers to section III.E., Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and use of Prior Authorization, Additional Continuity of Care Requirements, and Review of Utilization Management Tools for new requirements related to prior authorization and other utilization management policies being finalized in this rule.

After considering the comments revised and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision without modification.

L. Update of Terminology to “Individuals with Intellectual Disabilities” (§ 423.154)

We proposed a terminology update at § 423.154(c) to the outdated term “mentally retarded.” We inadvertently neglected to update this terminology in our regulations following two previous terminology updates found in the “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction” final rule which appeared in the **Federal Register** on May 16, 2012 (77 FR 29001) and the “Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” final rule which appeared in the Federal Register on February 12, 2015 (80 FR 7911). Consequently, we proposed to update the current language at § 423.154(c) (that is, update it to use the term “individuals with intellectual disabilities”).

We solicited comments on this proposal.

Comment: A commenter indicated their support for the transition to the term “intellectual disabilities.” They stated that CMS should prioritize the use of compassionate language when engaging with patient populations and noted that the intent of the proposed rule is consistent with CMS updates that have taken place over the last decade.

Response: CMS agrees that the language currently used at § 423.154(c) is outdated and inappropriate. The terminology update will improve the consistency of language used in regulations while following the intent and spirit of Rosa’s Law (Pub. L. 111-256). We are therefore finalizing the proposed update to § 423.154(c) without modification.

M. Technical Correction to Restore the Substantial Difference Requirement (§ 423.265)

We proposed to make a technical correction to § 423.265(b)(2) to restore language on requirements for substantial differences between Medicare Part D sponsors’ bids that was inadvertently removed in a recent revision of the section.

In the “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” final rule, which appeared in the **Federal**

Register on April 16, 2018 (hereinafter referred to as the April 2018 final rule, 73 FR 16440), we reorganized paragraph (b)(2) to incorporate a general rule in paragraph (b)(2)(i) and an exception in paragraph (b)(2)(ii), the latter of which excluded enhanced alternative plan bid submissions from the substantial difference requirement.

We added language placing limits on the number of Part D plan offerings as part of the final rule titled “Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” which appeared in the **Federal Register** on January 19, 2021 (hereinafter referred to as the January 2021 final rule, 86 FR 5864). However, the new language was incorrectly added to § 423.265(b)(2) rather than § 423.256(b)(3), and the previous regulatory text on substantial differences was inadvertently overwritten. To correct this inadvertent deletion, we proposed to:

- Redesignate the regulatory text from our January 2021 final rule limiting the number of bids a Part D plan sponsor may submit currently at § 423.265(b)(2) as § 423.265(b)(3);
- Restore the language from our April 2018 final rule on substantial differences at § 423.265(b)(2)(i) and (ii); and
- Redesignate the regulatory text currently at § 423.265(b)(3) as paragraph (b)(4).

As described previously, all of the regulatory language that we proposed to restore at § 423.265(b)(2) has previously undergone the full notice and comment process. This proposal would merely correct a technical error made by the January 2021 final rule.

We received no comments on the proposed technical correction to § 423.265(b)(2) and are finalizing our proposal without modification.

N. Gross Covered Prescription Drug Costs (§ 423.308)

Section 1860D-15(b)(3) of the Act defines “gross covered prescription drug costs” as, “with respect to a part D eligible individual enrolled in a prescription drug plan or MA-PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but

including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.” In our final rule, “Medicare Program; Medicare Prescription Drug Benefit,” which appeared in the **Federal Register** on January 28, 2005 (70 FR 4194), we codified the definition of “gross covered prescription drug costs” at § 423.308. This regulatory definition refers to “gross covered prescription drug costs” as “actually paid costs.” The term “actually paid” has a specific meaning in Medicare Part D and is separately defined at § 423.308 to mean costs actually incurred by the plan that are net of direct and indirect remuneration (DIR), including discounts, rebates, or other price concessions typically received and applied after the point of sale (POS). However, unlike the statutory definitions of “allowable reinsurance costs” and “allowable risk corridor costs” at sections 1860D-15(b)(2) and 1860D-15(e)(1)(B) of the Act, respectively, the statutory definition of “gross covered prescription drug costs” at section 1860D-15(b)(3) of the Act does not use the phrase “actually paid” or otherwise specify that such costs must be net of all DIR. As we explained in the December 2022 proposed rule (87 FR 79611), because the definition of “gross covered prescription drug costs” was codified in regulation for the sole purpose of describing the methodology for calculating the reinsurance payment amount, in using the phrase “actually paid” in the regulatory definition of “gross covered prescription drug costs,” CMS was incorporating a requirement from the statutory definition of “allowable reinsurance costs” to emphasize that DIR would be netted out in the calculation of costs eligible for Part D reinsurance.

In light of certain provisions added to the Social Security Act by the Inflation Reduction Act of 2022 (IRA) that refer to “gross covered prescription drug costs as defined in section 1860D-15(b)(3) [of the Act]” (see sections 1191(c)(5) and 1860D-14C(g)(4)(D) of the Act), we revisited the regulatory definition of “gross covered prescription drug costs.” We proposed to revise the regulatory definition of “gross covered prescription drug costs” to mirror the language

in the statutory definition and to remove any ambiguity that might arise from the current regulatory definition as it may now also be applicable outside of the reinsurance context. Specifically, we proposed to amend the definition of “gross covered prescription drug costs” at § 423.308 to remove the phrase “actually paid.”

As we explained in the proposed rule, the proposed revisions to the definition would not change the fact that Part D reinsurance is ultimately based on net drug costs or change the final reinsurance payment amount a Part D sponsor receives. Rather, allowable reinsurance costs would continue to be defined at § 423.308 as the subset of gross covered prescription drug costs actually paid. Thus, the revision would not constitute a change in policy or require a change in operations under Part D, and would not place any additional burden or reduce existing burden on Part D sponsors, nor result in government savings or costs.

1. Background

The term “gross covered prescription drug costs” (hereinafter referred to as “GCPDC”) is defined and used at section 1860D-15(b) of the Act for the purpose of describing the methodology for calculating the reinsurance payment amount. As specified in section 1860D-15(b)(1)(A) of the Act, the reinsurance payment amount for a year preceding 2025 is equal to “80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B).” Although the statutory definition of “allowable reinsurance costs” at paragraph (2) of section 1860D-15(b) of the Act specifies that such costs are the subset of GCPDC that are “actually paid (net of discounts, chargebacks, and average percentage rebates),” the statutory definition of GCPDC at paragraph (3) of section 1860D-15(b) of the Act does not use the phrase “actually paid” or otherwise specify that such costs must be net of all DIR. As we explained in the proposed rule, this distinction, coupled with the use of the modifier “gross” to describe these costs, indicates that the best reading of section

1860D–15(b)(3) of the Act is that GCPDC should reflect gross costs, not net costs that reflect all DIR that a Part D sponsor may receive. We also stated that CMS’ use of the phrase “actually paid” in the current regulatory definition of GCPDC was intended to emphasize that all DIR would be netted out in the calculation of costs eligible for Part D reinsurance consistent with the plain language of the statute, which requires that the reinsurance payment amount be based on net drug costs. While the use of the phrase in the current regulatory definition of GCPDC is consistent with the statute for this reason, we recognized that it may have led to ambiguity as to when the DIR would be netted out. We also recognized that the use of the phrase could create ambiguity when GCPDC is referenced outside of the reinsurance context.

We further noted in the proposed rule that the statutory definition of GCPDC describes these costs as “not including administrative costs, but including costs directly related to the dispensing of covered Part D drugs during the year and costs relating to the deductible.” CMS has long held that costs directly related to the dispensing of covered Part D drugs are most logically calculated as the accumulated total of the negotiated prices that are used for purposes of determining payment to the pharmacy or other dispensing entity for covered Part D drugs, and which are required under section 1860D-2(d)(1) of the Act to be made available to Part D beneficiaries and are used to adjudicate the Part D benefit (that is, used to determine plan, beneficiary, manufacturer, and government liability during the course of the payment year).^{135, 136}

¹³⁵We noted that this logic is borne out in the portion of our current regulatory definition of GCPDC at § 423.308 that states that GCPDC reflect “actual costs.” “Actual cost” is defined at § 423.100 as the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy.

¹³⁶The different components of the negotiated price of a drug, and ultimately of GCPDC, are required to be reported separately using the following cost fields on the Prescription Drug Event (PDE) record submitted to CMS by Part D plan sponsors for payment purposes, the sum of which must equal GCPDC: Ingredient Cost, Dispensing Fee, Vaccination Administration, and Sales Tax. GCPDC are also required to be reported using the following two payment fields on the PDE record depending on whether the costs fall in the catastrophic phase: Gross Drug Cost Below the Out of Pocket (OOP) Threshold (GDCB) and Gross Drug Cost Above the OOP Threshold (GDCA). The amounts reported in these fields are then used to update the Total Gross Covered Drug Cost (TGCDC) Accumulator on the PDE record, which tracks and indicates which non-catastrophic phase of the Part D benefit the beneficiary is in. See, for example, 2006 Prescription Drug Event Data Training Participant Guide, available at [https://www.csscooperations.com/internet/csscw3_a.nsf/DIDC/K3V5B8PN1H~Prescription%20Drug%20Program%20\(Part%20D\)~Training](https://www.csscooperations.com/internet/csscw3_a.nsf/DIDC/K3V5B8PN1H~Prescription%20Drug%20Program%20(Part%20D)~Training), and 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, available at [https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20\(Part%20D\)~Training](https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training).

As stated in several past rulemakings, we interpret the statutory definition of “negotiated prices” at section 1860D-2(d)(1)(B) of the Act as allowing the application of DIR at the POS, to reduce the negotiated price, either at the discretion of Part D plan sponsors or at the direction of CMS (see, for example, 70 FR 4244, 74 FR 1511, and 87 FR 27833). Therefore, even if the phrase “actually paid” were not included in the regulatory definition of GCPDC, GCPDC would continue to be reduced by POS DIR reflected in negotiated prices. However, such an accounting of POS DIR would not make the resulting amount “actually paid,” which requires accounting for all DIR, including DIR not applied at the POS.

As a supplement to the background we included in the NPRM, we also wish to clarify that in using Part D negotiated prices to calculate GCPDC, we currently include manufacturer discounts paid under the Coverage Gap Discount Program under section 1860D-14A of the Act and will continue to do so through 2024. Such manufacturer discounts are paid at the POS by the Part D sponsor on behalf of the manufacturer, and the manufacturer is required to reimburse the Part D sponsor on behalf of the Part D beneficiary, with the discounts counting as incurred costs as required by section 1860D-2(b)(4)(E) of the Act. Manufacturer discounts paid under the Coverage Gap Discount Program have been included in GCPDC since the beginning of the Coverage Gap Discount Program, and this practice is consistent with the current statutory and regulatory definitions of GCPDC, which generally require the inclusion of all costs incurred under the plan paid by the plan or by or on behalf of the Part D beneficiary. The change we proposed to the regulatory definition of GCPDC in the December 2022 proposed rule does not alter that fact, thus, GCPDC would continue to include Coverage Gap Discount payments even if the phrase “actually paid” is no longer included in the regulatory definition of GCPDC. We also note that section 11201(c)(2) of the IRA adds paragraph (h) to section 1860D-14A to sunset the Coverage Gap Discount Program on January 1, 2025. Section 11201(b)(2) of the IRA adds subparagraph (B) to section 1860D-15(b)(2) of the Act to require the inclusion of manufacturer discounts paid under the Manufacturer Discount Program under section 1860D-14C in the

calculation of allowable reinsurance costs, as defined in section 1860D-15(b)(2)(A), beginning in 2025. Additionally, section 11201(b)(3) of the IRA amends section 1860D-15(b)(3) in two places to also require the inclusion of manufacturer discounts paid under the Manufacturer Discount Program in the calculation of GCPDC (first, by specifying that the definition of GCPDC is subject to paragraph (2)(B) of section 1860D-15(b) and second, by adding language specifying that with respect to 2025 and subsequent years, in the case of an applicable drug, as defined in section 1860D-14C(g)(2), GCPDC shall be determined whether the costs are paid by the individual, under the plan, or by a manufacturer). There are two important differences between the Coverage Gap Discount Program and Manufacturer Discount Program that would result in manufacturer discounts paid under the two programs being treated differently for purposes of calculating allowable reinsurance costs and GCPDC absent the explicit statutory requirement to include manufacturer discounts paid under the Manufacturer Discount Program in the calculation of these amounts. First, unlike manufacturer discounts paid under the Coverage Gap Discount Program, manufacturer discounts paid under the Manufacturer Discount Program do not count toward incurred costs per section 1860D-2(b)(4)(C)(iii)(II) of the Act and thus are not considered paid by or on behalf of Part D beneficiaries. Second, the Manufacturer Discount Program creates a new manufacturer discount obligation in the catastrophic phase, so the treatment of such discounts has a direct impact on the calculation of the reinsurance payment amount for the first time beginning in 2025. Further information on the treatment of manufacturer discounts paid under the Manufacturer Discount Program under section 1860D-14C of the Act for purposes of calculating allowable reinsurance costs and GCPDC will be provided prior to the start of the Manufacturer Discount Program in 2025.

In the December 2022 proposed rule (87 FR 79612), we proposed to amend the definition of “gross covered prescription drug costs” at § 423.308 to mirror the statutory language in section 1860D-15(b)(3) of the Act and to remove any ambiguity that might arise from the current regulatory definition of GCPDC, as discussed in greater detail in this section of this final rule.

2. Proposed Change

Consistent with the language of section 1860D-15(b) of the Act, CMS policy, including the current reporting requirements, and operations, including how the industry tracks and reports costs (that is, industry practice), we proposed to amend the definition of “gross covered prescription drug costs” at § 423.308 to remove the two references to “actually paid” to clarify that GCPDC are not net of all DIR.

We explained that the proposed change would have no impact on Part D payment calculations or reporting requirements. Consistent with section 1860D-15(b)(2), the reinsurance payment amount would continue to be calculated based on drug costs net of DIR. Outside of the reinsurance context, CMS’ long-standing operational guidance has instructed plans to report costs without first netting out DIR applied after the POS, and thus, the guidance would not need to be adjusted as a result of this proposed change to the regulatory definition of GCPDC. For instance, the amounts reported in the Ingredient Cost, Dispensing Fee, Vaccine Administration, Sales Tax, GDCB, GDCA, and the TGCDL Accumulator fields on the PDE record are required to include costs incurred by the Part D sponsor and all amounts paid by or on behalf of an enrollee under a Part D plan. Further, CMS guidance instructs Part D sponsors to net out only plan administrative costs and any DIR applied at the POS when reporting GCPDC. Hence, a key step in calculating the Part D reinsurance payment amount is to determine the allowable reinsurance cost amount by subtracting from the GCPDC incurred in the catastrophic phase all DIR attributable to the proportion of catastrophic phase spending that was not already accounted for at the POS in order to determine the amount “actually paid” by the Part D plan and ensure that the reinsurance payment amount is ultimately calculated based on net drug costs. As we would continue to take this important step in determining allowable reinsurance costs for purposes of calculating the reinsurance payment amount even if “actually paid” were removed from the regulatory definition of GCPDC as proposed, there would be no change in the final reinsurance payment amount a Part D sponsor receives.

Moreover, we noted that no other rules or policies would be affected by this proposed change, including the rules regarding how to account for coverage not provided by the Part D sponsor, and instead provided by other payers, because they do not directly address the calculation of the reinsurance payment amount and thus do not rely on the current regulatory definition of GCPDC. For example, we explained that under rules regarding Medicare secondary payer (MSP) or subrogated claims, the amounts reported in the cost and payment fields of the PDE record reflect a reduction in the Part D plan's incurred cost for a drug resulting from other payer arrangements, which is currently captured in GCPDC and would continue to be captured in GCPDC under our proposed revisions.

We noted that in the 2022 final rule titled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (87 FR 27833 through 27851) which appeared in the **Federal Register** on May 9, 2022, we amended our regulations at § 423.100, to add a new definition of "negotiated price" effective January 1, 2024. The new definition specifies, among other things, that the negotiated price for a Part D drug is the lowest possible reimbursement a network pharmacy will receive, in total, for the drug, net of all pharmacy price concessions. Thus, as of January 1, 2024, all price concessions from network pharmacies, negotiated by Part D sponsors and their contracted pharmacy benefit managers (PBMs), will be reflected in the negotiated price that is made available at the POS and reported to CMS on a PDE record, meaning that these pharmacy price concessions will be reflected in GCPDC even if the phrase "actually paid" is removed from the regulatory definition of the term as proposed. We reiterated that, accounting for DIR, including pharmacy price concessions, applied at the POS in the calculation of GCPDC, does not make the resulting amount "actually paid," which requires accounting for all DIR, including DIR not applied at the POS.

While this proposed change to the regulatory definition would not be a change in policy and would not directly affect the way in which GCPDC are calculated and used for purposes of Part D, we stated that we believe it is important to revise the definition to remove any ambiguity regarding the meaning of the term “gross covered prescription drug costs.” As noted previously, the IRA added provisions to the Social Security Act that refer to “gross covered prescription drug costs as defined in section 1860D–15(b)(3) [of the Act].” Removing the phrase “actually paid” from the regulatory definition of GCPDC as proposed would eliminate any ambiguity in the regulation text and help to ensure there is a consistent understanding of the meaning of this term for purposes of both the Part D program and the relevant provisions of the IRA.

We further explained that nothing in the proposed change would place additional requirements on Part D sponsors or beneficiaries or change how CMS currently uses the GCPDC reported by the Part D sponsor on the PDE for purposes of determining payments under Part D. Rather the proposed change would be consistent with our current policy and operations, including the current reporting requirements. As such, the proposed change to the definition of “gross covered prescription drug costs” at § 423.308 would not place any additional burden on Part D sponsors, nor did we expect that the proposed change would result in savings.

We received 19 pieces of correspondence containing one or more comments in response to our proposal to amend the regulatory definition of “gross covered prescription drug costs” at § 423.308 by removing the phrase “actually paid.”

Comment: Several commenters supported the proposed revisions to the regulatory definition of GCPDC at § 423.308 to mirror the statutory definition. The commenters agreed that the statutory definition of GCPDC at section 1860D-15(b)(3) of the Act does not use the phrase “actually paid” or otherwise specify that such costs must be net of all DIR. Some of these commenters agreed with CMS that the use of the phrase “actually paid” in the statutory definition of “allowable reinsurance costs” at section 1860D-15(b)(2) of the Act, but not in the statutory definition of GCPDC at section 1860D-15(b)(3) indicates that GCPDC should not be

understood to mean net drug costs. These commenters agreed that removing the phrase “actually paid” from the regulatory definition would allow the definition to better reflect the definition of GCPDC in the Social Security Act and avoid any ambiguity.

Response: We appreciate the feedback and support from these commenters.

Comment: A few commenters asserted that the distinction between GCPDC and “allowable reinsurance costs” is not based on whether GCPDC is net of all DIR and that GCPDC does not need to reflect gross drug costs. These commenters contended that the statute merely requires allowable reinsurance costs to be the subset of costs (1) incurred by the plan alone, not the enrollee, and (2) for basic prescription drug coverage only.

Response: We disagree with the commenters. First, even if we accept the suggestion that GCPDC does not need to reflect gross drug costs, the commenters did not demonstrate why GCPDC should or must reflect net drug costs and thus why the change being considered is not reasonable and appropriate. Second, the commenters did not account for the fact that the phrase “actually paid” is used in the statutory definition of “allowable reinsurance costs” at section 1860D-15(b)(2) of the Act but does not appear in the statutory definition of GCPDC at section 1860D-15(b)(3). As a result, we believe the statute draws a distinction between the two terms with respect to the treatment of DIR. As stated in the proposed rule, this distinction, coupled with the use of the modifier “gross” to describe GCPDC, indicates that the best reading of section 1860D-15(b)(3) of the Act is that GCPDC should reflect gross costs, not net costs. Finally, we note that section 1860D-15(b)(2) of the Act requires that “allowable reinsurance costs” include costs incurred by the Part D sponsor as well as the enrollee (specifically defining such costs as those actually paid “by the sponsor or organization or by (or on behalf of) an enrollee under the plan”), and not, as the commenters suggest, just the costs incurred by the plan alone.

Comment: Several commenters stated that CMS did not complete an adequate regulatory impact analysis because the agency failed to account for the policy implications of this proposed change on IRA implementation, including on the selection of drugs for Medicare price

negotiation. A commenter added that the IRA impacts should have been part of CMS' analysis given that CMS acknowledged in the proposed rule that the term for which the regulatory definition is being amended is referenced in the IRA. These commenters further posited that, by omitting any discussion of the proposal's implications for the implementation of the IRA, CMS did not provide the specificity and clarity needed to allow interested parties to participate in the rulemaking process in a meaningful and informed manner and that finalizing the proposed change would therefore violate the requirements for notice-and-comment rulemaking under the Administrative Procedure Act (APA).

Response: We disagree with the commenters. We do not believe that it was necessary for the proposed rule to take into account possible impacts that the proposed change to the regulatory definition of GCPDC might have on IRA implementation. The regulatory definition that CMS is amending was adopted for use and currently applies only in the context of determining reinsurance payments under the Part D program. Guidance related to the IRA, including details of the requirements and procedures for implementing the Medicare Drug Price Negotiation Program, is being provided outside of this rulemaking, in accordance with the requirements under the IRA to implement certain provisions by program instruction instead of notice-and-comment rulemaking.^{137, 138}

Within the reinsurance context, as noted in the proposed rule, amending the regulatory definition of GCPDC as proposed creates no additional requirements or other burden on Part D sponsors or beneficiaries, nor does it change how CMS currently uses the GCPDC reported by the Part D sponsor on the PDE record for purposes of determining payments under Part D. Moreover, as discussed in the proposed rule, because we will continue to take the important step of removing all DIR in determining allowable reinsurance costs for purposes of calculating the

¹³⁷See sections 11001(c) and 11002(c) of the IRA.

¹³⁸We refer readers to the Initial Guidance for the Medicare Drug Price Negotiation Program for further discussion of implementation of the Medicare Drug Price Negotiation Program for initial price applicability year 2026. Available here: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>.

reinsurance payment amount, there will be no change in the final reinsurance payment amount a Part D sponsor receives, and thus no change in government costs. We believe this analysis is a sufficient assessment of the impact of the proposed revisions to the regulatory definition of GCPDC and meets all applicable APA requirements.

Comment: A commenter agreed with our impact assessment and noted that the level of information was helpful in providing clarity on the agency's thinking.

Response: We appreciate the feedback from the commenter.

Comment: A commenter encouraged CMS to make the proposed change effective as of September 1, 2023 to coincide with IRA implementation timelines.

Response: The revised definition of GCPDC will take effect on the effective date of this final rule and will also be applicable on that date.

Comment: A few commenters suggested that since a "clear interpretive rule" that defined GCPDC in regulation as "actually paid" already existed when the IRA was enacted, Congress intentionally used the term GCPDC to mean net drug costs.

Response: There is no reference in the IRA to the regulatory definition of GCPDC at § 423.308. Although certain provisions of the IRA reference GCPDC "as defined in section 1860D-15(b)(3)," the statutory definition of GCPDC does not use the phrase "actually paid" or otherwise specify that these costs must be net of all DIR. Furthermore, as we stated in the proposed rule, because the definition of GCPDC was codified in regulation for the sole purpose of describing the methodology for calculating the reinsurance payment amount, the use of the phrase "actually paid" in the regulatory definition of GCPDC was intended to incorporate a requirement from the statutory definition of "allowable reinsurance costs" to emphasize that DIR would be netted out in the calculation of costs eligible for Part D reinsurance as required by the statute. Thus, the current regulatory definition should not be understood to reflect the agency's interpretation of the plain language of section 1860D-15(b)(3) at the time the IRA was enacted.

Comment: Several commenters expressed concern that CMS' proposed revision of the regulatory definition of GCPDC serves as a determination by CMS that the selection of drugs for the Medicare Drug Price Negotiation Program will be based on gross drug costs instead of net drug costs. Commenters noted several concerns related to the selection of drugs based on gross drug costs. A few commenters also provided general comments about drug selection under the Medicare Drug Price Negotiation Program, including a request for CMS to publish gross expenditure data that will be used for ranking drugs selected for negotiation and provide guidance on drug pricing and selection for Medicare Drug Price Negotiation Program.

Response: We thank the commenters for their consideration. As previously stated, the regulatory definition that CMS is amending was adopted for use and currently applies only in the context of determining reinsurance payments under the Part D program. Guidance related to the IRA, including guidance on the selection of drugs for the Medicare Drug Price Negotiation Program, is being provided outside of this rulemaking. Specifically, we refer readers to the Initial Guidance for the Medicare Drug Price Negotiation Program issued on March 15, 2023 for further discussion of the topics raised by the commenters.

After considering all of the comments received, CMS is finalizing as proposed the revisions to the definition of "gross covered prescription drug costs" at § 423.308 and removing the two uses of the phrase "actually paid" and replacing the second use with "paid."

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 423.182, 423.184, and 423.186)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA) /Part C and Part D plans based on the requirement to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act and the collection of different types of quality data under section 1852(e) of the Act. The Part C and Part D Star Ratings system is used to determine quality bonus payment (QBP) ratings

for MA plans under section 1853(o) of the Act and the amount of beneficiary rebates under section 1854(b) of the Act. Cost plans under section 1876 of the Act are also included in the Part C and Part D Star Ratings system, as codified at § 417.472(k). We use multiple data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information provided directly from health and drug plans, and data collected by CMS contractors. Various regulations, including §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans. The methodology for the Star Ratings system for the MA and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively, and we have specified the measures used in setting Star Ratings through rulemaking. In addition, the cost plan regulation at § 417.472(k) requires cost contracts to be subject to the Part 422 and 423 Part C and Part D Quality Rating System. (83 FR 16526-27). As a result, the policies adopted as final in this rule apply to the quality ratings for MA plans, cost plans, and Part D plans. We generally use “Part C” to refer to the quality measures and ratings system that applies to MA and cost plans. Where a cost plan covers Medicare Part D, it is treated like an MA-PD plan and therefore must also report Part D measures.

We are working to ensure that the Star Ratings program is aligned with the CMS Quality Strategy as that Strategy evolves over time. This includes reducing the weight of patient experience/complaints and access measures and codifying clarifications to the rules for calculating the Part C and D Star Ratings related to disasters and contract consolidations. The current CMS National Quality Strategy encourages the highest quality outcomes, safest care, equity, and accessibility for all individuals (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>). In addition to focusing on a person-centric approach as individuals move across the continuum of care, the current CMS Quality Strategy aims to create a more equitable, safe, and outcomes-based health

care system and, where feasible, works to align performance metrics, programs, and policy across CMS programs.

In this final rule, we are finalizing a health equity index reward to further incentivize Part C and D plans to focus on improving care for enrollees with specified social risk factors (SRFs), and to support CMS efforts to ensure attainment of the highest level of health for all people. We are also finalizing the following measure updates:

- Remove the Part C Diabetes Care – Kidney Disease Monitoring measure;
- Add the updated Part D Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) measures; and

- Add the Part C Kidney Health Evaluation for Patients with Diabetes measure.

We are also finalizing several methodological changes:

- Reduce the weight of patient experience/complaints and access measures to further align the Part C and Part D Quality Rating System with other CMS quality programs;
- Add an additional basis for the subregulatory removal of Star Ratings measures; and
- Remove the 60 percent rule for the adjustment for extreme and uncontrollable circumstances (generally called the adjustment for disasters).

Finally, we are also finalizing a series of technical clarifications of the existing rules related to adjustments for disasters and contract consolidations, as well as a technical amendment to §§ 422.162(a)(2)(i) and 423.186(a)(2)(i) to fix a codification issue. Unless otherwise stated, the changes will apply (that is, data will be collected and performance measured) for the 2024 measurement period and the 2026 Star Ratings.

In addition, we proposed in the December 2022 proposed rule other policies to amend the Part C and D Star Ratings but are not addressing those proposals in this final rule; those other proposals will be addressed in a subsequent, second final rule. Any policies we proposed in the December 2022 proposed rule that are addressed in that subsequent rule would apply (that is,

data will be collected and performance measured) for no earlier than the 2025 measurement period and the 2027 Star Ratings. CMS appreciates the feedback we received on our proposals.

In the sections that follow, we summarize the comments we received on each proposal we are finalizing and provide our responses.

B. Definitions (§§ 422.162 and 423.182)

We proposed to add the following definition for Part 422, Subpart D (for Part C plans) and Part 423, Subpart D (for Part D plans) in paragraph (a) of §§ 422.162 and 423.182, respectively.

- Health equity index means an index that summarizes contract performance among those with specified SRFs across multiple measures into a single score.

We received no comments on this proposed definition in paragraph (a) of §§ 422.162 and 423.182 and are finalizing it without modification for the reasons in the proposed rule. This new definition is relevant for our policies discussed in section V.F. of this final rule and will be used in that context.

C. Contract Ratings (§§ 422.162(b) and 423.182(b))

1. Contract Type

In the April 2018 final rule (83 FR 16440) at §§ 422.162(b) and 423.182(b), we codified the methodology for calculating the same overall and summary Star Ratings for all plan benefit packages (PBPs) offered under each MA-only, MA-PD, or PDP contract.

As different organization or contract types offer different benefits, the overall and summary Star Ratings differ across contract types when the set of required measures differs. For example, non-SNP contracts do not currently submit the following measures and, therefore, their overall and Part C summary ratings do not include them: SNP Care Management, Care for Older Adults - Medication Review, and Care for Older Adults - Pain Assessment.

We proposed to amend §§ 422.162(b)(1) and 423.182(b)(1) to add a sentence at the end to clarify that the overall and summary Star Ratings are calculated based on the measures required

to be collected and reported for the contract type being offered for the Star Ratings year. This is our current practice and how the Star Ratings have historically been calculated. For example, the 2023 Star Ratings were calculated for the 2023 contract year using data primarily from measurement year 2021.¹³⁹ The 2023 Star Ratings were published on Medicare Plan Finder in October 2022 to provide comparative quality performance information about plans for people with Medicare to use in making enrollment decisions for the 2023 calendar year. If a contract offered a SNP PBP in measurement year 2021, but is no longer offering a SNP PBP for the 2023 contract year, the 2023 Star Ratings excluded the SNP-only measures and the contract was rated as “Coordinated Care Plan without SNP.” This is our current (and historical) process and how the proposed regulatory clarification would be applied.

We solicited comments on this proposal.

Comment: A commenter expressed support.

Response: CMS appreciates the support.

After considering the comments we received and for the reasons outlined in the proposed rule, we are finalizing the clarification at §§ 422.162(b)(1) and 423.182(b)(1) regarding the scope of measures used in calculating the overall and summary ratings without modification. We are also finalizing a revision related to adoption of the health equity index and future removal of the reward factor, which is discussed in more detail in section V.F. of this final rule.

2. Contract Consolidations

The process for calculating measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). As described in the April 2018 final rule (83 FR 16528 through 16531), we use the enrollment-weighted means of the measure scores of the consumed and surviving contract(s) to calculate the measure-level ratings for the first and

¹³⁹There are exceptions to this for some measures. For example, as adopted in the April 2018 final rule and used now, the measures from the CAHPS survey are based on the most recent data submitted from surveys of enrollees; the surveys ask about the experience of the enrollees over the last six months. The annual Medicare Part C & D Star Ratings Technical Notes (available online here: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData>) identify the measures and their data sources for each year’s Star Ratings.

second years following the contract consolidation. For all contracts, under §§ 422.164(f)(4) and 423.184(f)(4), the Part C and Part D improvement measures compare current contract-level measure scores with scores from the prior year across all measures included in the improvement measures calculations. Given there are no comparable prior year measure-level scores available for contracts in the first year of the consolidation, historically we have not calculated the Part C and D improvement measures for the first year after a consolidation.

We proposed to amend §§ 422.162(b)(3)(iv)(A)(I) and 423.182(b)(3)(ii)(A)(I) to clarify the calculation of the Part C and Part D improvement measures for contracts that consolidate. For the first year after a consolidation, we proposed to clarify that the Part C and Part D improvement measures will not be calculated for the consolidated contract. The prior year measure-level scores only include data from the surviving contract; using those as the comparison point for a consolidated contract would not be an accurate comparison because it does not include any information about performance of the consumed contract(s). For the second year after a consolidation, the improvement measure is calculated using the enrollment-weighted measure scores for the current and prior year because scores for both years are available for the consolidated contract. This is our current (and historical) process and how the proposed regulatory clarification would be applied.

We proposed to revise the current regulation text at §§ 422.162(b)(3)(iv)(A)(I) and 423.182(b)(3)(ii)(A)(I) to clarify that the Part C and Part D improvement measures are not calculated for the first year after a contract consolidation in order to codify our current application of the ratings rules.

We solicited comments on this proposal.

Comment: All commenters supported this proposed provision.

Response: CMS appreciates the support.

After considering the comments we received and for the reasons outlined in the proposed rule, we are finalizing the clarification at §§ 422.162(b)(3)(iv)(A)(I) and 423.182(b)(3)(ii)(A)(I) without modification.

D. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. In the April 2018 final rule, at 83 FR 16532, we stated that we are committed to continuing to improve the Part C and Part D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-substantive updates. See also 83 FR 16534-37. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and their specifications) adopted for the Part C and Part D Star Ratings program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued with publication of the Star Ratings. We proposed measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2024 unless noted otherwise. We also proposed a new rule for the removal of measures.

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

We proposed to remove the Diabetes Care – Kidney Disease Monitoring measure because it has been retired by the measure steward.¹⁴⁰ NCQA, the measure steward, announced the retirement of the Diabetes Care – Kidney Disease Monitoring measure after measurement year 2021. As we stated in the Announcement of Calendar Year (CY) 2023 Medicare Advantage

¹⁴⁰The measure, which has the HEDIS label “Comprehensive Diabetes Care (CDC) – Medical Attention for Nephropathy” was retired after the 2021 performance period as noted here <https://www.ncqa.org/wp-content/uploads/2022/07/Summary-Table-of-Changes-HEDIS-MY-2022.pdf> and does not appear in the list for the 2022 performance period.

(MA) Capitation Rates and Part C and Part D Payment Policies, since NCQA will no longer be collecting data for this Healthcare Effectiveness Data and Information Set (HEDIS) measure beginning with measurement year 2022, CMS will not have data for this measure to be included in the 2024 Star Ratings. The measure was included in the 2023 Star Ratings using data from measurement year 2021. We proposed to replace this measure with the Kidney Health Evaluation for Patients with Diabetes measure (described in section V.D.3. of this final rule).

CMS proposed to permanently remove the Diabetes Care – Kidney Disease Monitoring measure starting with the 2024 Star Ratings because we will not have data to calculate the measure.

We solicited comments on removing this measure from the Star Ratings program.

Comment: All commenters supported the removal of the Diabetes Care – Kidney Disease Monitoring measure from the Star Ratings program.

Response: CMS appreciates the support.

After considering the comments we received and for the reasons outlined in the proposed rule, we are finalizing the removal of the Diabetes Care – Kidney Disease Monitoring measure from the Star Ratings program.

2. Measure Updates

In the April 2018 final rule, we specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. (83 FR 16534 and 16535). Where an update by the measure steward is substantive within the scope of §§ 422.164(d)(2) and 423.184(d)(2), CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then engage in rulemaking to make substantive changes to a Star Ratings measure. Per §§ 422.164(d)(2) and 423.184(d)(2), CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings. This 2-year period for the

updated measure to be on the display page may overlap with the period during which CMS solicits comment and engages in rulemaking. Further, the legacy measure may continue to be used in the Star Ratings during this period.

a. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D) – Substantive Change

CMS proposed to implement risk adjustment (also sometimes referred to as case-mix adjustment) based on sociodemographic status (SDS) characteristics, a substantive update, to the three Part D medication adherence measures for the 2028 Star Ratings (2026 measurement year). The adherence measures would be adjusted for the following beneficiary-level SDS characteristics: age, gender, low-income subsidy/dual eligibility (LIS/DE) status, and disability status. Health outcomes are affected by patient-related and external factors such as existing clinical conditions and SDS. Currently, the three medication adherence measures (Diabetes, Hypertension, and Cholesterol) are included in the determination of the Star Ratings Categorical Adjustment Index (CAI) because they are not excluded by the criteria established in §§ 422.166(f)(2) and 423.186(f)(2); for example, the measures are not case-mix adjusted for socioeconomic status (SES). The CAI was implemented in the 2017 Star Ratings to adjust for average within-contract disparity in performance associated with the percentages of beneficiaries who receive LIS/DE and/or have disability status. The CAI was initially developed as an interim analytical adjustment to address concerns about disparities while longer-term solutions were explored, including engaging with measure stewards to examine if re-specification is warranted for measures used in the Star Ratings. The methodology for the CAI was codified at §§ 422.166(f)(2) and 423.186(f)(2); the factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part D for MA-PDs, and Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

In addition, the National Quality Forum (NQF) convened an expert panel in 2014 and recommended that performance-based measures should be risk adjusted for SES and other socio demographic factors in 2017. On June 28, 2020, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) submitted a second Report to Congress;¹⁴¹ ASPE is required under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) to study the effects of certain SRFs of Medicare beneficiaries on quality measures and measures of resource use in Medicare value-based purchasing programs.

CMS contracted with the Pharmacy Quality Alliance (PQA), the steward of these measures, to examine the medication adherence measures for potential risk adjustment. PQA recommended SDS risk adjustment for the Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. PQA recommended and endorsed the following changes related to SDS in their Measure Manual:

- All three adherence measures should be risk adjusted for SDS characteristics to adequately reflect differences in patient populations.
- The measures should be adjusted for the following beneficiary-level SDS characteristics: age, gender, LIS/DE status, and disability status.
- The measures should be stratified by these four beneficiary-level SDS characteristics (listed in the prior bullet) to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA measure specifications were endorsed by NQF in the 2019 Spring cycle (NQF endorsed #0541) (CMIT ID: 00436-01-C-PARTD for Diabetes, 00437-01-C-PARTD for Hypertension, and 00435-01-C-PARTD for Cholesterol).

¹⁴¹ <https://www.aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs>.

CMS has included stratifications by age, gender, LIS/DE status, and disability status in the Medication Adherence patient safety reports to Part D sponsors beginning with the 2019 measurement year.

We proposed to implement risk adjustment for the medication adherence measures based on the PQA specifications, which would be reflected in the Star Ratings. Additionally, because the medication adherence measures will be risk adjusted based on SDS characteristics (that is, for age, gender, LIS/DE status, and disability status), the medication adherence measures will be excluded from the CAI adjustment per §§ 422.166(f)(2)(ii)(A) and 423.186(f)(2)(ii)(A). We found in our analysis that implementing the SDS risk adjustment to the patient safety reports can be very time consuming and should be incorporated at one period of time. Therefore, since we proposed to implement the SDS risk adjustment to the medication adherence measures (which will remove these measures from the Star Ratings CAI determination), we intend to incorporate the SDS risk adjustment operationally to the medication adherence measures reported by CMS to Part D sponsors in the last monthly patient safety report for the measurement year.

In developing this proposal, we considered how this change might affect Star Ratings for MA-PD and PDP contracts. We calculated SDS risk adjusted medication adherence measure rates using year of service (YOS) 2019 measurement year data and recalculated the CAI values excluding these three adherence measures. We then recalculated the overall and Part D summary ratings using the SDS risk adjusted medication adherence measure rates, revised CAI values, the final 2021 Star Ratings for other measures, and the reward factor. In our analysis, we found that the threshold shifts for measure-level cut points with SDS risk adjustment were minimal for both MA-PD and PDP contracts, ranging from -2 to +1 percentage point(s) for MA-PD contracts and about -2 to +3 percentage points for PDP contracts. We found that for both MA-PD and PDP contracts, approximately 60-70 percent of contracts retained the same star level across the Medication Adherence for Hypertension (RAS Antagonists) and Medication Adherence for Cholesterol (Statins) measures. When a star level shift was observed, most of the MA-PD and

PDP contracts shifted by one-star level and usually shifted upwards when the SDS risk adjustment was applied to the adherence measures. One percent of MA-PD contracts shifted two-star levels for the Medication Adherence for Hypertension (RAS Antagonists) and Medication Adherence for Cholesterol (Stains) measures. The two-star level shifts were primarily upwards, but one contract did shift down two stars in the Medication Adherence for Cholesterol (Stains) measure. For the Medication Adherence for Diabetes Medication measure, 82 percent of MA-PD contracts and 59 percent of PDP contracts retained the same star level. When a star level shift was observed for the Medication Adherence for Diabetes Medication measure, most MA-PD and PDP contracts saw a one-star downward movement with the SDS risk adjustment applied to the measure.

As previously noted, if CMS implements SDS risk adjustment for the three medication adherence measures, the measures would no longer be included in determining the Star Ratings CAI. Therefore, we also conducted an analysis to simulate calculating the CAI values without case-mix adjusting the three adherence measures for LIS/DE and disability; these simulated CAI values were used in the application of the simulated summary rating calculations. For most MA-PD contracts, this resulted in a negative shift in the CAI adjustment values for the overall and Part D summary ratings, and in contrast, most PDPs had a positive shift in values. Additionally, the analysis found a minimal change in reward factor thresholds, ranging from -0.07 to +0.02 for mean percentile thresholds and -0.08 to +0.008 for variance percentile thresholds. In the analysis of the overall and Part D summary rating, 91 percent of MA-PD contracts retained the same overall rating, 7 percent decreased by half a star, and 2 percent increased by half a star. We found that 81 percent of MA-PD contracts retained the same Part D summary rating, 11 percent decreased by half a star, and 7 percent increased by half a star. The impact on PDP contracts was neutral or positive; 63 percent of PDP contracts retained the same Part D summary rating star level while 37 percent increased by a half a star. No PDP contracts had a decrease in their Part D summary rating.

The Part C and Part D improvement measures were not recalculated for this simulation. The final 2021 Star Ratings for both improvement measures were used for the summary rating recalculations in the simulations to illustrate the impact of this proposed change to the three medication adherence measures. Additionally, the final 2020 Star Ratings for both improvement measures and for the three adherence measures were used for the CAI value recalculations in the simulations. It is possible that the simulated differences could vary if or when we are able to have two consecutive years of adjusted data for recalculating these components.

Per § 423.184(d)(2), the change to implement SDS risk adjustment for the three Part D medication adherence measures would be a substantive update. We signaled this potential update and solicited initial feedback on incorporating the SDS risk adjustment in the Advance Notice and Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

A majority of the comments submitted in response to the CY 2023 Advance Notice supported SDS risk adjustment for the medication adherence measures. Some of those comments also requested information on how the CAI will be affected by this update. We completed testing of the impact of the adjustment and are including the additional information about the simulations in this final rule, as summarized previously. If finalized, the legacy medication adherence measures would remain in the Star Ratings and the updated medication adherence measures with the SDS risk adjustment would be on the display page for at least 2 years (beginning with the 2024 measurement year for the 2026 display page). Beginning with the 2026 measurement year and 2028 Star Ratings, CMS would then move the re-specified measures from display page to Star Ratings and the legacy measures would be removed under this proposal.

In addition, to provide a more complete explanation of the changes in the specifications to the three medication adherence measures, the December 2022 proposed rule included a summary of non-substantive updates to the medication adherence measures. As noted in the

proposed rule and in the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, our intent was to implement the non-substantive changes regardless of whether we ultimately finalized changes to add risk adjustment for SDS factors to the three medication adherence measures. The non-substantive updates are to: (1) apply continuous enrollment (CE) instead of member-years (MYs) adjustment and (2) no longer adjust for stays in inpatient (IP) settings and skilled nursing facilities (SNFs). More information about the non-substantive updates is in section V.D.2.b. of this rule and in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies issued on March 31, 2023.

We solicited comments on this substantive update to incorporate SDS risk adjustment for the medication adherence measures. In addition, we summarize here the comments received regarding the non-substantive updates that specifically reference the proposed substantive measure updates to the medication adherence measures.

Comment: The majority of commenters supported the proposal to implement SDS risk adjustment for the Part D Star Ratings medication adherence measures. Commenters also expressed their support for CMS's efforts to promote health equity in the Star Ratings program. Commenters believed that including case-mix adjustment based on SDS characteristics would help improve health care quality for underserved individuals and incentivize plan sponsors to both seek and improve the care for additional vulnerable beneficiaries. Some commenters requested that SDS risk adjustment be carefully monitored to ensure overall quality shortcomings are not concealed.

Response: CMS appreciates the support received for the proposal to incorporate SDS risk adjustment for the three medication adherence measures: Diabetes, Hypertension (RAS), and Cholesterol (Statins). We do not want to mask quality issues and intend to carefully monitor the SDS risk adjusted measure rates while they are on the display page for two years and after they

are implemented in the Star Ratings. The stratified Medication Adherence patient safety reports and SDS risk adjusted measures provided to plan sponsors should incentivize plans to improve performance, provide high quality of care to Medicare beneficiaries, and identify disparities.

Comment: A commenter requested clarification on whether implementing SDS risk adjustment for the three adherence measures is a substantive update.

Response: The change to implement SDS risk adjustment for the three Part D medication adherence measures is a substantive update according to § 423.184(d)(2) because it sufficiently changes the nature or scope of the three medication adherence measures and is not similar to any of the examples of non-substantive updates listed in § 423.184(d)(1)(i) through (v). Therefore, the process for non-substantive updates does not apply. According to § 423.184(d)(1)(i) through (v), examples of non-substantive updates include those that: narrow the denominator or population covered by the measure with no other changes; do not meaningfully impact the numerator or denominator of the measure; update the clinical codes for quality measure; provide additional clarifications such as adding additional qualifiers that would meet the numerator requirements, clarifying documentation requirements, or adding additional instructions; or adding additional data sources. As required by § 423.184(d)(2) for substantive updates to measures, CMS solicited initial feedback to incorporate the SDS risk adjustment in the Advance Notice and Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and received support on this substantive update.

Comment: Several commenters opposed the proposal to apply SDS risk adjustment for the medication adherence measures. Commenters were concerned about the complexity of the SDS risk adjustment, that it contradicts CMS's expressed interest to simplify the Part C and D Star Ratings, that it could make tracking individual performance complicated for plans, and that it could make it difficult for beneficiaries to understand when comparing plans. Others were concerned SDS risk adjustment would create multiple standards by which plans are measured or that there is no definition of success or "ceiling" for medication adherence ratings. One

commenter noted that the removal of the Part C Medication Reconciliation Post-Discharge measure will have a negative impact on adherence since the measure is an intervention to ensure adherence and that these changes to implement SDS risk adjustment would dissuade sponsors from enrolling sicker populations associated with poor adherence.

Response: While risk adjustment does add complexity, CMS does not have concerns about applying the SDS risk adjustment and has tested this change. The update to implement SDS risk adjustment aligns with the PQA's recommendations as the measure steward. We will work to provide technical and non-technical information as appropriate about the updated measures for plans, beneficiaries, and other interested parties to help understand the specifications and to make comparisons. We will continue to provide contract-level and beneficiary-level information to Part D sponsors through the patient safety reports to assist plans with tracking their performance improvement efforts on medication adherence measures. Additionally, the medication adherence measures are intermediate outcome measures, while the other Part D patient safety measures included in the Star Ratings are process measures and not recommended for SDS risk adjustment by the PQA. Therefore, we are aligning with the PQA and implementing the SDS risk adjustment on only the three medication adherence measures. We remind commenters that the thresholds for the medication adherence measure rates in the Medicare Part D Star Ratings are not predetermined. They are based on the distribution of data for the year the data are collected. CMS uses the clustering methodology in accordance with § 423.186(a)(2) to determine thresholds for the medication adherence measures. Additionally, the Part C Medication Reconciliation Post-Discharge measure will continue to be measured as part of the Transitions of Care (Part C) measure.

Comment: Commenters expressed concerns surrounding the adherence measures being excluded from the CAI adjustment and unintended harm or impacts to sponsors with high enrollment of beneficiaries with SRFs. One commenter requested CMS to continue adjusting the

three adherence measures through the CAI. Some commenters opposed implementation of SDS risk adjustment since the SDS characteristics are already accounted for in the CAI.

Response: Currently, the Star Ratings CAI adjusts for the average within-contract disparity in performance for LIS/DE and/or disability status. The SDS risk adjustment for the adherence measures adjusts for additional beneficiary-level SDS characteristics: age, gender, LIS/DE status, and disability status. The CAI is designed to adjust for the impact of SES on measure scores and ratings when the measures do not already include an adjustment to account for SES or similar sociodemographic factors. Because case-mix adjustment (that is, risk adjustment) of a measure adjusts scores to account for certain respondent characteristics not under the control of the health or drug plan, adjusting again for the same or similar factors through the CAI is duplicative and unnecessary. CMS has encouraged and supported measure stewards to continue examining their measures for possible re-specification to include case-mix adjustment as appropriate. The PQA updated the measure specifications for the three adherence measures to include the SDS risk adjustment to account for SDS characteristics of age, gender, LIS/DE status, and disability status that may impact beneficiary health outcomes. As noted in the preamble, the PQA medication adherence measure specifications with the SDS risk adjustment were endorsed by the NQF. Per the Star Ratings rules, the medication adherence measures must be excluded from the CAI adjustment per § 423.186(f)(2)(ii)(A) once the measure is already case-mix adjusted for beneficiary-level SDS characteristics: age, gender, LIS/DE status, and disability status. With the updated measure-level specifications, the adherence measures no longer needed to be included in the CAI since the measure scores are already adjusted for differences in the enrollee case mix across contracts.

Comment: One commenter requested that the risk adjustment for the three adherence measures be introduced earlier in the 2026 Star Ratings. A commenter was concerned with program stability of moving the risk adjusted measures to the display page for two years and then reintroducing the measures to the Star Ratings with a triple weight. A few commenters

suggested decreasing the weight of the adherence measures when incorporating the new methodology for program stability.

Response: We appreciate the feedback we received. Measures with substantive updates are on the display page for a minimum of two years prior to becoming a Star Ratings measure and therefore cannot be introduced into the Star Ratings earlier per § 423.184(d)(2). CMS will keep the three legacy adherence measures in the Star Ratings during the period when the updated adherence measures are placed on the display page. CMS and sponsors will have the opportunity to monitor the three updated measures' rates while on the display page. New measures to the Star Ratings program are assigned a weight of 1 for their first year in the Star Ratings and then in subsequent years, the weight associated with the measure weighting category would be used. When substantive updates are made to an existing measure in the Star Ratings, the updated measure is then added to the display page for at least 2 years prior to its introduction to the Star Ratings. For weighting purposes, a substantively updated measure is treated as a new measure and will receive a weight of 1 for the first year in the Star Ratings. In subsequent years, an updated measure is assigned the weight associated with its category. (See 86 FR 5919 and 87 FR 79616). Therefore, being consistent with the Star Ratings policy, during the first year the SDS risk adjusted adherence measures will be in the Star Ratings with a weight of 1, but then beginning with the following Star Ratings year, the weight will increase to 3, as these measures are categorized as intermediate outcome measures.

Comment: Some commenters appreciated the lead time provided for implementation of the proposed update and the advance notification that the SDS risk adjustment would be included in the last monthly patient safety report of the measurement year. A commenter noted that the lead time allows them to find solutions to automate the process internally. Only a couple of commenters suggested that SDS risk adjustment be provided to plans prior to year-end or possibly monthly to give plans an understanding of the impact of these adjustments.

Response: We appreciate the comments submitted on the proposed rule; however, CMS is unable to provide monthly patient safety reports with SDS risk adjustment. As CMS noted previously, implementing the SDS risk adjustment to the patient safety reports is very time consuming and labor intensive. As a result, we are unable to provide this information on a monthly basis because of the tight production timelines for the monthly patient safety reports. We intend to apply the SDS risk adjustment for the final medication adherence patient safety reports of the measurement year which is typically in July of the following calendar year. During the display page transition period, CMS will assess the feasibility of providing the medication adherence patient safety reports with SDS risk adjustment at an additional time period prior to the determination of the final rates.

Comment: Commenters requested that CMS publish detailed methodology and analysis results for the SDS risk adjustment. One commenter requested additional analysis examining contracts that were impacted by the SDS risk adjustment.

Response: Thank you for the additional requests to increase transparency about the SDS risk adjustment. As a reminder, CMS provides detailed contract-level reports and user guides to Part D plan sponsors for each of the current Part D patient safety measures. Similarly, we will update the medication adherence measure report user guides to reflect the implementation of the SDS risk adjustment and provide SDS risk adjustment methodology. As we align with the PQA,¹⁴² CMS will continue to monitor the SDS risk adjusted medication adherence measures while on the display page and will conduct further analyses if needed. We will also explore adding additional information to the reports provided to plan sponsors to help understand the non-adjusted and SDS risk adjusted rates.

¹⁴²Risk-Adjusted Adherence Measures:
https://www.pqaalliance.org/index.php?option=com_dailyplanetblog&view=entry&year=2020&month=04&day=23&id=8:risk-adjusted-adherence-measures

Comment: We received one comment encouraging CMS to adopt the PQA Proportion of Days Covered (PDC) Medication Adherence “combined” measure and to apply the case-mix adjustment to that measure.

Response: The PQA endorsed the PDC composite health plan measure in 2022. CMS defers to the measure steward, PQA, regarding questions on the composite health plan measure specifications and evaluation for risk adjustment. CMS would need to propose through rulemaking to add PQA’s composite health plan measure as a new measure to the Part C and Part D Quality Star Ratings system. CMS will consider testing the new PQA measure in the future as part of our continued oversight and maintenance of the Star Ratings program.

Comment: A commenter expressed concerns that the medication adherence performance measures used by plans to evaluate pharmacies may not be risk adjusted and recommended that CMS implement standardized pharmacy performance measures. Additionally, a commenter expressed concerns of potential downstream implications of the SDS risk adjustment update to the adherence measures on the pharmacy community and that Part D sponsors will structure reimbursement to penalize pharmacies if PDC thresholds are not achieved. A commenter was concerned that plans would “game” the measure by having their pharmacies auto-ship prescriptions.

Response: These comments are out of scope for the proposed SDS risk adjustment to the Star Ratings medication adherence measures used to evaluate Part D plan performance. The SDS risk adjusted medication adherence measures are endorsed by the PQA and used by CMS at the plan-level, not the pharmacy-level. We encourage the PQA and industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency, and fairness. CMS is not addressing the proposals around auto-ship policies in this final rule.

Comment: Commenters expressed concern that removing the IP/SNF stay adjustment may undermine or counteract the proposed SDS risk adjustment updates, may not simplify the

measure, or that implementing SDS risk adjustment for the adherence measures and removing the adherence measures from the CAI may provide additional complexity to these calculations which may disadvantage some populations with more IP/SNF stays. A commenter was concerned about the disproportionate impact of removing the IP/SNF stay adjustment on plans with enrollees with frequent or prolonged IP stays even after adjusting for LIS status; the commenter also requested more data.

Response: CMS understands these concerns about removing the IP/SNF stay adjustment in the context of adding the SDS risk adjustment. As noted in the proposed rule, we conducted testing on the impact of the combined changes of the SDS risk adjustment and removing the IP/SNF stay adjustment. Our testing indicated that applying both the SDS risk adjustment and the IP and SNF stay adjustments added complexity to the measure and created concerns about the accuracy of the SDS risk adjustment. As a reminder, the IP/SNF stay adjustment does not align with current PQA measure specifications that were endorsed for the adherence measures. CMS and plan sponsors will have the opportunity to monitor their measure scores while the SDS risk adjusted medication adherence measures are on the display page for two years. The patient safety report user guides provided to Part D plan sponsors will include more information to describe how the SDS risk adjustment is applied to help sponsors understand the calculations.

Comment: A few commenters suggested additional updates to the medication adherence measure specifications to: (1) apply the IP/SNF stay adjustment prior to or as part of the SDS risk adjustment; or (2) exclude beneficiaries who reside in long-term care (LTC) facilities. For the second suggestion, the commenter stated that exclusion of LTC residents is appropriate because such enrollees generally have a potential higher disease burden and their medications are actively monitored, and because inclusion of LTC residents could skew the performance rates on the measure based on other enrollees. Some commenters were concerned that the SDS risk adjustment would not directly account for IP/SNF stays or would not offset the removal of

IP/SNF stay adjustment from the adherence measures since many of the reasons for IP/SNF stays may be unrelated to the SDS characteristics included in the risk adjustment.

Response: As finalized in this rule, CMS will implement SDS risk adjustment for the following beneficiary-level SDS characteristics: age, gender, LIS/DE status, and disability status, as developed and endorsed by the PQA (the measure steward) and endorsed by NQF, for the three medication adherence measures. The PQA medication adherence measure specifications do not adjust for IP/SNF stays or exclude beneficiaries who reside in LTC. We will consider additional updates made by the measure steward in the future. For further details regarding the non-substantive updates to the medication adherence measures, refer to the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies which was published on March 31, 2023.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the implementation of the SDS risk adjustment to the three medication adherence measures (Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins)). We will first display the updated SDS risk adjusted medication adherence measures for the 2024 measurement year (2026 display page). Then, the updated SDS risk adjusted measures will replace the existing medication adherence measures beginning with the 2026 measurement year (2028 Star Ratings). The IP/SNF stay adjustment will be removed from the medication adherence measures starting with the 2026 measurement year (2028 Star Ratings). CMS will implement the CE to the medication adherence measures starting with the 2024 measurement year (2026 Star Ratings). Publishing the display measures for at least two years will allow Part D sponsors and CMS additional experience with contract-specific results using the new measure specifications.

b. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D) – Non-Substantive Changes

As discussed in the December 2022 proposed rule, our analysis of the proposed substantive changes (to add risk adjustment for SDS for the three adherence measures) included two non-substantive changes to the adherence measures, based on the current PQA measure specifications, which are endorsed by NQF. While we did not need to propose non-substantive changes through rulemaking, given that we intend to make the non-substantive changes to the measures along with the proposed substantive changes to risk adjust the adherence measures, we described the non-substantive updates as well in the preamble to the proposed rule in order to provide a full picture of the changes to these measures. However, implementing these non-substantive updates was not dependent on finalizing the SDS risk adjustment proposal and was included in the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. These specification changes are non-substantive in accordance with § 423.184(d)(1) because they narrow the denominator population or do not change the target population or intent of the measure: (1) apply continuous enrollment (CE) instead of member-years (MYs) adjustment and (2) no longer adjust for stays in inpatient (IP) settings and skilled nursing facilities (SNFs). The comments that we received that were solely about the non-substantive updates are addressed in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, which was issued by CMS on March 31, 2023. As noted in section V.D.2.a., comments on the interaction or overlap of the substantive changes and the non-substantive changes to the three medication adherence measures are addressed as part of our discussion of the substantive changes.

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

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. (83 FR 16521, 16533). For example, we regularly review measures developed by NCQA and PQA. CMS proposed to adopt the new measure described in this rule, which was developed by NCQA. The Kidney Health Evaluation for Patients with Diabetes (KED) measure has been collected from MA (including MA-only and MA-PDs) and cost plans since the 2020 measurement year.

We proposed to add the KED measure beginning with the 2024 measurement year and 2026 Star Ratings. This measure was introduced as a HEDIS measure for the 2020 measurement year. NCQA, in collaboration with the National Kidney Foundation, developed a kidney health evaluation measure, and NCQA tailored the measure specifically for health plans. The KED NCQA measure assesses whether adults who have diabetes received an annual kidney profile evaluation, defined by an estimated Glomerular Filtration Rate (eGFR)¹⁴³ and a Urine Albumin-Creatinine Ratio (UACR) during the measurement year. This new measure aligns with recommendations from the American Diabetes Association and provides critical information for screening and monitoring of kidney health for patients with diabetes. This measure would replace the prior related measure, Diabetes Care – Kidney Disease Monitoring, which was removed beginning with the 2024 Star Ratings as the measure steward, NCQA, retired the measure beginning with the 2022 measurement year.

CMS began reporting the KED measure on the display page for the 2022 Star Ratings. As provided at §§ 422.164 (c)(3) and (4) and 423.184(c)(3) and (4), as new performance measures are developed and adopted they are initially posted on the display page for at least 2 years.

¹⁴³NCQA added the new Logical Observation Identifiers Names and Codes (LOINC) for the new race-free eGFR equations to the KED value sets.

We submitted the KED plan measure through the 2022 Measures Under Consideration process for review by the Measures Application Partnership, which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs, and the Measures Application Partnership provided support for this measure. The MIPS program had also submitted it to the 2021 Measures Under Consideration process and this measure will also be implemented for qualified health plans (QHPs).¹⁴⁴

We solicited comments on adding this measure to the 2026 Star Ratings program.

Comment: Most commenters supported adding the KED measure beginning with the 2024 measurement year and 2026 Star Ratings. A commenter stated that adding the measure will serve to increase early diagnosis and treatment of kidney disease, stop or slow disease progression for chronic kidney disease, and continue the agency's prioritization of the efficient management of end-stage renal disease.

Response: CMS thanks the commenters for their support of our proposal to add this measure beginning with the 2026 Star Ratings.

Comment: A commenter stated there is concern about not using the race-neutral eGFR when monitoring kidney health and recommended that CMS wait to implement the measure until the race-neutral eGFR is incorporated into the measure specifications.

Response: The new race-neutral eGFR codes are already incorporated into the measure specifications. Currently, NCQA includes all codes for eGFR, including both new and old codes, to allow transition to the race-neutral eGFR. Starting with the 2023 measurement year, only the race-neutral eGFR will be included in the technical specification for the KED measure.¹⁴⁵

¹⁴⁴<https://www.cms.gov/files/document/final-2022-call-letter-grs-qhp-enrollee-survey.pdf>.

¹⁴⁵Measurement year 2023 Technical Specifications Update available under Volume 2: <https://www.ncqa.org/hedis/measures/>.

Comment: A commenter suggested that CMS cover CPT code 80050 under Original Medicare given its inclusion in the KED measure code set since the commenter suggested not including it could create provider hesitation to order the test.

Response: The KED measure assesses whether members 18-85 with diabetes received an annual kidney health evaluation including both a uACR and an eGFR. The intent is that any code that indicates that an eGFR was completed can count towards the measure. CPT code 80050 is one of several codes included in the value set for eGFR. Our proposal to add the KED measure to the Part C and Part D Quality Star Ratings program was not about whether and how Medicare covers all of the tests under CPT code 80050. Comments about the scope of services covered by Medicare are outside the scope of the proposal to add the KED measure to the Star Ratings.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the addition of the KED measure to the 2026 Star Ratings.

Table 2 summarizes the additional and updated measures addressed in this final rule for the 2026 Star Ratings, unless otherwise noted. Due to the level of detail and changes in measure specifications, CMS does not list the measures and their specifications in the regulation text for the Part C and Part D Quality Star Ratings, but their final adoption and required use are addressed in this final rule. The measure descriptions listed in this table are high-level descriptions. The annual Star Ratings measure specifications supporting document, the Medicare Part C & D Star Ratings Technical Notes, provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. The annual Star Ratings are produced in the fall of the prior year. For example, Stars Ratings for the year 2026 will be produced in the fall of 2025. If a measurement period is listed as "the calendar year

2 years prior to the Star Ratings year” and the Star Ratings year is 2026, the measurement period is referencing the January 1, 2024 to December 31, 2024 period.

TABLE 2: SUMMARY OF NEW AND REVISED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2024

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Kidney Health Evaluation for Patients with Diabetes (KED)	Percent of plan members ages 18-85 with diabetes (type 1 and type 2) who received a kidney health evaluation during the measurement year.	Managing Chronic (long term) Conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	00989-03-C-PARTC	Clustering	MA-PD, MA-only, and cost
Part D Measures								
Medication Adherence for Diabetes Medication*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for diabetes medications during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	00436-01-C-PARTD	Clustering	MA-PD and PDP and cost (if drugs offered)
Medication Adherence for Hypertension (RAS Antagonists)*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for RAS antagonists during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	00437-01-C-PARTD	Clustering	MA-PD and PDP and cost (if drugs offered)
Medication Adherence for Cholesterol (Statins)*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for statins during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	00435-01-C-PARTD	Clustering	MA-PD and PDP and cost (if drugs offered)

*Revised Measures

++Updates for 2028 Star Ratings (2026 Measurement Year)

4. Measure Removal (§§ 422.164(e)(1) and 423.184(e)(1))

CMS proposed adding a new rule for measure removal. We proposed that CMS would have the authority to remove a measure from calculations of Star Ratings when a measure steward other than CMS retires the measure. CMS continually reviews measures that are used in calculations of Star Ratings. As codified at §§ 422.164(e)(1) and 423.184(e)(1), CMS may remove a measure when either (1) the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes; or (2) a measure shows low statistical reliability. See also 83 FR 16533–16537. In both of these circumstances, as codified at §§ 422.164(e)(2) and 423.184(e)(2), CMS will announce the removal of any measure in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

We proposed adding a rule at §§ 422.164(e)(1)(iii) and 423.184(e)(1)(iii) to allow removal of a Star Ratings measure, without separate rulemaking, when a measure steward other than CMS (for example, NCQA or PQA) retires a measure. Under the proposal, which we are finalizing, CMS will have the authority to remove the measure from calculations of Star Ratings through the process described at §§ 422.164(e)(2) and 423.184(e)(2). When a measure steward such as NCQA retires a measure, they go through a process that includes extensive review by their various measurement panels and they solicit public comment regarding proposed measure retirements so health plans, purchasers, consumers, and other stakeholders have an opportunity to weigh in on the relevance and scientific soundness of any changes to the measurement set. This change will allow CMS to respond more quickly to measure removals by external measure stewards to ensure that measures included in Star Ratings are clinically meaningful, reliable, and up-to-date. We solicited comments on this proposal.

Comment: Commenters supported CMS having the authority to remove Star Ratings measures when an external measure steward retires a measure from its program. A couple of commenters stated they would like to see CMS continue to communicate to plans which measures will be removed.

Response: CMS appreciates the support to be able to quickly remove Star Ratings measures when an external measure steward retires a measure. This will ensure that measures included in the Star Ratings program are clinically meaningful, reliable, and up-to-date. CMS agrees that transparency is important. Prior to removing any measure, CMS will announce the removal in advance of the measurement period, as required by §§ 422.164(e)(2) and 423.184(e)(2), through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act, that is, through the Advance Notice and Rate Announcement.

Comment: A commenter raised the concern that there will be a gap in the 2024 Star Ratings program for immunization measures, including influenza and pneumococcal vaccinations, since NCQA is retiring these measures from the HEDIS measurement set.

Response: CMS understands this concern and wants to clarify that the influenza measure used in the Star Ratings program will continue to be included in the 2024 Star Ratings because the Star Ratings influenza measure is different than the NCQA HEDIS measure being retired. The HEDIS measure for influenza is limited to Medicare members who are 65 or older. For the Star Ratings, the influenza vaccination measure is currently assessed for a sample of Medicare members through the Medicare CAHPS survey and covers all Medicare members, regardless of age. Pneumococcal vaccination is also assessed for a sample of Medicare members through the Medicare CAHPS survey and reported on the display page. As noted in the 2023 Rate Announcement¹⁴⁶ and the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies issued on March 31, 2023, any substantive changes to the current influenza vaccination measure or the addition of a more comprehensive immunization measure would need to be proposed through rulemaking.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the additional rule at §§ 422.164(e)(1)(iii) and 423.184(e)(1)(iii) as proposed without modification.

E. Patient Experience/Complaints and Access Measure Weights (§§ 422.166(e)(1)(iii) and (iv), 423.186(e)(1)(iii) and (iv))

CMS proposed to lower the weight of patient experience/complaints and access measures to 2 beginning with the 2026 Star Ratings covering the 2024 measurement period. The weight for the patient experience/complaints and access measures is codified at §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv). Process measures receive a weight of 1, outcome measures

¹⁴⁶Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (cms.gov).

receive a weight of 3, and the Part C and D improvement measures receive a weight of 5. In the April 2018 final rule, we finalized an increase in the weight of patient experience/complaints and access measures from 1.5 to 2, starting with the 2021 Star Ratings. (83 FR 16575-77). These measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints measures. We also stated in the April 2018 final rule (83 FR 16575–16576) that, given the importance of hearing the voice of patients when evaluating the quality of care provided, CMS intended to further increase the weight of patient experience/complaints and access measures in the future. In the June 2020 final rule, CMS finalized an additional increase in the weight of patient experience/complaints and access measures from 2 to 4 for the 2023 Star Ratings. At that time, we stated we were putting more weight on this category of measures that primarily reflect patient experience of care measures to put patients first and to emphasize CMS’s goal of listening to the voice of the patient to identify opportunities to improve care delivery (85 FR 33837). We still believe these measures focus on critical aspects of care such as care coordination and access to care from the perspective of enrollees, but taking into consideration additional stakeholder feedback we have received and the effect of the policy on the 2023 Star Ratings, we have reconsidered our position from the June 2020 final rule and now believe these measures currently receive an undue weight in the Star Ratings program.

One of the guiding principles of the Part C and Part D Star Ratings program is to align with the CMS Quality Strategy (83 FR 16521). As part of the current CMS Quality Strategy, CMS is trying to create a resilient, high-value health care system that promotes quality outcomes, safety, equity, and accessibility for all individuals, as described at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>. One of the goals of the CMS Quality Strategy is to increase alignment across the CMS quality programs to improve value. Currently, the measure weight of 4 for the patient experience/complaints and access measures is not consistent with the

contribution of these types of measures in the overall performance scores for other CMS quality measurement programs. For example, in the hospital value-based purchasing program, person and community engagement measures, which are measures collected through the Hospital CAHPS Survey, account for 25 percent of the total performance score for hospitals (<https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospital-value-based-purchasing->). As another example, one-sixth of the global score for the Quality Rating System for QHPs is based on enrollee experience (<https://www.cms.gov/files/document/2022-qrs-and-qhp-enrollee-survey-technical-guidance.pdf>). In contrast, for the 2023 Star Ratings, with a weight of 4, the patient experience/complaints and access measures account for approximately 58 percent of the overall rating for MA-PDs. For the Part C and Part D Star Ratings, we include a broader set of measures related to person and community engagement relative to other CMS quality programs. For example, we include appeals measures given the importance of access to care and services for Part C plan enrollees. However, if the patient experience/complaints and access measures had a weight of 2, these measures would account for 41 percent of the overall rating. Reducing the weighting to 2 for this category of measures would align the patient experience/complaints and access measures more closely with other programs, without exactly matching the lower influence measures of this type have on the overall (that is, total performance or global) score in these other programs. We did not propose to reduce the weight further than 2 given the important link between patient experience, adherence, and health outcomes. We stated that reducing the weight for these measures from 4 to 2 is a significant change and a more extensive change may be too much to adopt at this time. Prior to the April 2018 final rule, the weight of 1.5 given to the patient experience/complaints and access measures in the Part C and Part D Stars Ratings had been in place since the 2012 Star Ratings, so we have extensive experience with how using a weight lower than 2 for these categories of measures influences plan behavior. We stated that we continue to believe that a weight higher than 1.5 is appropriate.

The weighting of measures within the Star Ratings program is important as not all measures contribute equally to the goals of the program. Patient experience, complaints, and access to care have been linked to improved clinical outcomes and are important aspects of health care. For example, patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary health care use, and fewer inpatient complications (Anhang Price et al., 2014; Anhang Price et al., 2015; Quigley et al., 2021).¹⁴⁷ We also recognize that whether clinicians acknowledge patient preferences¹⁴⁸ may be another factor that is important to measure and include in the Star Ratings program; consequently, we tested a question for the CAHPS survey related to whether an enrollee's personal doctor dismisses symptoms that are important to them for potential incorporation in the survey and Star Ratings in the future. CMS continues to believe, as we stated in the April 2018 final rule at 83 FR 16576, that we must listen to the perceptions of care from people with Medicare, as well as ensure they have access to needed care. While focusing on patient experiences of care and ensuring that care is person-centric are critical, health and drug plans also have a responsibility to consider and work toward improving clinical outcomes. Improving clinical outcomes is an important goal for the Part C and Part D programs to meet the CMS Quality Strategy goal of promoting the highest quality outcomes and safest care for all individuals. High-value care does not always align with patient experiences of care, and we must take this into consideration as we consider how to weight the different Star Ratings measures. Clinical quality measures, for example, are also important in that they measure health outcomes, clinical processes, and adherence to clinical

¹⁴⁷Anhang Price, R., Elliott, M.N., Zaslavsky, A.M., Hays, R.D., Lehrman, W.G., Rybowski, L., Edgman-Levitan, S., & Cleary, P.D. (2014). Examining the role of patient experience surveys in measuring health care quality. *Medical Care Research and Review*, 71(5), 522–554.

Anhang Price, R., Elliott, M.N., Cleary, P.D., Zaslavsky, A.M., & Hays, R.D. (2015). Should health care providers be accountable for patients' care experiences? *Journal of General Internal Medicine*, 30(2), 253–256.

Quigley D.D., Reynolds K., Dellva S., & Anhang Price, R. (2021). Examining the business case for patient experience: a systematic review. *Journal of Healthcare Management*, 66(3), 200–224.

¹⁴⁸Cohen, Marc A., Hwang, Ann and Hawes, Frances M. (July 13, 2022). Could Person-Centered Care Be The Secret To Achieving the Triple Aim? *Health Affairs Forefront*.

guidelines. They measure whether plans are following the best practices for health care delivery, including providing preventive care such as immunizations and cancer screenings and caring for enrollees with ongoing health problems such as diabetic enrollees who need blood sugar tests, eye exams, and blood pressure monitoring. It is also important to create incentives for health and drug plans to continuously focus on quality improvement by giving sufficient weight to the Health Plan Quality Improvement and Drug Plan Quality Improvement measures relative to the patient experience/access and complaints measures. In the proposed rule, we stated that we believe the weight given to measures in the Part C and Part D Star Ratings program should be in line with how the measures are linked to health care and the value they have in improving health care.

Subsequent to finalizing the weight of 4 for patient experience/complaints and access measures in the June 2020 final rule, we have received significant stakeholder feedback on this issue through the Part C and D Advance Notices, the 2023 Part C and D proposed rule (CMS-4192-P), the COVID-19 interim final rules (CMS-1744-IFC and CMS 3401-IFC), letters sent to CMS, and meetings with plans. A number of concerns have been raised by stakeholders related to a weight of 4, including devaluing measures of health outcomes, encouraging plans to abandon efforts to drive clinically appropriate care, sending the message that preventive care such as cancer screenings are not important, and not balancing appropriately clinical excellence and patient experience. Stakeholders have also raised concerns around disproportionately overweighting patient experience measures, which in turn diminishes the importance of other measures. MedPAC noted in their response to the CY 2021 and 2022 proposed rule (CMS-4190-P) that the increased weight would give disproportionate weight to patient experience measures relative to outcome measures and create an imbalance between the two most important measure groupings—outcome and patient experience measures. Stakeholders have continued to raise concerns about the disproportionate weight given to patient experience/complaints and access measures. Stakeholders have continued to suggest that clinical outcomes should count more than

patient experience of care measures. Additionally, we have received feedback that cancer screenings, medication reconciliation, and other Star Ratings measures are critical areas of focus in particular in underserved communities but have a diminished role in the Star Ratings program due to the high weight of patient experience/complaints and access measures.

Given these concerns, as well as the impact of the weighting policy on the 2023 Star Ratings, CMS re-evaluated its decision to weight these measures higher than outcome measures. We were concerned that the higher weight of 4 may create incentives for plans to not focus as much on patient outcomes, screenings, and preventive care. This could lead to ineffective or inappropriate care and increased costs if providers primarily focus on patient experiences. Although patient experience/complaints and access to care measures have been linked to improved clinical outcomes and are important aspects of health care, we proposed to move back to a weight of 2 to more appropriately balance the value these measures contribute to achieving high quality care without weighting them higher than clinical outcome measures and to better align the total contribution of patient experience and outcome measures with other CMS quality reporting programs.

To better align the Part C and Part D Star Ratings with the current CMS Quality Strategy and other CMS quality programs and to better balance the contribution of the different types of measures in the Star Ratings program, we proposed to modify § 422.166 at paragraphs (e)(1)(iii) and (iv) and § 423.186 at paragraphs (e)(1)(iii) and (iv) to decrease the weight of patient experience, complaints, and access measures from 4 to 2 beginning with the 2026 Star Ratings. At a weight of 2, the patient experience, complaints, and access measures would be weighted higher than process measures but not as high as outcome measures. This is in line with the value these measures add to achieving high quality care without weighting them higher than clinical outcome measures. In addition, this would align more closely with the weight these types of measures are given in other CMS quality programs.

We solicited feedback on this proposed change.

Comment: The majority of commenters strongly supported CMS's response to stakeholder concerns regarding the overemphasis on patient experience/complaints and access measures in the Part C and D Star Ratings program. Commenters noted that by lowering the weight from 4 to 2, CMS will continue to emphasize patient experiences in the Star Ratings, but the Star Ratings will also highlight preventive care and clinical outcomes more and be more in line with other quality programs. There was concern that undue weight for patient experience/complaints and access measures may shift payer priorities and lessen emphasis on clinical outcomes.

Some commenters noted that they recognize the importance and value of patient experience/complaints and access measures, but agree that they should not account for more than half of the overall Star Ratings. A commenter noted that bringing patient experience, complaint, and access measures back to their prior weight of 2 rebalances the impact of different measure types, signals the critical importance of clinical outcome and process measures, which had been underweighted when the weighting was doubled, and ensures that the Quality Rating System reflects the continuum of care from patient experiences to health outcomes. A commenter noted that access to care, care coordination, and health care quality cannot be measured solely through a member perception survey, and plan performance related to members receiving timely preventive screenings and care for chronic conditions should receive substantial weighting in the Star Ratings program. By reducing the weight of CAHPS measures back to a weighting of 2, a commenter stated that the Star Rating program will return to a more balanced framework that extends relatively equal weighting across domains. In doing so, this commenter noted that CMS will positively impact population health-based quality measures, such as cancer screenings, chronic condition management, and medication adherence that are the ultimate path to health equity. Another commenter noted that patient experience and access measures are critical to evaluating plan quality; however, the weights should not be higher than clinical outcomes. Weighted at 2, patient experience measures will still play a critical part in rating a plan.

Response: We appreciate and agree with these comments. As we noted, this weight reduction further aligns efforts with other CMS quality programs and the current CMS Quality Strategy, and better balances the contribution of the different types of measures in the Star Ratings program.

Comment: Multiple commenters stated that the weight reduction appropriately accounts for the value these types of measures contribute to achieving high quality care and better aligns the total contribution of patient experience/complaints and outcome measures within the Star Ratings program. Another commenter supported this change and noted that while enrollees' perspectives and experiences with the plan are critical components of a plan's Star Ratings, and highly rated plans should have reasonably satisfied enrollees, enrollee satisfaction should not overshadow a plan's obligations to the quality of care and health outcomes it delivers or ability to meet clinical and operational performance standards.

Response: We agree and note that concerns from interested parties after the weight was increased to 4, including concerns about disproportionately overweighting patient experience measures and subsequently diminishing the importance of other measures, are what led to our proposal to reduce the weight to 2.

Comment: Some commenters strongly encouraged that CMS make the weight change sooner than the 2026 Star Ratings to correct the current weighting imbalance and ensure plans are also focused on patient outcomes, screenings, and preventive care.

Response: In the June 2020 final rule, CMS finalized an increase in the weight of patient experience/complaints and access measures from 2 to 4 for the 2023 Star Ratings and since then we have not proposed further changes to the measure weights. Any changes to the weights need to be proposed and finalized through rulemaking to amend §§ 422.166 and 423.186. The 2026 Star Ratings is the soonest this change can be implemented to ensure adequate notice to plans about this change in advance of the performance period. We do not intend for this change to rebalance the weight of the patient experience/complaints and access measures to unfairly

surprise plans or undermine efforts during the 2023 performance period to improve performance consistent with measure weights in place at the start of the year.

Comment: A commenter recommended that the weight be decreased further so that there is not a negative impact on preventive care and patient outcomes. This commenter further suggested we might want to evenly weight CAHPS/HOS, HEDIS, and Part D measures. Another commenter stated that patient experience of care measures should receive a weight of 1 and outcome measures should be weighted more heavily.

Response: At a weight of 2, the patient experience, complaints, and access measures would be weighted higher than process measures but not as high as outcome measures. We believe this is in line with the value these measures add to achieving high quality care without weighting them higher than clinical outcome measures. Prior to the 2012 Part C and D Star Ratings, all measures were weighted equally. Beginning with the 2012 Star Ratings, CMS has placed greater weight on outcome measures compared to process measures; at that time, patient experience/complaints and access measures were weighted higher than process measures, but not as high as outcome measures. This differential weighting was implemented to create incentives to drive improvement in clinical outcomes, patient experience/complaints, and access measures. Patient experience of care measures are related to positive clinical outcomes so receive a higher weight than process measures. Assigning all measures within HEDIS with the same weight, for example, would weight process measures the same as outcome measures in the set of Star Ratings measures derived from HEDIS. This would no longer place greater weight on outcome measures and would assume that all measures within a group, whether HEDIS, CAHPS/HOS, or Part D, are equally important. One of the primary goals of the MA and Part D Star Ratings system is to encourage improved health outcomes (83 FR 16520) and the weighting of individual measures in the program reflects this goal.

Comment: A handful of commenters encouraged CMS to continue efforts to modernize the CAHPS surveys and appreciated CMS's efforts to test the web mode and other updates to the survey.

Response: We thank these commenters for their support.

Comment: A commenter recommended regular patient satisfaction surveys around network access questions such as how many clinicians the patient contacted before finding an appointment and how long a patient had to wait for an appointment.

Response: There are two existing Star Ratings measures, Getting Needed Care and Getting Appointments and Care Quickly, that are collected through the CAHPS survey and focus on issues related to accessing care. Contracts are permitted to add a limited number of supplemental questions to the MA and PDP CAHPS questionnaire so long as they do not contain content similar to existing MA and PDP CAHPS survey items or affect responses. In this case, contracts can add additional survey items if the added questions capture different aspects of patient experiences getting appointments and care.

Comment: Some commenters opposed the weight decrease and noted that the patient experience, complaints, and access measures are critical indicators of plan quality and important factors for a beneficiary making plan decisions. A commenter noted that complaints against plans can include issues regarding terminated coverage and denied authorization requests that impact beneficiaries' health and care and should be given significant weight in the Star Ratings. Another commenter suggested that patient experience is underweighted in other CMS quality programs. A commenter also stated that there is a positive association between various aspects of patient experience, such as good communication between providers and patients, and several important health care processes and outcomes.

A commenter noted that CAHPS patient experience of care and access measures help support an age-friendly health system that encourages age-friendly care.¹⁴⁹ This commenter noted

¹⁴⁹Age-Friendly Care (johnahartford.org)

that the 4x weighting of the CAHPS experience of care and access measures has shifted the clinical and operational discussions within their organization more than any payment innovation in recent organizational history since it created incentives for an adaptive approach to the evolving and variable needs of Medicare enrollees. The commenter noted that while HEDIS measures have drawbacks since they are limited to the eligible populations, CAHPS measures include more of the enrollee population and help drive interventions to address social needs to improve access to care. This commenter also noted that plans can influence CAHPS scores to a greater degree than many currently recognize. They stated that examining grievances, appeals, and call center statistics can also reveal gaps in member education, delays, or process issues in utilization management, as well as provider abrasion that is communicated to members. This commenter further noted that MA is sufficiently unique such that CAHPS weightings in other programs are not directly relevant.

Response: We appreciate these comments but remain concerned that the higher weight of 4 may create incentives for plans to not focus as much on patient outcomes, screenings, and preventive care. This could lead to ineffective or inappropriate care and increased costs if providers primarily focus on patient experiences. We believe a weight of 2 more appropriately balances the value these measures contribute to achieving high quality care without weighting them higher than clinical outcome measures. We agree with the commenters that patient experience/complaints and access measures are critical aspects of care, and with the weight change to 2, these measures will account for approximately 40 percent of the overall rating for MA-PD contracts, 45 percent of the Part C summary rating for MA-only contracts, and 37 percent of the Part D summary rating for PDPs so they will still have a significant contribution to a contract's overall rating. We acknowledge the commenter's position that other programs are underweighting patient experience of care measures. However, similar to our approach here to tailor the weights to reflect an overall balance for the Part C and Part D Quality Star Ratings program, other CMS programs are trying to balance creating incentives for facilities, providers,

or plans to ensure Medicare beneficiaries get high quality care across different domains of quality in each of the programs. For example, the hospital value-based purchasing program has multiple goals focused on improving the quality, efficiency, patient experience, and safety of care that Medicare beneficiaries receive during an inpatient stay and must balance the weights across these different goals.¹⁵⁰ While we believe consistency and alignment across programs is important and a consideration for alignment with the CMS Quality Strategy, the specific goals and circumstances of each program also need to be taken into account. The change in weights for patient experience/complaints and access measures will not be implemented prior to the 2026 Star Ratings to allow adequate notice to plans in advance of the 2024 measurement period. This will allow any efforts during the 2023 performance period to be reflected in the 2025 Star Ratings.

Comment: A commenter does not support the reduction in the weight for access measures, noting that the current four access measures are the only quality measures in the program that specifically address, and hold plans accountable for, a timely appeals process and adequate interpreter services. Another commenter suggested that Members Choosing to Leave the Plan (a measure of ultimate plan satisfaction) and the Call Center – Foreign Language Interpreter and TTY Availability measures (which support CMS’s health equity goals) be weighted as 4.

Response: We agree access measures and Members Choosing to Leave the Plan remain critical measures given the importance of access to care and services for Part C plan enrollees. We also agree that the Call Center – Foreign Language Interpreter and TTY Availability measures are important in measuring the operational performance of a plan and, as a result, for an MA-PD, we include both a Part C measure and a Part D measure. Since there are already two measures focused on call center monitoring, we do not agree that these measures should be

¹⁵⁰<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing>

weighted a 4. We remain concerned that a weight of 4 for access, disenrollment, and call center measures devalues measures of health outcomes and encourages plans to abandon efforts to drive clinically appropriate care. We also note that CMS has other means to evaluate compliance by plans with the regulatory requirements for appeal processes and interpreter services, and CMS can take action as necessary to address deficiencies in performance (including issuing notices of non-compliance).

Comment: A few commenters recommended a weight of 3 for CAHPS measures so there would be proportionate weighting between patient experience measures relative to outcome measures and to avoid creating an imbalance between the two most important measure groupings. A commenter noted that having patient experience and outcome measures weighted equally ensures that the patient voice is heard but would help assuage concerns that it is overweighted. A commenter recommended CAHPS measures that they believe are subjective survey questions receive a weight of 2 and measures related to health plan operations and access maintain the current weight of 4.

Response: Outcome measures reflect improvements in a beneficiary's health and are central to assessing quality of care. Although patient experience measures have been linked to improved clinical outcomes and are important aspects of health care, we believe a weight of 2 more appropriately balances the value these measures contribute to achieving high quality care without weighting them higher than clinical outcome measures and better aligns the total contribution of patient experience and outcome measures with other CMS quality reporting programs. If we used a weight of 3 for CAHPS measures of patient experience, nearly one third of an MA-PD's overall rating would be from CAHPS patient experience of care measures, which we believe is still too high. We also believe it is appropriate to continue to weight patient experience, complaints, and access measures equally. Further, CAHPS surveys focus on matters that patients themselves say are important to them and for which patients are the best and/or only source of information, so we do not agree that CAHPS measures are subjective.

Comment: A commenter stated that it was unable to reach a consensus among its diverse set of patient, provider, payer, and purchaser members on a specific weight for patient experience measures in the Star Ratings program and encourages CMS to continue finding ways to incorporate the beneficiary experience into Star Ratings.

Response: We understand the differing viewpoints and agree that patient experience is a critical component of the Star Ratings program. We will continue to work to enhance the measures focused on patient experience. As noted in other responses to comments and in the proposed rule, we believe that a weight of 2 for the patient experience measures appropriately balances the importance of these measures with other measures that address health outcomes, plan processes, and improvement.

Comment: A couple of commenters recommended that CMS not make significant methodological changes year-over-year in the Star Ratings program since it makes it more difficult for payers and providers to make stable, strategic investments in targeted quality improvement efforts. A commenter suggested waiting to reduce the patient experience/complaints and access measure weights in half until there is compelling evidence of the policy effects of the current methodology. A commenter noted that reducing the weight is not aligned with CMS's commitment to achieve person-centered care across its programs and there have been recent drops in the national averages for CAHPS measures, as well as the Members Choosing to Leave the Plan and Call Center – Foreign Language Interpreter and TTY Availability measures.

Response: CMS is committed to listening to feedback from stakeholders and providing advance notice of methodological changes. As stated in the April 2018 final rule, the methodology for the Star Ratings program was codified in regulation to give Part C and D sponsors more predictability as the rulemaking process creates a longer lead time for all changes and measure changes are announced several years in advance. (83 FR 16519-20). Any changes to the Star Ratings methodology are finalized prior to the measurement year so Part C and D

sponsors can adapt their investments and focus. The weight change we are finalizing here will be effective for the 2024 measurement year and 2026 Star Ratings. We note that from the 2021 to 2022 MA and PDP CAHPS surveys, two MA-PD CAHPS national average measure scores changed by less than 2 points, a “small” change, and seven changed by less than 1 point, a “trivial” amount.¹⁵¹ These small changes are unlikely to persist at the time the new weights will be applied. We believe that we should not wait until there is additional evidence for the need for this change since multiple stakeholders have expressed concern over the increase of the weight to 4 and it is taking away the focus of plans on improving clinical care. As part of CMS’s Strategic Plan, “CMS serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes.” With the weight of 4 for patient experience/complaints and access measures, we are diverting attention away from improving health outcomes. The most recent Star Ratings show there is a need for sponsors to refocus efforts on clinical care measures, as multiple clinical measures’ performances have declined over the last few years. Given the pandemic’s impacts on health care, we believe better balancing the proportion of the different measure types in the Star Ratings will encourage Part C and D sponsors to also balance their investments on patient experience/access as well as clinical care.

Comment: A commenter raised concerns about the CAHPS survey’s ability to adequately and appropriately capture and measure patient experiences. This commenter encouraged CMS to focus on improving the quality and representativeness of the data itself by making it more representative of all racial and ethnic groups.

Response: CMS agrees that it is important to hear the voice of all beneficiaries. CAHPS surveys follow scientific principles in survey design and development. The surveys are designed to reliably assess the experiences of a large sample of patients. The MA and PDP CAHPS surveys use standardized protocols to collect data from random samples of contract enrollees.

¹⁵¹Quigley DD, Elliott MN, Setodji CM, Hays RD. (2018) “Quantifying Magnitude of Group-Level Differences in Patient Experiences with Health Care.” *Health Services Research*, 53: 3027-3051.

Extensive quality control mechanisms are employed to collect valid, reliable survey data. The implementation protocols are designed to increase the likelihood of survey participation and achieve as high a response rate as possible. For the MA and PDP CAHPS survey, we currently require a mixed mode survey (mail with telephone follow-up) since telephone outreach helps improve response rates for some groups. In the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies published on February 1, 2023 and the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies published on March 31, 2023, we announced that starting with the 2024 survey administration we will be adding the web mode of data collection to the mixed mode methodology. Offering the survey sequentially in multiple modes helps improve response rates and the representativeness of the data. In the CAHPS field test we found that for enrollees with email addresses, the web-mail-phone protocol increased MA response rates by 4 percentage points. We believe that the availability of better email addresses across all contracts will help improve response rates overall.

In addition to English, CMS provides survey materials in Chinese, Korean, Spanish, Tagalog, and Vietnamese. Offering the survey in multiple languages helps improve response rates for Asian and Pacific Islander and Hispanic respondents. CMS issues an annual HPMS memo about the Medicare CAHPS survey that includes strategies contracts can use to promote member participation in the survey, including providing survey vendors with language preference data and current phone numbers for all enrollees as well as avoiding fielding other surveys of beneficiaries during or close to the MA and PDP CAHPS survey administration period. Finally, the scoring methodology takes into account reliability, and there are extensive quality control checks to ensure programming is accurate. More information on CMS guidelines for MA and PDP CAHPS and recommendations to achieve high survey response rates is also available at <https://ma-pdpcahps.org/>.

Comment: A commenter recommended the weight change be delayed until marketing complaints decline.

Response: With the weight of 4 for patient experience/complaints and access measures, we are diverting attention away from improving health outcomes. A weight of 2 will still incentivize plans to address marketing issues that may be reflected in the complaints measures, but it ensures that the weighting of patient experience/complaints and access measures is appropriate relative to outcome measures. There are other efforts being made by CMS to address marketing misrepresentation and other marketing issues.

Comment: A couple of commenters supported testing of a new CAHPS question about whether an enrollee's personal doctor dismisses symptoms that are important to them.

Response: CMS appreciates the support for the testing of this CAHPS question. We are continuing to analyze the data from our field test.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the weight change for patient experience/complaints and access measures at § 422.166 at paragraphs (e)(1)(iii) and (iv) and § 423.186 at paragraphs (e)(1)(iii) and (iv) as proposed without modification.

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

As discussed in section III.A. of this final rule, advancing health equity is the first pillar of the 2022 CMS Strategic Plan and a goal of the CMS National Quality Strategy. In reports on accounting for social risk factors (SRFs) in value-based purchasing programs, the National Academies of Sciences, Engineering, and Medicine (NASEM) define SRFs as factors related to health outcomes that are evident before care is provided, are not consequences of the quality of care, and are not easily modified by health care providers.¹⁵² CMS agrees with the NASEM definition of SRFs because it captures the elements we consider important in defining SRFs.

¹⁵²Social Risk Factors: Definitions and Data | Accounting for Social Risk Factors in Medicare Payment | The National Academies Press | <https://nap.nationalacademies.org/read/23635/chapter/4>.

There are often disparities in health care and outcomes between groups with and without SRFs. For example, the within-contract LIS/DE and non-LIS/DE differences in performance for Part C and D Star Ratings measures can be found at: <https://www.cms.gov/files/document/2023-categorical-adjustment-index-measure-supplement.pdf> or <https://www.cms.gov/files/document/2024-categorical-adjustment-index-measure-supplement.pdf>.

As discussed in the proposed rule, the current approach to addressing SRFs in the Part C and Part D Star Ratings program has focused on adjusting for the average within-contract disparities in performance through the CAI, as described at §§ 422.166(f)(2) and 423.186(f)(2), in order to not inappropriately penalize or reward health and drug plans for factors that are difficult for plans to control. For certain current Star Ratings measures, it may be more difficult for most plans to achieve the same level of care for groups that are socioeconomically disadvantaged, disabled, or more complex due to a variety of issues, including transportation issues, lower health literacy, communication challenges, and residential instability. The CAI is a factor that can be positive or negative and is added to a contract's overall and summary Star Ratings and that adjusts for the average within-contract performance disparity based on a contract's composition of LIS/DE and disability status enrollees.

The CAI was implemented in the Part C and Part D Star Ratings program to address SRFs while measure stewards evaluated adjustment on a measure-specific basis. The CAI is a data-driven approach to account for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. The CAI does not incentivize contracts to focus on reducing disparities. Although all contracts have incentives in the Star Ratings program to improve performance, prior to the proposed HEI reward, there were no methodological adjustments that specifically created incentives to address disparities of care among a contract's enrollees.

In addition to adjusting for within-contract disparities through the CAI, we also want to encourage MA organizations, cost plans, and Part D plan sponsors to better identify and then address disparities in care provided to enrollees with a particular SRF, with the ultimate goal of reaching equity by eliminating health disparities or differences in contract performance by SRFs, consistent with CMS efforts to advance health equity.

CMS developed a health equity index (HEI) factor that we proposed for use in the Part C and Part D Star Ratings to reward contracts for obtaining high measure-level scores for the subset of enrollees with specified SRFs. Our intent in implementing an HEI reward is to improve health equity by incentivizing MA, cost, and PDP contracts to perform well among enrollees with specified SRFs. The CAI is designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts; in contrast, our proposed HEI reward is specifically designed to create an incentive to reduce disparities in care. As discussed in the proposed rule, the HEI reward, therefore, would not replace the CAI but rather assist plan sponsors in better identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reaching equity in the level and quality of care provided to enrollees with SRFs. We explained in the proposed rule that there would be no changes to the current CAI with the implementation of the HEI reward.

We proposed to replace the current reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) with the new HEI reward at proposed §§ 422.166(f)(3) and 423.186(f)(3) starting with the 2027 Star Ratings; the HEI reward for the 2027 Star Ratings would be calculated using data collected or used for the 2026 and 2027 Star Ratings (2024 and 2025 measurement years). As discussed in the preamble to the proposed rule, the current reward factor was included in the Part C and Part D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures (that is, a mix of low performance and high performance across measures). We proposed that the removal

of the current reward factor would be contingent on finalizing the addition of the proposed HEI reward.

CMS proposed to add the HEI reward as a methodological enhancement to the Part C and Part D Star Ratings program starting with the 2027 Star Ratings because, similar to the current reward factor, it provides a summary of how performance varies across existing Star Ratings measures. However, our proposed HEI reward is intended to be a methodological enhancement using data from existing Star Ratings measures rather than a new measure with additional burden for contracts. In the case of the HEI reward, however, this summary of performance would be based on performance related to a subset of enrollees with specified SRFs. Adding the HEI as a reward also would allow for the methodology to include a performance threshold below which contracts will not be eligible for the HEI reward, which would incentivize improved performance by contracts for their enrollees with the specified SRFs and help reduce disparities. CMS could also potentially increase this performance threshold over time to incentivize continued efforts to reduce disparities in care.

In developing the proposed HEI reward, we considered a number of goals to ensure the incentives of the HEI and the associated reward were in line with our intent. We aim to improve health equity by incentivizing MA plans, cost plans, and Part D plan sponsors to perform well among enrollees with certain SRFs. These goals include the following:

- Avoiding rewarding large contracts over small contracts that may be providing high quality care for enrollees with the SRFs included in the HEI but lack the number of enrollees needed to reliably calculate the HEI.
- Avoiding rewarding contracts that may do well among enrollees with the SRFs included in the HEI but serve very few enrollees with those SRFs, making it easier to do well.
- Only rewarding contracts that have high relative performance among enrollees with the SRFs included in the HEI compared to other contracts to incentivize high performance for enrollees with the SRFs included in the HEI.

- Ease of use and understanding for contracts and other interested parties.
- Minimizing the number of years of data needed to calculate the HEI and HEI reward

such that the data used are as current as possible.

- Allowing for updates to the measure set included in the HEI and updates to accommodate the addition of other SRFs to the HEI over time.
- Promoting improvement in performance among individuals with certain SRFs and enrollment of individuals with certain SRFs in high quality MA plans, cost plans, and Part D plans.
- Accurately reflecting true performance among contracts serving enrollees with certain SRFs and minimizing sensitivity to measurement error.

The proposed HEI would summarize contract performance in relation to enrollees with certain SRFs across multiple existing Star Ratings measures into a single score using data from the most recent 2 measurement years. We proposed at §§ 422.166(f)(3)(i)(A) and 423.186(f)(3)(i)(A) to initially include LIS/DE or having a disability as the group of SRFs used to calculate the HEI. Prior research has shown that dual eligibility for Medicare and Medicaid is one of the most influential predictors of poor health outcomes, and disability is also an important risk factor linked to health outcomes.¹⁵³ The SRFs included in the HEI may be expanded over time. For purposes of the HEI, we proposed to define an LIS/DE beneficiary as one who was designated as a full-benefit or partial-benefit dually eligible individual or who received a low-income subsidy (LIS) at any time during the applicable measurement period, as we do currently for the calculation of the CAI. If a person meets the criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. We proposed to use the original reason for entitlement to the Medicare program to identify enrollees with a disability for purposes of the HEI as we do for the calculation of the CAI.

¹⁵³https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?_ga=2.49530854.1703779054.1662938643-470268562.1638986031

We solicited feedback on potential additional ways to identify enrollees who have a disability that could be incorporated over time and whether the same process and standards should be used for the CAI adjustment as well. In particular, we noted our interest in how we could expand the definition to include enrollees who develop a disability after aging into the Medicare program. LIS/DE and disability are the SRFs that have been used in the CAI for many years and are included in the confidential Part C and D Stratified Reports provided to MA and Part D contracts in HPMS as of 2022. We proposed that enrollees with these SRFs would be identified for the HEI the same way they are identified for the CAI at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B).

We also considered including the Area Deprivation Index (ADI) in the HEI. The ADI is a measure of socioeconomic neighborhood deprivation, including measures of income, employment, housing, education, social environment, and readmissions. As discussed in the preamble to the proposed rule, we will continue to explore the feasibility of adding other SRFs to the HEI over time. As we noted in the proposed rule, the addition of other SRFs or other mechanisms to identify enrollees with one or more of the SRFs that are part of the HEI reward methodology would be proposed through future notice-and-comment rulemaking.

We proposed that the HEI would examine performance among those with certain SRFs for all Star Ratings measures unless they meet one of the specified exclusions. As we proposed in §§ 422.166(f)(3)(ii)(A)-(D) and 423.186(f)(3)(ii)(A)-(D), measures would be excluded from the HEI if one or more of the following criteria are met:

- The focus of the measurement is not the enrollee but rather the plan or provider (for example, the appeals and call center measures focus on the plan and its operations rather than on the enrollee). Measures meeting this criterion would be excluded because enrollee-level SRF information for these measures is not available for inclusion in the HEI.

- The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI. Measures meeting these criteria would be excluded because there are not enough data to calculate the HEI for these measures.

- The measure is applicable only to SNPs. Measures meeting this criterion would be excluded because these measures are not relevant for all contracts.

- At least 25 percent of contracts are unable to meet the criteria described at proposed paragraph (f)(3)(iv), which provides that a measure is only included for the HEI for a contract if the measure has a reliability of at least 0.7 for the contract when calculated for the subset of enrollees with the specified SRF(s) and the contract meets the measure denominator requirement when the measure is calculated for only the enrollees with the specified SRF(s) (that is, the SRFs included in the HEI). For Part D measures, these criteria are assessed separately for MA-PDs and cost contracts, and PDPs consistent with how the Part D measure cut points and CAI are calculated separately for MA-PDs and cost contracts, and PDPs for the Part D summary rating. We proposed to exclude any measures from the HEI that less than 25 percent of contracts can have reliably calculated because scores would be missing for most contracts.

We proposed, at §§ 422.166(f)(3)(iii) and 423.186(f)(3)(iii), that the measures being evaluated for inclusion in the HEI would be announced annually in the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. These announcements (of the measures being evaluated for inclusion in the HEI) would not include the final list of measures used in the HEI for the upcoming Star Ratings because the data to determine that final set will not yet be available. In general, measures from HEDIS, HOS, and CAHPS would be included unless they meet one of the four exclusion criteria, proposed at §§ 422.166(f)(3)(ii)(A)-(D) and 423.186(f)(3)(ii)(A)-(D). Additionally, medication adherence, MTM Program Completion for CMR, and Statin Use in Persons with Diabetes measures would be included as long as they meet the requirements for inclusion for more than 25 percent of contracts as proposed at §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B).

We described in the proposed rule the five steps that CMS would take to analyze the measure-level scores for each contract and to roll up to the HEI scores in order to assess when an adjustment is available for a contract's ratings.

Step 1: For each measure included in the HEI, measure-level scores calculated for each contract among enrollees with the included SRFs (that is, all enrollees who are DE, LIS, or disabled combined into one group) would be combined over the two most recent measurement years. CMS carefully considered the number of years of data needed for the proposed HEI. We believe that using 2 years of data allows for a balance between increasing measure-level reliability so that smaller contracts may still have enough data to have the HEI calculated and minimizing the number of years of data used. As outlined in our goals in designing the HEI, it is important to minimize the number of years of data used to avoid carrying forward very old data in the Star Ratings and to allow new measures and newer contracts to more quickly be included in the HEI.

As proposed at §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B), the scores for the subset of enrollees with SRFs of interest included in the HEI would be calculated using a modeling approach that includes year (that is, an indicator for whether the data are from year 1 or year 2) as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Scores are adjusted for year to account for situations where mean scores were, for the average contract, different in the 2 years (for example, higher in year 2 than year 1, or vice versa) and for contracts that have measure sample sizes that differ across years. In the calculation of the HEI, the measure-level scores will be used for contracts that have data for only the most recent year of the 2 years, but measure-level scores will not be used for contracts that have data for only the first of the 2 years in order to ensure use of the most current data possible.

Step 2: Measures that are case-mix adjusted in the Star Ratings would be adjusted using all standard case-mix adjustors for the measure except for those adjustors that are the SRFs of

interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest. The CAHPS measures included in the Star Ratings are currently adjusted for DE and LIS but are not adjusted for disability as defined by the original reason of entitlement. For the proposed HEI, for the subset of enrollees who identified as having the SRFs of interest in Step 1 (that is, the enrollees who are DE or LIS), we would not include the case-mix adjustment for DE and LIS when calculating the scores over the 2-year period for the CAHPS measures. For the three Star Ratings medication adherence measures based on the PQA specifications that will be risk adjusted as described in section V.D.2.a. of this rule, we would not include the measure-based risk adjustment for DE, LIS, and disabled enrollees when calculating the scores for these measures over the 2-year period as described in Step 1 if these measures meet the inclusion criteria for the HEI.

Step 3: For a measure to be included in the HEI score for a specific contract, both of the following inclusion criteria in proposed §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv) would need to be met: (1) reliability of at least 0.7 when the measure is calculated for the combined subset of enrollees with the specified SRFs across 2 years of data, and (2) measure-specific denominator criterion (for example, most HEDIS measures require a minimum denominator of at least 30) is met when the measure is calculated for the combined subset of enrollees with the specified SRFs across 2 years of data. We proposed at paragraph (f)(3)(vi) that contracts would also need to have at least 500 total enrollees at the contract level in the most recent measurement year used in the HEI. We proposed a minimum in order to have reliable measure-level scores. For many of the Star Ratings measures (for example, HEDIS and HOS measures) at least 500 enrollees are needed to have a sufficient number of enrollees to reliably measure the performance of the contract.

Step 4: As we proposed in §§ 422.166(f)(3)(v) and 423.186(f)(3)(v), to calculate the HEI score assigned to a contract, the distribution of contract performance on each eligible measure among enrollees with the specified SRFs (that is, all enrollees who are DE, LIS, or disabled

combined into one group) would be calculated and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point for each measure. For example, for the Breast Cancer Screening measure, we would calculate performance for all contracts for the enrollees with one or more of the specified SRFs (that is, for the enrollees who are DE, qualify for LIS, and/or are disabled) using the two most recent measurement years. We would then look at the distribution of scores for this measure for all contracts that have at least 0.7 reliability and meet the minimum denominator size for the measure. Contracts that score in the top third of all contracts would receive 1 point for this measure, the middle third of contracts would receive 0 points for this measure, and the bottom third of contracts would receive 1 negative point for this measure. The same analysis would be repeated for each measure included in the HEI.

Step 5: For each contract, the HEI would then be calculated as the weighted average of these points using the Star Ratings measure weights and including only measures for which the contract met all of the inclusion criteria specified at §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv). The weighted average would be the weighted sum of points across all included measures divided by the weighted sum of the number of included measures. We proposed to use the weight for the measure in the current Star Ratings year. For example, if the HEI were being calculated using data from the 2026 and 2027 Star Ratings year, the measure weight used would be the weight for the 2027 Star Ratings. To ensure that the HEI is not driven by a very small number of measures for some contracts, we proposed at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) that a contract must meet the reliability and denominator criteria for at least half of the measures included in the HEI in order to have the HEI calculated for the contract. Contract performance on the HEI will vary from -1.0 (performance was in the bottom third for each included measure) to 1.0 (performance was in the top third for each included measure).

Table 3 is a high-level summary of the steps CMS proposed to take to calculate the HEI.

TABLE 3: STEPS TO CALCULATE THE HEI

Steps	High-Level Description of Steps to Calculate the HEI
Step 1	Measure-level scores for each measure included in the HEI are calculated for each contract using data from the two most recent measurement years based on enrollees with the specified SRFs using a modeling approach that accounts for year.
Step 2	Measures that are case-mix adjusted in the Star Ratings employ all standard case-mix adjustors except for adjustors that are the same as the SRFs included in the HEI, are strongly correlated with the included SRFs, or are conceptually similar to the included SRFs.
Step 3	A contract needs to meet the reliability and minimum denominator criteria for at least half of the measures included in the HEI based on data from the two most recent measurement years and have at least 500 enrollees at the contract level in the most recent measurement year to have the HEI calculated.
Step 4	For each measure using all contract-level scores calculated in Step 1/Step 2 that have at least 0.7 reliability and meet the minimum denominator criteria, points will be assigned as follows: 1 point to those contracts that score in the top third of all contracts, 0 points to those that score in the middle third of all contracts, and 1 negative point to those that score in the bottom third of all contracts.
Step 5	For each contract, the HEI will be calculated as the weighted average of the points assigned in Step 4 using the Star Ratings measure weights and including only measures for which the contract met all inclusion criteria.

As discussed in the proposed rule, the HEI would be calculated separately for the overall and summary ratings, as we proposed at §§ 422.166(f)(3)(i) and 423.186(f)(3)(i), since the set of included measures differs for the overall, Part C summary, and Part D summary ratings. The HEI calculated for the overall rating would be based on all of the Part C and Part D measures that meet the inclusion criteria for the HEI for each MA-PD contract. The HEI for the Part C summary rating would include all of the Part C measures that meet the inclusion criteria for the HEI for the contract. The HEI for the Part D summary rating would be calculated separately for MA-PD (including cost) and PDP contracts and would include all of the Part D measures that meet the inclusion criteria for the HEI for the contract.

In order to qualify for an HEI reward, we proposed at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) that contracts must have a minimum rating-specific HEI score of greater than zero. We also proposed a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified SRFs. Requiring both a minimum HEI score and a

minimum percentage of enrollees in a contract with the specified SRFs is intended to avoid rewarding contracts that serve very few enrollees with the specified SRFs or do not perform well among enrollees with the specified SRFs relative to other contracts.

We proposed that contracts that have percentages of enrollees with any of the specified SRFs in a given year that are greater than or equal to one-half of the contract-level median percentage of enrollees with the specified SRFs up to, but not including, the contract-level median would qualify for one-half of the potential HEI reward. Contracts that have percentages of enrollees with any of the specified SRFs greater than or equal to the contract-level median would qualify for the full potential HEI reward. Table 4 is a high-level summary of how we proposed that the HEI score would be converted into the HEI reward.

TABLE 4: CONVERTING HEI SCORE INTO HEI REWARD

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

We also considered an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRFs greater than or equal to one-half of the contract-level median would qualify for the full HEI reward. As we discussed in the proposed rule preamble, both the tiered and non-tiered HEI reward structures align with our goal of not rewarding contracts that may do well among enrollees with SRFs but serve very few enrollees in this population, although the tiered HEI reward structure goes further in aligning with this goal. The non-tiered HEI reward structure aligns better with the goal of ease of use and understanding for contracts and other stakeholders.

We proposed at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) that the contract percentages of enrollees with SRFs included in the HEI would be based on enrollment in the most recent of the 2 years of data used to calculate the HEI. For example, if the HEI includes data from measurement years 2024 and 2025, the enrollment used would be from 2025. We recognize D-SNP only contracts would meet the enrollment thresholds under either the tiered or non-tiered HEI reward structure; however, other plans that do not initially meet the thresholds can also work to increase enrollment of people with SRFs to meet the enrollment thresholds. D-SNP only contracts would also need to perform sufficiently well among enrollees with the specified SRFs to qualify for a reward based on the HEI. One consideration in developing the proposed thresholds for the minimum percentages of enrollees with SRFs included in the HEI needed to qualify for an HEI reward was that higher thresholds could potentially create geographic barriers in certain parts of the country to qualifying for the HEI reward because there is variation by State in the percent of enrollees who are LIS/DE or disabled. Both the tiered HEI reward and non-tiered HEI reward structures account for this as all states have percentages of LIS/DE/disabled enrollees that are greater than one-half the contract-level median based on 2019 data, although the non-tiered structure goes further in addressing this concern, as many states do not have percentages of LIS/DE/disabled enrollees that are greater than the contract-level median. As specified at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) the contract-level median and half of the contract-level median would be calculated and assessed separately for MA (that is, Part C) and standalone Part D (that is, PDP) contracts.

Because enrollees in Puerto Rico are not eligible for LIS, we believe that a different approach is necessary for contracts with services areas wholly located in Puerto Rico. We proposed at §§ 422.166(f)(3)(vii)(A) and (B) and 423.186(f)(3)(vii)(A) and (B) to use a modified calculation to determine the percentage of enrollees with SRFs included in the HEI for contracts with service areas wholly located in Puerto Rico. We proposed to limit this treatment to contracts with service areas wholly in Puerto Rico because our analysis indicates that for plans

with service areas that include Puerto Rico and other locations, only a small portion of the enrollment is in Puerto Rico. We proposed to estimate the number of enrollees with the specified SRFs in these contracts differently. We would start with the percentage of DE/disabled enrollees calculated from administrative data, and then add the estimated percentage LIS by taking the LIS/DE percentage calculated for the CAI for contracts with service areas wholly in Puerto Rico as described at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees. We need to estimate the number of LIS enrollees because LIS is not available in Puerto Rico; we would use the estimated LIS/DE information from the CAI calculations since these are the only data available on the estimated percentage of enrollees in Puerto Rico contracts that would qualify for LIS. We would then add the estimated LIS percentage to the DE/disabled percentage calculated from administrative data to get the LIS/DE/disabled percentage of enrollees in Puerto Rico. This calculation could result in a slight overestimate since some disabled enrollees may also be captured in the estimated LIS percentage; therefore, contracts with service areas wholly in Puerto Rico would be excluded from our calculations to determine one-half of the contract-level median and the contract-level median of enrollees with SRFs included in the HEI. We believe that this approach would ensure equitable treatment of contracts with service areas outside of Puerto Rico. In our simulations of the HEI, we found that the slight overestimate had little impact on whether contracts with service areas wholly in Puerto Rico met the one-half of the contract-level median or contract-level median thresholds.

We also proposed that contracts would need to have an HEI score greater than zero on the HEI calculated for the given rating (overall or summary rating) to qualify for a reward for that rating. We proposed at §§ 422.166(f)(3)(i) and 423.186(f)(3)(i) that the HEI score for the overall rating would include the applicable Part C and D measures, the HEI score for the Part C summary rating would include only the applicable Part C measures, and the HEI score for the Part D summary rating would include only the applicable Part D measures. An HEI score of

greater than zero means that the contract on average scored in the middle third or better across measures included in the HEI for enrollees with the SRF(s). HEI scores closer to 1.0 indicate better performance for enrollees with the SRFs included in the HEI. While we proposed to require a minimum HEI score of greater than zero for contracts to receive an HEI reward, we may consider increasing this minimum score over time to continue to encourage improved contract performance for enrollees with SRFs included in the HEI. Any such increase to the minimum HEI score would be proposed through subsequent notice-and-comment rulemaking.

We proposed at §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii) that the HEI reward would vary from 0 to 0.4 on a linear scale for contracts that meet the threshold for the median percentage of enrollees with SRFs included in the HEI, with a contract receiving 0 reward if the contract received a score of 0 or less on the HEI and a 0.4 reward if the contract received a score of 1 on the HEI. Similarly, the HEI reward would vary from 0 to 0.2 on a linear scale for contracts that meet the threshold for one-half of the contract-level median percentage of enrollees with SRFs included in the HEI, but do not meet or exceed the contract-level median percentage of enrollees with SRFs included in the HEI. Contracts that cannot have an HEI score calculated (that is, contracts that do not have reliable measure scores or do not meet the denominator criteria for at least half of the measures included in the HEI or contracts that do not have at least 500 enrollees) would not receive an HEI reward.

As an example, if a contract meets the contract-level median percentage of LIS/DE/disabled enrollees and receives an HEI score of 0.722325, this would translate on a linear scale to a reward of 0.288930. That is, the size of the HEI reward would equal 0.4 times the difference between the HEI score and the threshold, divided by the difference between the maximum HEI score and the threshold. In this example, this would be $0.4 * (0.722325 - 0) / (1 - 0)$, which equals 0.288930. As another example, if a contract meets one-half the contract-level median percentage of LIS/DE/disabled enrollees but does not meet the contract-level median percentage of LIS/DE/disabled enrollees and receives an HEI score of 0.722325, this would

translate on a linear scale to a reward of 0.144465. That is, the size of the HEI reward would equal 0.2 times the difference between the HEI score and the threshold, divided by the difference between the maximum HEI score and the threshold. In this example, this would be $0.2 * (0.722325 - 0) / (1 - 0)$, which equals 0.144465. The HEI reward would be rounded and displayed with 6 decimal places similar to how the CAI values are displayed.

As we proposed at §§ 422.166(f)(3)(ix) and 423.186(f)(3)(ix), once each of the HEI rewards are calculated, the applicable HEI reward would be added to the unrounded overall and Part C and D summary ratings after the addition of the CAI and the application of the improvement measures described in §§ 422.166(g)(1) and 423.186(g)(1) and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star. For example, if the HEI reward was 0.288930, as previously described in the example, and the unrounded overall rating was 4.234210 after the addition of the CAI and the application of the improvement measure hold harmless rule, the unrounded overall rating would be 4.523140 ($4.234210 + 0.288930$) resulting in a final, rounded overall rating of 4.5.

We also proposed changes in the following sections to revise references to the existing reward factor or to limit application of the current reward factor to the Star Ratings through the 2026 Star Ratings: §§ 422.166(c)(1), 422.166(d)(1) 422.166(f)(1), 422.166(f)(2)(i), 422.166(g)(1), 423.186(c)(1), 423.186(d)(1) 423.186(f)(1), 423.186(f)(2)(i), and 423.186(g)(1). We proposed that the new HEI reward would be implemented for the 2027 Star Ratings covering primarily the 2024 and 2025 measurement years. The existing reward factor would continue to be calculated through the 2026 Star Ratings.

We simulated the impact of removing the current reward factor and adding the proposed HEI reward and summarized those results in the proposed rule. In simulations using data from the 2020 and 2021 Star Ratings,¹⁵⁴ the median percentage of LIS, DE, and disabled enrollees was

¹⁵⁴Since data collections for HEDIS and CAHPS were curtailed for the 2021 Star Ratings due to the COVID-19 pandemic (CMS-1744-IFC), these simulations used HEDIS and CAHPS measure data from the 2019 and 2020 Star Ratings.

41.645 percent and one-half the median was 20.822 percent for MA and cost contracts. Half of MA and cost contracts were at or above the median, 33 percent were at or above one-half the median up to but not including the median, and 17 percent were below one-half the median. In the simulations, 88 percent of MA-PD contracts that received an overall rating received an HEI score, 42 percent received an HEI score greater than zero, and 34 percent received an HEI reward. The range of HEI scores among MA-PD contracts for the overall rating was -0.888889 to 1.000000. The average reward for the overall rating among MA-PD contracts with an HEI score greater than zero was 0.109. When simulating the removal of the current reward factor and addition of the proposed new HEI reward, 7 (1.7 percent) MA-PD contracts gained one-half star on the overall rating and 54 (13.4 percent) MA-PD contracts lost one-half star on the overall rating compared to the 2021 Star Ratings. Among PDP contracts, the median percentage of LIS, DE, and disabled enrollees was 13.848 percent and one-half the median was 6.924 percent. Fifty-one percent of PDP contracts were at or above the median, 39 percent were at or above one-half the median up to but not including the median, and 11 percent were below one-half the median. Among PDP contracts that received a Part D summary rating, 91 percent received an HEI score, 47 percent received an HEI score greater than zero, and 40 percent received an HEI reward. The range of HEI scores among PDP contracts was -1.000000 to 1.000000. The average reward among PDP contracts with an HEI score greater than zero was 0.160. Compared to the 2021 Star Ratings, 3 (5.3 percent) PDP contracts gained one-half star on the Part D summary rating and 7 (12.3 percent) PDP contracts lost one-half star on the Part D summary rating.

We solicited comments on these proposals.

Comment: Nearly all commenters supported advancing health equity, and a majority of commenters supported the HEI reward as proposed, including replacing the current reward factor. A few commenters also specifically endorsed the tiered threshold structure for the percentage of enrollees with the specified SRFs that we proposed contracts must meet to qualify for the HEI reward. Some commenters provided reasons for supporting the HEI reward, such as

it is in line with CMS's goal of advancing health equity, it will help to shed light on deep-seated disparities in the health care system, and it will drive reductions in disparities in care and result in 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.

Response: CMS thanks these commenters for their support of the HEI reward.

Comment: A commenter stated they do not believe that the HEI aligns with CMS's health equity definition or the ultimate goal of improved and more equal health outcomes. The commenter suggested that CMS create a more wholistic and systemic approach to improving health equity, including accurately capturing data, aligning incentives not just for MA organizations but across other demonstrations, and providing mechanisms to address at-risk populations through benefits and plan design.

Response: CMS developed the HEI reward to further incentivize Part C and D plans, as part of the Star Ratings, to focus on improving care for enrollees with specified SRFs and reward contracts for excellent care for these populations with the goal of reducing disparities in care. As such, CMS believes the HEI reward aligns with CMS's health equity definition. We agree that it is important to capture accurate data to identify beneficiaries with SRFs, and there are ongoing efforts to improve data accuracy, as well as efforts across multiple CMS programs to create similar incentives to improve care for more vulnerable enrollees. For example, starting in 2023, a health equity adjustment to an accountable care organization's quality score as part of the Medicare Shared Savings Program (MSSP) was added to incentivize improvement in the care for vulnerable beneficiaries.¹⁵⁵ In addition, proposals to address improved access to benefits for MA

¹⁵⁵HHS Finalizes Physician Payment Rule Strengthening Access to Behavioral Health Services and Whole-Person Care | CMS

enrollees and require MA coordinated care plans ensure that services are provided in a culturally competent manner are addressed in sections II.A.2. and III.A. of this rule.

Comment: A commenter recommended CMS not proceed with the HEI reward proposal and instead release a white paper describing a range of possible methodologies and approaches for addressing health equity for stakeholders to react to. This commenter also requested CMS to detail the relationship between the HEI and the Health Equity Summary Score (HESS) and to illustrate exactly how the HEI is calculated using specific examples.

Response: CMS first requested feedback on a possible HEI reward in the spring of 2022 through the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. CMS considered the feedback received on the Advance Notice as we continued to develop the HEI reward for the proposed rule. Considering the feedback we received on the proposed rule, CMS believes there has been sufficient opportunity for stakeholder input on the HEI reward methodology. We note that, to prepare health plans for implementation of the HEI reward, CMS will calculate the HEI reward beginning with the 2024 Star Ratings and will share the results in confidential contract-level reports in HPMS.

The HESS is a quality improvement tool developed by the CMS Office of Minority Health with a similar goal of improving health equity. The HESS differs from the HEI developed for the Part C and D Star Ratings program in that it currently focuses on CAHPS and HEDIS measures, while the HEI focuses on a broader set of measures included in the Part C and D Star Ratings. The HESS examines differences by race and ethnicity and LIS/DE status and assigns each contract composite scores for CAHPS and HEDIS (translated to diamonds, ranging from 1-5, with 5 being the best) based on a combination of current performance and improvement in performance over a four-year period. The HEI only requires two years of data and focuses on the specified SRFs. The HESS is separate from the Part C and D Star Ratings program and has no link to payment.

Comment: A couple of commenters supported including LIS/DE and disability as the SRFs in the HEI reward methodology and supported the proposed definitions of these populations used in the HEI reward.

Response: CMS thanks these commenters for their support.

Comment: A commenter supported using the proposed methodology to calculate the percentage of LIS/DE enrollees for contracts in Puerto Rico because LIS is not available in Puerto Rico.

Response: CMS thanks this commenter for their support.

Comment: A commenter requested that CMS provide clarification on whether the HEI reward applies to standalone PDPs or just MA-PD plans.

Response: The HEI reward applies to both standalone PDP and MA-PD contracts as proposed and finalized at §§ 422.166(f)(3)(i) and 423.186(f)(3)(i). The HEI is a rating-specific factor added to the summary and overall ratings of contracts that qualify. We proposed and finalized calculating the HEI separately for the Part D summary rating for MA-PDs and cost contracts, and PDPs.

Comment: A commenter requested that CMS provide clarification on how the HEI reward would impact a contract's Star Rating and whether it would help or harm a contract's Star Rating.

Response: The HEI reward is an upside only reward, incentivizing high quality care for underserved populations. Any applicable HEI reward would be added to the unrounded overall and Part C and D summary ratings after the addition of the CAI and the application of the improvement measures described in §§ 422.166(g)(1) and 423.186(g)(1) and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star. Since it is an upside only reward, it avoids penalizing contracts.

Comment: Several commenters questioned how measure reliability will be calculated.

Response: Measure reliability is a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (“signal”) rather than random variation (“noise”). In order to calculate this signal to noise ratio for each measure included in the HEI, measure reliability is calculated based on the combined subset of enrollees with the specified SRFs across two years of data. Reliability calculations for MA and PDP CAHPS patient experience measures are provided in the “Quality Assurance Protocols & Technical Specifications,” available at <https://ma-pdpcahps.org/en/quality-assurance>, in section IX Data Analysis and Public Reporting, sub-section Significance Testing, Reliability and Star Assignment. The reliability calculations for all other measures are implemented using SAS PROC MIXED as documented in the report “The Reliability of Provider Profiling – A Tutorial,” available at https://www.rand.org/pubs/technical_reports/TR653.html, which is consistent with the reliability calculations used to determine inclusion for Part C HEDIS measures in the Star Ratings for low enrollment contracts (500 to <1000 enrollees).

Comment: A commenter did not support a measure reliability of 0.7 in the HEI reward. This commenter also did not support requiring that a contract must meet the reliability criteria for at least half the measures in the HEI because measure rates will increase over time with the introduction of the HEI reward, and it may take several years for the measure rates to stabilize such that they can be included in the HEI reward.

Response: Measure reliability will be calculated based on the combined two measurement years of data for the subset of enrollees with the specified SRFs. Reliability assesses variability in performance that is attributable to real differences in performance versus measurement error. CMS’s intent with the introduction of the HEI reward is to incentivize improvements in performance among populations with SRFs. Such performance improvements do not mean that measures are not reliable or that measures should not be included in the HEI reward.

Comment: A few commenters suggested that CMS provide clarification on how rates will be calculated for the 2-year combined rate.

Response: As specified at §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B), measure-level scores for the subset of enrollees with the SRFs of interest included in the HEI will be calculated using a regression model that includes year (that is, an indicator for whether the data are from year 1 or year 2) as an adjustor or independent variable to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the two years of data used. Through this modeling approach, data can be combined across the two years for each contract and can be adjusted to account for situations where mean scores were, for the average contract, different in the two years.

Comment: A commenter questioned how the HEDIS hybrid measures will be addressed.

Response: The HEI reward is calculated using patient-level data. The HEDIS hybrid measures combine administrative claims data with data abstracted through medical record review. The patient-level data submitted for these patients correspond to the summary-level data from administrative claims and medical record review. In order to calculate the HEI reward, no additional steps are necessary for HEDIS hybrid measures compared to HEDIS administrative measures.

Comment: A commenter questioned how survey measures will be addressed since LIS/DE stratification reports do not include calculated values for CAHPS measures.

Response: The CAHPS measures included in the Star Ratings are currently adjusted for DE and LIS status. For the HEI reward, case-mix adjustment is recalculated without adjustment for DE and LIS when calculating the CAHPS measure scores for the purposes of the HEI over the 2-year period as described at §§ 422.166(f)(3)(i)(A) and 423.186(f)(3)(i)(A). Case-mix adjustment of the CAHPS measures used for the measure-level Star Ratings is not affected.

Comment: A commenter questioned how enrollees in a health plan for one year will be handled.

Response: As proposed and finalized at §§ 422.166(f)(3)(B) and 423.186(f)(3)(B), the HEI is calculated by combining data across the two most recent measurement years. Data from enrollees in a health plan for one of the two measurement years will be included for the year in which they are enrolled in the plan.

Comment: A commenter requested that CMS provide clarification on which measures are included and why certain measures are removed from the calculation.

Response: As proposed and finalized, CMS will take five steps to analyze the measure-level scores for each contract and to roll up to the HEI scores in order to assess when an adjustment is available for a contract's ratings. As proposed and finalized in §§ 422.166(f)(3)(ii) and 423.186(f)(3)(ii), all Star Ratings measures would be included in the HEI unless a measure meets one or more of the four exclusion criteria listed in paragraphs (f)(3)(ii)(A) through (D): (A) the focus of measurement is not the enrollee but rather the plan or provider; (B) the measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI; (C) the measure is applicable only to SNPs; or (D) at least 25 percent of contracts do not meet the measure-level denominator and reliability criteria. These exclusion criteria ensure we have enrollee-level data for most contracts to include these measures in the HEI.

For a contract's HEI score, measures are included if the two criteria in paragraphs (f)(3)(iv)(A) and (B) are met. To meet the measure-level denominator and reliability criteria, a measure for a contract must have a reliability of at least 0.7 and meet the measure denominator requirement when calculated for the subset of enrollees with the specified SRFs across the two years of data. These criteria for determining when a measure would be used for a contract's HEI score are necessary to ensure the HEI is reliably calculated for each contract.

Comment: A commenter questioned if the data layout used for presenting information about the HEI reward will be the same layout used in the Part C and D Star Ratings Stratified Reports shared through the May 11, 2022 HPMS memo titled, "Stratified Reporting for Part C

and D Star Ratings Measures,” and whether data from the stratified reports will be used to determine which third of the distribution a contract is in for each measure.

Response: The stratified reports are for quality improvement purposes and are not used in calculating Star Ratings or otherwise used in the Star Ratings methodology. Both the HEI reward methodology and the stratified reports use data from measures included in the Star Ratings program. The stratified reports may be useful to sponsoring organizations for identifying opportunities for improvement for the Star Ratings measures included in the HEI because the data are stratified by LIS/DE and disability status and the reports provide national performance scores to help inform and target quality improvement initiatives.

Comment: A commenter questioned how the percentage of enrollees with SRFs will be calculated for the tiered HEI reward structure.

Response: As proposed and finalized, §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) address this. The contract percentages of enrollees with SRFs included in the HEI will be based on enrollment in the most recent of the two years of data used to calculate the HEI. For example, if the HEI includes data from measurement years 2024 and 2025, CMS would use enrollment from 2025. The percentage of enrollees with SRFs would include any enrollees who are LIS/DE or have a disability. This is treated as one group of enrollees with SRFs. As specified at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii), the contract-level median and half of the contract-level median enrollment percentages will be calculated and assessed separately for contracts that offer Part C and standalone Part D contracts.

Comment: A commenter suggested that CMS provide clarification regarding whether the three specified SRFs would be treated independently and thus the HEI score would be calculated separately for each SRF or, alternatively, if they would be combined in a manner similar to the calculation of the CAI. This commenter also recommended that CMS clarify whether the weights of selected measures would be used when calculating the final HEI reward. A commenter stated that CMS did not specify which SRFs would be included in the HEI.

Response: As described in the proposed rule, all enrollees who are DE, LIS, or disabled would be combined into one group as described at §§ 422.166(f)(3)(i)(A), 422.166(f)(3)(i)(B), 423.186(f)(3)(i)(A), and 423.186(f)(3)(i)(B). See also 87 FR 79628. We believe combining the enrollees with these specified SRFs into one group will help ensure that measure-level contract performance can be reliably measured for most contracts. The measure weights will be used when calculating the final HEI as described at §§ 422.166(f)(3)(v) and 423.186(f)(3)(v).

Comment: A commenter questioned whether a contract's measure-level score will be included for purposes of the performance thresholds to determine if a contract's measure score is in the bottom third, middle third, or top third if the contract does not meet the minimum enrollment percentage of enrollees.

Response: For all contracts, the scores meeting the criteria in §§ 422.166(f)(3)(iv) and 423.183(f)(3)(iv) will be included in the calculations to determine the distribution of contract performance for each eligible measure. Similarly, only the scores for each contract's performance that meet those criteria will be used to determine the contract's HEI score.

Comment: Another commenter noted that there are no Z-codes to identify issues around social determinants of health and recommended that the HEI reward should not be implemented until data collection improves.

Response: While there are no Z-codes to identify issues around social determinants of health, CMS administrative data (that is, the Medicare Advantage Prescription Drug System (MARx)) currently includes data about DE, LIS, and disability status for the specified SRFs we proposed and finalized for the HEI. As more data are available to identify beneficiaries with additional SRFs, we will explore adding other SRFs to the HEI reward methodology through future notice-and-comment rulemaking, but in the meantime, we believe it is important to start incentivizing improved care with the data we have to identify beneficiaries with SRFs.

Comment: While a majority of commenters supported replacing the current reward factor with the HEI reward, some did not support removing the current reward factor even if they

supported adding the HEI reward. A handful of commenters stated that removing the reward factor would penalize and lower Star Ratings for high-performing plans and adversely impact Medicare enrollees by reducing funding for supplemental benefits offered by plans or increasing cost-sharing requirements. A few commenters recommended combining the HEI reward and the reward factor, with each reward having a maximum value of 0.2, and several commenters recommended a transition period before fully removing the reward factor. A couple of commenters recommended including both the HEI reward and the current reward factor in the Star Ratings in order to reward contracts for overall positive performance. A couple of commenters suggested taking the better of the HEI reward and the current reward factor.

Response: Contracts are already rewarded for high and consistent performance when they do well on the measure-level Star Ratings and the Part C and D improvement measures. We believe contracts will still have incentives to perform well and improve on all measures if the reward factor is removed because high performance on individual Star Ratings measures, as well as the improvement measures that incentivize improvements in performance from the prior year (Health Plan Quality Improvement and the Drug Plan Quality Improvement), translate into better overall and summary ratings.

The current reward factor was included in the Part C and Part D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures (that is, a mix of low performance and high performance across measures). At the beginning of the Star Ratings program, the distribution of ratings across contracts looked very different, with overall performance much lower than it is today. At that time, 38 percent of MA contracts received less than 3 stars for the Part C summary rating (the overall rating was not implemented yet at that time). Over time, we have established additional methodological enhancements to incentivize performance improvement across measures, such as the addition of the Health Plan Quality Improvement and the Drug Plan

Quality Improvement measures as described at §§ 422.164(f) and 423.184(f). MA organizations have also responded to the incentive to perform well across measures as a result of the link between Star Ratings and QBP ratings for MA contracts. As contract performance has improved and stabilized over time, different incentives are needed to continue to drive quality improvement so that all Medicare beneficiaries are receiving high quality care. CMS believes that even with the removal of the current reward factor from the Star Ratings methodology, contracts will still have incentives to perform well and improve because high performance on individual Star Ratings measures, including the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures, translates into better overall and summary ratings.

As noted in the April 2018 final rule, the Star Ratings are designed to provide information to beneficiaries that is a true reflection of plan quality and encompasses multiple dimensions of high quality care. The goals of the Star Ratings are to publicly display quality information to inform plan choice, to provide information for public accountability, incentivize quality improvement, provide information to oversee and monitor quality, and accurately measure and calculate scores and stars to reflect true performance. (83 FR 16519). QBPs, as defined in § 422.260(b), tie increases in payment benchmarks and rebate percentage to providing high quality care, as reflected in quality ratings and performance data. CMS's goal is to continue to evolve the Star Ratings methodology over time to ensure that the methodology encourages continued improved plan performance across beneficiaries.

In simulations using data from the 2023 Star Ratings, even before factoring in the HEI reward, the majority of contracts (80 percent of MA and cost contracts, and 82 percent of PDP contracts) would have no change in their overall rating as a result of taking away the reward factor, and no contracts would lose QBPs. Simulations replacing the current reward factor with the HEI reward using data from the 2021 Star Ratings show that no contracts would lose QBPs and only 9.4 percent of contracts would lose rebate dollars. Further, we note that the reward factor should not be seen as an extra funding source; removing the reward factor supports our

efforts to continue to evolve the Star Ratings program to incentivize improved plan performance for all enrollees. We did not consider a transition or blend to use both the current reward and the new HEI reward over a period of time because that approach would dilute the impact of the health equity incentives and be methodologically complex to implement. Based on this, we are finalizing the proposed removal of the current reward factor with additional revisions to the regulation text at §§ 422.162(b)(1) and 423.182(b)(1) and to the definition of “highly rated contract” in §§ 422.162(a) and 423.182(a) to remove references to the current reward factor.

Comment: A couple of commenters suggested that the HEI reward methodology focus on within-contract differences. A commenter stated the HEI reward sets separate and unequal performance benchmarks for different SRF groups. The commenter also stated a contract could widen its internal inequities while doing well on the HEI.

Response: If the HEI focused on within-contract inequities based on the reduction of disparities between members with and without SRFs within a contract, this would be problematic because disparities could be reduced when performance is poor for both groups. Additionally, rewarding a reduction in disparities for within-contract disparities only would disproportionately reward those contracts with historical inequities. The inclusion of thresholds based on the percentage of enrollees with the specified SRFs is important to ensure that contracts are not being rewarded if they serve relatively few enrollees with the specified SRFs, making it easier to do well among this population. Further, CMS expects contracts to perform well among all enrollees with SRFs; there should be no incentive to perform worse among any groups with SRFs, as that would be detrimental to the contract’s measure-level and overall and summary Star Ratings. The HEI reward methodology does not set performance benchmarks. Contracts will be evaluated based on the distribution of performance on each measure in the given measurement years. These distributions may change from year to year and contracts will not know a priori which third of the distribution their performance will be in; therefore, contracts should be incentivized to continue to improve year over year.

Comment: A couple of commenters stated the HEI reward would have a disproportionately negative impact on rural beneficiaries, given that members with SRFs in rural communities will likely perform lower than similar members in non-rural locations due to the general disparities in care. These commenters expressed concern that contracts that consist mainly of metropolitan areas with many forms of accessible transportation and robust provider networks will find remaining in the top third of industry contracts to receive their HEI reward much more achievable compared to contracts in rural areas with limited transportation and provider options. These commenters were concerned that rural Medicare beneficiaries report lower satisfaction with their care than their urban counterparts. They also raised a concern that any changes to benefits may worsen patient experiences and cause less favorable health outcomes.

Response: We do not see significant differences in quality scores for urban versus rural beneficiaries, which suggests that any potential differences in provider networks or transportation do not impact quality scores. For CAHPS measures, in fact, we see the opposite, with scores in rural locations being slightly higher than urban locations.¹⁵⁶ We have also seen significant improvements for rural residents on HEDIS scores when comparing performance from 2009 to 2018. By 2018, most of the large inequities we had previously observed were eliminated on the measures analyzed.¹⁵⁷ Further, we understand that rural areas may have different transportation challenges relative to urban areas and that contracts serving rural populations may need to have different approaches for addressing transportation needs, such as ride sharing and volunteer driver models.¹⁵⁸

Comment: A commenter stated that many plans will need to increase the number of enrollees with SRFs after the current reward factor is removed in order to qualify for the HEI

¹⁵⁶<https://www.cms.gov/about-cms/agency-information/omh/research-and-data/stratified-reporting>

¹⁵⁷Trends in Racial, Ethnic, Sex, and Rural-Urban Inequities in Health Care in Medicare Advantage: 2009-2018 (cms.gov).

¹⁵⁸<https://www.ruralhealthinfo.org/toolkits/transportation>

reward, even in rural areas where this may not be a possibility, and that this consequence is not aligned with CMS's goal to close the Star Ratings performance disparity among existing membership.

Response: In our simulations using data from the 2021 Star Ratings, no contracts lost QBPs when the HEI reward replaced the current reward factor. Contracts may earn the highest rating of 5 stars without qualifying for the HEI reward. Further, the minimum percentage enrollment threshold to qualify for the HEI reward is one-half the median percentage of contract-level enrollees with SRFs. This is a relatively low bar and is intended to accommodate areas and circumstances which may make it more difficult to enroll individuals with the specified SRFs. In our simulations using data from the 2021 Star Ratings, only 17 percent of MA and cost contracts and 11 percent of PDPs did not meet this threshold.

Comment: A few commenters stated the HEI reward would drastically change the current reward factor so that it becomes a two-sided, net-zero approach. A commenter recommended that CMS not finalize the HEI reward and instead propose an improved framework that continues to take a reward-only approach.

Response: CMS does not agree with this characterization of the HEI reward. The HEI reward is an upside only reward. Contracts that perform well across the Star Ratings measures included in the HEI reward and that serve a minimum percentage of enrollees with the specified SRFs will be eligible for the reward. Contracts that do not qualify for the reward will not be penalized and can still earn the highest rating of 5 stars without the current reward factor.

Comment: A commenter recommended the HEI reward methodology include a subset of measures initially, such as HEDIS measures, and gradually expand to include other measures. Another commenter recommended that CMS allow for notice and public comment on the exact measures that will be used in the HEI reward to ensure there is an opportunity for stakeholders to prioritize measures that are most meaningful to achieving equitable care among beneficiaries with SRFs. A commenter did not support including HOS measures in the HEI reward. Another

commenter recommended that SRF researchers, community leaders, and patients be engaged to determine which subset of Star Ratings measures should be included in the HEI.

Response: CMS believes it is appropriate to incentivize high performance among enrollees with the specified SRFs across all of the Star Ratings measures included in the HEI reward rather than only a subset of measures since there are interactions across measurement sets. For example, improving care coordination as measured through CAHPS will impact other more clinical measures. CMS proposed, and is finalizing, the criteria that will be used to determine which Star Ratings measures are included in the HEI reward. Therefore, the public has had an opportunity to review and comment on the HEI reward methodology, including the rules for determining which measures are included in the calculation of the HEI. As specified at §§ 422.166(f)(3)(iii) and 423.186(f)(3)(iii), the measures being evaluated for inclusion in the HEI will be announced annually in the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. These announcements (of the measures being evaluated for inclusion in the HEI) will not include the final list of measures used in the HEI for the upcoming Star Ratings because the data to determine that final set will not yet be available.

Comment: A commenter suggested adjusting the Star Ratings to account for SRFs by setting different cut points for contracts with higher levels of enrollees who are dually eligible. Another commenter recommended risk-adjusting the Star Ratings thresholds (cut points) to account for high numbers of dually eligible enrollees.

Response: CMS does not believe it would be appropriate to set different cut points for contracts based on the proportion of dually eligible enrollees. We do not want to set lower standards of care for treating underserved populations.

Comment: A commenter recommended ensuring additional resources, such as payments from the HEI reward, flow through to providers that serve higher proportions of dually eligible individuals and ensuring funds earned from the HEI reward are directly allocated to patient care.

Response: CMS cannot require that sponsoring organizations pay their contracted providers or pharmacies how the commenter suggested. Section 1854(a)(6)(B)(iii) of the Act prohibits the Secretary (and CMS) from “require[ing] any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this title or require[ing] a particular price structure for payment under such a contract to the extent consistent with the Secretary’s authority under this part.” There is a similar, but broader, prohibition on interference with the negotiations between drug manufacturers and pharmacies and Part D sponsors in section 1860D-11(i) of the Act.

Comment: A commenter suggested that it may be useful to include performance benchmarks in calculating the HEI reward rather than distributing performance into thirds to ensure that equity performance does not lag.

Response: CMS believes that contracts will continue to be incentivized to improve performance among populations with SRFs because contracts will continue to strive to earn a sufficiently high score on the HEI to be eligible for a reward. A contract that is in the top third of the distribution in one year will not know how well other contracts will perform from year to year and therefore will be incentivized to continue to improve in order to stay in the top third of the distribution.

Comment: A commenter suggested including SNP-only measures in the calculation of the HEI reward because these measures are important for health equity goals. The commenter noted that leaving the measures out of the HEI reward reduces their importance and does not provide an opportunity to recognize excellence.

Response: CMS thanks this commenter for this suggestion and will take this comment into consideration. We proposed and are finalizing the exclusion of SNP-only measures, however, because they apply only to a subset of contracts. Additionally, based on our simulations, we do not believe that addition of these measures would have a significant impact on the HEI reward distribution. However, if SNP-only measures were to be added to the

calculation of the HEI reward, we would first propose this change through notice-and-comment rulemaking.

Comment: A commenter stated CMS should look for opportunities to encourage plans to serve enrollees with SRFs and that they were not aware of any new incentives to serve this population.

Response: The HEI reward provides an incentive to serve this population, since to be eligible for the full HEI reward contracts must meet the median percentage threshold of enrollees with the specified SRFs, and to be eligible for one-half of the reward, contracts must meet the one-half median percentage threshold of enrollees with the specified SRFs.

Comment: A commenter suggested that CMS incorporate historical data in the HEI reward methodology prior to the 2024 measurement year to account for equity efforts already undertaken by some health plans that opted to care for historically underserved populations prior to the implementation of the HEI reward. A couple of commenters recommended CMS implement the HEI reward beginning with the 2026 Star Ratings rather than the 2027 Star Ratings.

Response: We appreciate these suggestions; we propose substantive and methodological changes to the Part C and D Star Ratings and finalize them prior to the measurement year. This approach ensures that sponsoring organizations are aware of the quality measures that will be used and have an opportunity to change or improve performance before the contract is rated on specific performance measures. Since the HEI reward includes two years of data, the earliest measurement year data it can use is from 2024 and 2025, and the earliest it can be implemented is the 2027 Star Ratings.

Comment: A commenter suggested that CMS could adjust the HEI reward relative to the change in LIS/DE enrollee percentages in the 2024 and 2025 measurement years compared to a baseline in order to limit health plans seeking to benefit from the new rewards of the HEI from crowding out health plans that currently serve underserved populations.

Response: CMS appreciates this suggestion; however, we do not believe it would be appropriate. With the HEI reward, CMS aims to improve health equity by incentivizing all MA plans, cost plans, and Part D plan sponsors to perform well among enrollees with certain SRFs. Any plans that enroll more members who are LIS, DE, or disabled will also have to perform well among these enrollees to be eligible for the HEI reward. The HEI reward methodology focuses on performance in the measurement years when contracts are actually serving LIS/DE or disabled enrollees. The HEI reward would not create the same incentives if we adjusted for changes in LIS/DE and disabled enrollment compared to a baseline before the HEI was implemented.

Comment: A commenter recommended CMS implement a temporary approach for the 2025 Star Ratings to account for plans that have already been working to reduce disparities by taking the better of a plan's measure-level Star Rating or the HESS for those measures for which there is overlap between the two programs, or by incorporating the HESS as a bonus component to account for plans that scored well on the HESS. Another commenter recommended adding the HESS to the Star Ratings as soon as possible beginning with the 2026 Star Ratings.

Response: We appreciate these suggestions; however, we make such substantive and methodological changes to the Part C and D Star Ratings through rulemaking and generally finalize them prior to the measurement year. At this time, we are not considering adding the HESS to the Star Ratings program as a basis for a reward factor since it is methodologically complex to calculate HESS scores within the tight timeframes for producing the Star Ratings. The HESS also requires 4 years of data, which would exclude a number of newer contracts from a reward based on the HESS. Additionally, given the 4 years of data needed, it would be more complex to implement as measure specifications are updated.

Comment: Some commenters suggested adding additional SRFs to the HEI such as 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. A commenter stated that the SRFs proposed to be included in the HEI reward do not adequately capture the population of members included in CMS's health equity definition and those who experience SRFs. A commenter stated that focusing on limited SRFs ignores other SRFs where there are disparities and requested a timeline for the inclusion of additional SRFs in the HEI reward. Another commenter recommended including additional SRFs beginning with the 2027 Star Ratings or as soon as possible.

Response: CMS appreciates these suggestions and will consider including additional SRFs with data readily available at this time, such as rurality and gender, in the HEI reward methodology in the future. Other SRFs will be considered over time as data become available to measure the specified SRFs. The addition of SRFs would be proposed through notice-and-comment rulemaking. While it is true that not all populations with SRFs are captured in the HEI reward we proposed and are finalizing in this rule, CMS does not believe this biases the HEI reward. Health plans should strive to perform well among all populations with SRFs regardless of whether they are included in the HEI reward. We see differences in performance for the SRFs included in the HEI reward. For example, prior research has shown that dual eligibility is one of the most influential predictors of poor health outcomes, and disability is also an important risk factor linked to health outcomes.¹⁵⁹

Comment: Several commenters suggested using the ADI, the Social Vulnerability Index (SVI), or the Social Deprivation Index (SDI) in the HEI instead of LIS/DE and disabled status. A commenter recommended that CMS continue to monitor different indices that measure socioeconomic status and adopt them if they are found to be more accurate measures than the ADI.

¹⁵⁹https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?_ga=2.49530854.1703779054.1662938643-470268562.1638986031

Response: We will continue to consider additional SRFs for the HEI reward over time through notice-and-comment rulemaking. As we noted in the preamble to the proposed rule, consistent with literature on the ADI, and other neighborhood-based indices,¹⁶⁰ our analyses showed that for the Part C and D Star Ratings measures, the ADI explains very little of the variation in the quality of care received beyond enrollee-level LIS/DE 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, for example. The MSSP's health equity adjustment applies to Accountable Care Organizations (ACOs) that report the all-payer/patient electronic clinical quality measures (eCQMs) or Merit-based Incentive Payment System (MIPS) CQMs; these measures are reported in aggregate, so beneficiary-level data are not readily available. The MSSP adopted a health equity adjustment that will upwardly adjust an ACO's quality performance score to reward ACOs that report all-payer eCQMs/MIPS CQMs, and are high performing on quality and serve a high proportion of underserved beneficiaries. The health equity adjustment adds up to 10 bonus points to the ACO's MIPS quality performance category score based on the percentage of the ACO's assigned beneficiaries who are LIS and/or DE and reside in census blocks with high ADI as described at 87 FR 69781.¹⁶¹ Since the MSSP does not have Medicare-only beneficiary-level data linked to the quality performance data, CMS does not stratify the quality measure data by LIS/DE and disability status and analyze performance like we can for the Part C and D Star Ratings program.

In the CY 2023 Advance Notice, we solicited feedback on the use of the ADI in the HEI reward methodology. At that time there was limited support for adding the ADI to the index. A number of concerns were raised, including that the ADI does not always reflect some of the more deprived areas; it does not adequately distinguish between areas that have both extreme poverty

¹⁶⁰Beckett MK, Martino SC, Agniel D, Mathews M, Hudson Scholle S, James C, Wilson-Frederick S, Orr N, Darabidian B, Elliott MN. (2021). "Distinguishing neighborhood and individual social risk factors in health care" *Health Services Research*: 1-14.

¹⁶¹<https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf>

and extreme wealth; and it is not fully representative of systemic disparities for historically marginalized communities. There was also concern that including the ADI may create incentives for plans to focus on certain geographic areas versus focusing on improving care for those with the greatest needs.

The SVI was designed to identify communities at increased risk of negative impacts from natural disasters and infectious disease outbreaks that require community-level response and is calculated at both the census tract and county level. Similar to other geography-based measures of social risk, the SVI is constructed using census data on socioeconomic status, household composition and disability, minority status and language, and housing and transportation characteristics. The Social Deprivation Index (SDI) was developed to identify the extent of disadvantage in small geographic areas and assess the association of level of disadvantage with health outcomes and health inequities. The SDI is a composite of sociodemographic characteristics, including poverty, education, unemployment, housing characteristics, household composition, and car ownership.¹⁶² It is constructed at the county, census tract, aggregated Zip Code Tabulation Areas, and Primary Care Service Area¹⁶³ levels using 5-year estimates from the American Community Survey. Studies have shown that different geography-based measures of social risk have very similar associations with measures of quality of care and health outcomes.¹⁶⁴ However, for the Part C and D Star Ratings measures, geography-based indices of social risk do not substantively explain variation in care received beyond beneficiary-level SRFs

¹⁶²*Social deprivation index (SDI)*. Robert Graham Center - Policy Studies in Family Medicine & Primary Care. (2018, November 5). Accessed 2/23/23, from <https://www.graham-center.org/rgc/maps-data-tools/sdi/social-deprivation-index.html>.

¹⁶³Goodman DC, Mick SS, Bott D, et al. Primary care service areas: a new tool for the evaluation of primary care services. *Health Services Research* 2002; 38(1 Pt 1):287-309. doi: 10.1111/1475-6773.00116.

¹⁶⁴Herb J, Dunham L, and Stitzenberg K. A comparison of area-level socioeconomic status indices in colorectal cancer care. *J Surg Res* 2022; 280:304-311.

such as dual-eligibility for Medicare and Medicaid, receipt of the Part D LIS, and disability as the original reason for Medicare eligibility,¹⁶⁵ which are used in the HEI.

Comment: A commenter questioned why CMS decided against using the ADI in the HEI reward but is using the ADI as a factor in calculating the health equity adjustment in the MSSP.

Response: 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. Unlike for the Part C and D Star Ratings program, the MSSP's health equity adjustment is only available to those ACOs that report aggregate quality data for all-payer eQMs/MIPS CQMs. For the HEI reward, CMS has access to beneficiary-level data on each quality measure included in the HEI and can match that beneficiary-level information to dual eligibility, LIS, and disability status. As we noted in the proposed rule, our analyses suggest that ADI explains little variation in care received beyond beneficiary-level LIS/DE and disability information for the Part C and D Star Ratings measures.

Similar to our goals for the HEI reward in terms of creating incentives for MA plans, cost plans, and Part D plan sponsors to perform well among enrollees with certain SRFs, the MSSP adopted a health equity adjustment that will upwardly adjust an ACO's quality performance score to reward high quality performance across all populations served by an ACO; encourage all ACOs to treat underserved populations; provide an incentive for ACOs to provide high quality care to all of the populations they serve; and ensure there are not incentives for ACOs to avoid underserved populations as CMS transitions to all-payer eQMs/MIPS CQMs as described at 87 FR 69839.

Comment: A commenter raised concerns about using dual eligibility, LIS, and disability as the SRFs including in the HEI reward. The commenter stated there is mixed evidence on the

¹⁶⁵*Social deprivation index (SDI)*. Robert Graham Center - Policy Studies in Family Medicine & Primary Care. (2018, November 5). Accessed 2/23/23, from <https://www.graham-center.org/rgc/maps-data-tools/sdi/social-deprivation-index.html>.

effectiveness of these variables as indicators for health equity and noted issues with comparability given state-by-state differences in Medicaid eligibility criteria.

Response: The HEI reward methodology we proposed not only includes dual eligibility (which could differ by state), but it also includes enrollees who apply for an LIS subsidy (which allows us to capture enrollees whose income and resources are limited) and disability status. Prior research has shown that dual eligibility is one of the most influential predictors of poor health outcomes, and disability is also an important risk factor linked to health outcomes.¹⁶⁶ Further, we set the minimum percentage of enrollees with the specified SRFs at the relatively low bar of one-half the contract-level median in part to address geographic variation in enrollment.

Comment: Some commenters stated that large plans may serve many enrollees with SRFs but not meet the percentage of enrollees with the specified SRFs thresholds to qualify for the HEI reward, and some commenters recommended including thresholds for both the total number of enrollees as well as the percentage of enrollees. A commenter stated that larger plans not meeting the enrollment thresholds set for the HEI for enrollees with specified SRFs may be disincentivized from improving health equity even if they have a significant number of members experiencing SRFs, and another commenter stated that enrollees with SRFs will be overlooked if they are in plans that serve a significant SRF population but do not meet the thresholds. A commenter believes that an unintended consequence of our proposed methodology is that plans will not be eligible for an HEI reward due to the limited number of beneficiaries with those SRFs, and recommended that all plans be eligible for an HEI reward even if the proportion of their members with the specified SRFs is low. This commenter also stated that all plans should be working to improve the care for members with SRFs even if the proportion of enrollees with the specified SRFs does not meet the specifications to be eligible for the HEI reward.

¹⁶⁶https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?_ga=2.49530854.1703779054.1662938643-470268562.1638986031

Response: CMS believes all plans should work to improve health equity regardless of whether they qualify for the HEI reward. Further, improving performance among members with SRFs will improve performance on Star Ratings measures even in the case where plans do not qualify for the HEI reward. One of the goals CMS considered when developing the HEI reward was to avoid rewarding contracts that may do well among enrollees with the SRFs included in the HEI but serve few enrollees with those SRFs relative to their total enrollment, making it easier to do well. If a number, rather than a percentage, of enrollees with the specified SRFs were used as the threshold for qualifying for the HEI reward, this goal would not be met. Larger contracts might be able to meet a minimum number threshold even though they serve a relatively small number of enrollees with the specified SRFs compared to their total enrollment. This would make it easier for these contracts to do well among these enrollees.

Additionally, based on current data, few contracts that do not meet the percentage of enrollees with the specified SRFs threshold serve a large number of LIS/DE/disabled enrollees. In simulations using data from the 2021 Star Ratings data, we see that, on average, 15 percent of enrollees are LIS/DE/disabled in MA and cost contracts that do not meet the minimum percentage of LIS/DE/disabled enrollees to be eligible for the HEI reward; 5 percent of enrollees are LIS/DE/disabled in PDP contracts that do not meet the minimum percentage of LIS/DE/disabled enrollees to be eligible for the HEI reward. Thus, most contracts that do not meet the percentage of enrollees with the specified SRFs threshold would also not meet a threshold based on a number of enrollees with the specified SRFs. Additionally, we note that contracts that serve a low percentage of LIS/DE/disabled enrollees tend to perform well in Star Ratings. Contracts are not penalized for not meeting the percentage of enrollees with the specified SRFs threshold. As the HEI reward only has an upside, we expect that these contracts will continue to perform well even if they do not qualify for the HEI reward. Contracts will still have the HEI score calculated and will be able to see how they perform on the HEI even if they do not meet the enrollment thresholds. To prepare health plans for implementation of the HEI

reward, CMS will calculate the HEI reward beginning with the 2024 Star Ratings and will share the results in confidential contract-level reports in HPMS.

Comment: Some commenters stated it would be more challenging for employer group contracts to meet the proposed enrollment thresholds because this population is less likely to be LIS/DE or disabled, and that the HEI reward could undermine advances in health equity in these plans. A commenter recommended this could be addressed by using a total enrollment threshold rather than a percentage enrollment threshold. Another commenter suggested that enrollment in employer group plans be excluded from the determination of whether a contract meets the percentage enrollment thresholds.

Response: CMS believes that since enrollees in employer group plans contribute to contracts' performance scores, these enrollees also should contribute to the contract's enrollees with the specified SRFs percentage. While employer group plans on average enroll a smaller percentage of LIS/DE/disabled enrollees than other plans, most contracts are a mix of different plan types, and contracts that include employer group plans may still meet the percentage enrollment thresholds we proposed and are finalizing for the HEI. In addition, contracts that serve a low percentage of LIS/DE/disabled enrollees tend to perform well in Star Ratings since they are serving a less vulnerable population. Contracts are not penalized for not meeting the percentage enrollment threshold. As the HEI reward only has an upside, we expect that these contracts will continue to perform well even if they do not qualify for the HEI reward. The HEI reward is structured so as to support our goals to avoid rewarding contracts that do not serve many enrollees with specified SRFs, making it easier for them to do well. For that reason, we are finalizing the HEI reward methodology such that contracts with employer groups plans will be treated like all other contracts.

Comment: Some commenters raised various concerns around some contracts possibly having more difficulty meeting the percentage of enrollees with the specified SRFs threshold to qualify for the HEI reward, including contracts in states that require sponsors to establish

separate contracts that only include dual eligible special needs plans (D-SNPs). These commenters raised concerns that other MA organizations may be less likely to meet the threshold of enrollees with specified SRFs to qualify for an HEI reward.

Response: There is currently a limited number of states that require MA organizations to have separate D-SNP-only contracts under § 422.107(e), and the provisions of § 422.107(e) only apply when specific minimum conditions are met, including a requirement that D-SNPs in the state have exclusively aligned enrollment with an affiliated Medicaid managed care organization and a requirement that D-SNPs use certain materials that integrate Medicare and Medicaid content. Further, even in states that require MA organizations to have separate D-SNP-only contracts, dually eligible individuals may still enroll in other MA organization contracts, and such contracts may still meet the minimum threshold of enrollees with SRFs (which includes not only LIS/DE individuals but also those with disability status). Based on our simulations, other contracts would meet the minimum percentage to qualify for an HEI reward in these States. We estimate that approximately 3 million LIS/DE individuals were enrolled in non-D-SNP MA plans in 2022.¹⁶⁷

Comment: A commenter raised a concern that the percentage of enrollees with the specified SRFs thresholds would make it difficult for plans to receive an HEI reward, as the percentage of members with SRFs falls under the national median for the majority of contracts.

Response: Contracts may still qualify for half of the HEI reward if they have at least one-half the median and up to but not including the median percentage of enrollees with the specified SRFs. CMS believes one-half the median enrollment is a relatively low bar for a minimum enrollment threshold. In simulations using data from the 2021 Star Ratings, only 17 percent of MA and cost contracts and 11 percent of PDPs did not meet the one-half the median threshold.

¹⁶⁷We approximated the percentage of LIS/DE individuals enrolled in non-D-SNP MA plans based on the number of LIS enrollees per PBP, as listed in the 2022 Low Income Subsidy Enrollment by Plan report: <https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatalis-enrollment/2022-low-income-subsidy-enrollment-plan>

Comment: A couple of commenters recommended using one-half the median percentage of enrollees with the specified SRFs as the threshold to be eligible for the full HEI reward rather than the tiered threshold that uses both one-half the median and the median percentage of enrollees with the specified SRFs.

Response: CMS believes the tiered threshold structure is more appropriate because it allows for a greater maximum HEI reward among contracts that have larger proportions of enrollees with the specified SRFs and smaller rewards for contracts with smaller proportions of enrollees with the specified SRFs.

Comment: A commenter raised a concern that D-SNP look-alikes may benefit more from the HEI reward because these plans are permitted to crosswalk members from these plans to other standard plans.

Response: In order to qualify for the HEI reward, contracts must not only meet the minimum percentage of enrollees with the specified SRFs thresholds but also meet the minimum performance threshold. CMS adopted contracting limitations for D-SNP look-alike plans at § 422.514(d), which provides that starting with Contract Year 2023, CMS will not renew a contract for a MA plan – other than a SNP – that has actual enrollment in the January of the prior contract year of 80 percent or more of enrollees who are entitled to Medicaid, unless the MA plan has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination. D-SNP look-alikes have the opportunity to transition enrollees under § 422.514(e). The number of D-SNP look-alike plans is relatively small compared to the overall number of MA plans. For Contract Year 2022, there were 47 D-SNP look-alike plans and for Contract Year 2023, there are 15 D-SNP look-alike plans. While D-SNP look-alikes do have the opportunity to transition membership under § 422.514(e), we do not have reason to expect that D-SNP look-alikes would benefit more from the HEI reward than other MA plans that transition membership using crosswalk authority at § 422.530(b) or crosswalk exception authority at § 422.530(c).

Comment: A commenter recommended using regional or service area medians instead of national medians for the percentage enrollment thresholds. The commenter also recommended CMS conduct an assessment based on service areas to determine whether all contracts would have the ability to enroll a sufficient number of individuals in the target SRF groups.

Response: We believe our proposed minimum percentage enrollment threshold of one-half the median percentage of contract-level enrollees with SRFs to qualify for the HEI reward is a relatively low bar and is intended to accommodate areas and circumstances that may make it more difficult to enroll individuals with the specified SRFs.

Comment: A commenter stated the HEI reward would disqualify smaller contracts because of the percentage enrollment thresholds and that this would discourage the enrollment of beneficiaries with SRFs in smaller tailored plans that best meet their needs, such C-SNPs.

Response: The minimum enrollment thresholds are one of the ways in which we have designed the HEI reward to avoid rewarding large contracts over small contracts. If a total number, rather than a percentage, of enrollees were used as the threshold, this would disadvantage small contracts. In simulations using data from the 2021 Star Ratings, there were small contracts that met both tiers of the percentage enrollee thresholds, including contracts with fewer than 1,000 enrollees. The median contract size for contracts meeting the median percentage enrollee threshold in our simulations is 12,000 enrollees for MA and cost contracts and 14,000 for PDP contracts, the median contract size for contracts meeting the one-half median percentage enrollee threshold is 23,000 enrollees for MA and cost contracts and 26,000 for PDP contracts, and the median contract size for contracts with less than one-half the median is 20,000 enrollees for MA and cost contracts and 64,000 for PDP contracts. Setting the minimum enrollment percentage threshold at one-half the contract-level median is a relatively low bar. Additionally, we proposed and are finalizing using two years of data to calculate the HEI reward to allow smaller contracts to be reliably evaluated. Using two years of data increases the sample size when calculating the measure-level scores among the subset of enrollees with the specified

SRFs and makes it more likely that smaller contracts can meet the criteria for a measure to be included in the calculation of the HEI score as described at §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv).

Comment: A commenter recommended that CMS not exclude contracts with less than 500 enrollees from the HEI reward as proposed at §§ 422.166(f)(vi) and 423.186(f)(vi).

Response: In general, contracts with less than 500 enrollees are too small to have Star Ratings calculated because the data are not reliable. In general, the measure-level data for these contracts do not meet a reliability of 0.7. Contracts with less than 500 enrollees also often do not meet measure-level minimum denominator requirements. These issues are further exacerbated with the HEI since the HEI requires the calculation of measure-level scores for a subset of the contract's enrollees with the specified SRFs and, thus, these very small contracts do not meet the criteria in §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv).

Comment: A commenter was concerned that measures with lower minimum denominator requirements would invalidate the HEI results.

Response: The HEI reward methodology includes several steps to ensure the measure data used are reliable. A measure is only included for the HEI for a contract if the measure has a reliability of at least 0.7 when calculated for the subset of enrollees with SRFs in the contract with the specified SRF(s), and the contract meets the measure denominator requirement when the measure is calculated for only the enrollees with the specified SRF(s). In addition, if at least 25 percent of contracts are unable to meet these criteria, the measure will be excluded from the HEI.

Comment: 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.

Response: To prepare health plans for implementation of the HEI reward, CMS 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. Each sponsoring organization will be able to see its contract-level percentage of enrollees with the specified SRFs; whether each measure included in the HEI met the reliability and denominator criteria to be included in the HEI; whether contract performance was in the upper, middle, or lower third of performance for each measure included in the HEI; the HEI value; and the HEI reward for contracts that qualify. The performance thresholds for each of the thirds at the measure level will be dependent on the distributions of measure data for the measurement years of data being used to calculate the HEI reward for each Star Ratings year. This information will also be available in the HPMS reports. We will share the percentage of enrollees with the specified SRFs thresholds, including for Puerto Rico contracts. CMS will also share summary-level results by type of contract for informational purposes.

CMS does not intend to display these results as display measures. Since the HEI is not a measure, we believe that sharing the information through HPMS will allow us to provide contracts with more detailed information about the HEI for their quality improvement efforts. Sections 422.164(c)(3) and (d)(2) and 423.184(c)(3) and (d)(2) require only new measures and measures with substantive specifications changes to be on the display page for two years prior being in the Star Ratings. Historically, we have not displayed methodological changes on the display page since it would be confusing to the public to have two sets of ratings, one on Medicare Plan Finder on www.medicare.gov and an alternative rating on cms.gov.

In simulations using data from the 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 (that is, one-half of the contract-level enrollment median); 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; and 61 percent for MA and cost contracts and 37 percent for PDPs that meet the median enrollment threshold. The percent of enrollees who are LIS/DE/disabled is 42 percent for MA and cost contracts and 13 percent for PDP contracts that received an HEI reward (that is, met an enrollment threshold to be eligible for a reward and received an HEI score of greater than zero).

Comment: A commenter requested more time so that regional plans would not be penalized for not having the minimum enrollment amount yet.

Response: In simulations using data from the 2021 Star Ratings, many regional plans met the minimum percentage enrollment thresholds. No plans will be penalized by the HEI reward if they do not have enough enrollees to qualify for the reward since it is an upside only reward.

Comment: Some commenters suggested the HEI should be a measure rather than a reward.

Response: CMS believes including the HEI as a reward in place of the current reward factor will better incentivize MA, cost plan, and PDP contracts to perform well among enrollees with specified SRFs than if the HEI were included as a Star Ratings measure. The HEI reward is upside only and is focused on those contracts serving a disproportionate percentage of enrollees in underserved populations in order to incentivize high quality care for these populations. If the HEI was a measure, contracts could have their overall and summary ratings negatively impacted if they did not do well serving these enrollees because they would earn low measure-level Star Ratings on an HEI measure, which could bring down their overall and summary ratings. Additionally, contracts that serve a small percentage of enrollees with the specified SRFs may do

well on a measure because they serve relatively few of these beneficiaries, making it easier for them to do well. Adding the HEI as a reward rather than a measure also allows for the methodology to include a performance threshold below which contracts will not be eligible for the HEI reward, which will incentivize improved performance by contracts for their enrollees with the specified SRFs and help reduce disparities.

Comment: A commenter recommended that the HEI reward replace the CAI rather than the current reward factor. Another commenter stated that eliminating the reward factor and replacing it with the HEI reward while retaining the CAI would create a duplication in ratings and that plans may be penalized by having both the CAI and the HEI.

Response: The HEI reward serves a different purpose than the CAI. The CAI is a data-driven approach to account for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. As we stated in the April 2018 rule, the CAI accounts for within-contract disparities and adjusts for those disparities in order to allow fair comparisons among contracts; it also addresses the sensitivity of the Star Ratings to the composition of the enrollees in a contract. 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. The HEI, therefore, will not replace the CAI but rather will assist plan sponsors in better identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reaching equity in the level and quality of care provided to enrollees with SRFs. Neither the CAI nor the HEI reward penalize plans. The CAI adjusts for the within-contract differences in performance to create a level playing field across contracts, and the HEI reward is an upside only reward.

Comment: A commenter stated continued support for the CAI and stated that they assume the CAI will continue to be implemented.

Response: CMS appreciates the continued support for the CAI and, as stated in the proposed rule, CMS will continue to implement the CAI.

Comment: A couple of commenters raised concerns that replacing the current reward factor with the HEI reward would dilute the effectiveness of the current quality incentive structure or not achieve CMS's goal of driving quality improvement and minimizing unintended consequences. A commenter stated that replacing the current reward factor with the HEI reward would risk undermining market competition and disincentivizing quality improvement investments.

Response: CMS believes there is still an incentive within the current Star Ratings methodology for sponsoring organizations to invest in quality improvement. Any such investments will be reflected in high measure-level Star Ratings and higher improvement measure stars. Further, contracts can still do well on the Star Ratings and achieve the highest rating of 5 stars without receiving either the current reward factor or the HEI reward. CMS's goal is to continue to evolve the Star Ratings methodology over time to ensure that the methodology encourages continued improved plan performance across beneficiaries.

Comment: 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.

Response: In our simulations, we 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. In the 2023 Star Ratings, the reward factor was lower on average for both D-SNP-only contracts and contracts offering any D-SNPs compared to contracts without D-SNPs. When the reward factor is removed in our simulations, 17 percent of contracts with any D-

SNPs have a decrease in overall Star Ratings versus 22 percent of all other contracts. This indicates that contracts with D-SNPs are less impacted than other contracts by the removal of the reward factor.

Comment: A commenter stated most plans at the 5-star level earn 5 stars due to the addition of the reward factor and that removal of the reward factor will result in many plans losing their 5-star rating.

Response: While it is true that the reward factor bumps up some 4.5 star contracts to 5 stars, the replacement of the current reward factor with the HEI reward will provide contracts with additional opportunities for an upside reward. This means there are still opportunities for contracts to increase their Star Rating from 4.5 to 5 stars. Additionally, we note that there is nothing that would prevent a contract from still earning 5 stars even if it did not earn an HEI reward.

Comment: A few commenters suggested alternatives to using the original reason for Medicare entitlement to identify enrollees who have a disability and are therefore included in the HEI as having a SRF. 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. Another commenter supported the proposed definition of disability and recommended limiting to this definition for consistency.

Response: CMS appreciates these comments, and we will continue to evaluate how we could expand the ways we identify individuals who have a disability for purposes of calculating and applying the HEI reward and CAI. Any changes would need to be proposed through notice-and-comment rulemaking.

Comment: A commenter suggested CMS compare disability eligibility data with the Medicare Current Beneficiary Survey (MCBS) to assess the gap in measuring disability under the current definition included in the HEI reward, which identifies individuals with a disability based on original reason for entitlement.

Response: While looking at data from the MCBS would show some of the gap in our identification of enrollees with a disability using the original reason for entitlement compared to those enrollees who developed a disability after enrolling in Medicare, we would not be able to use data from the MCBS for the HEI reward. In order to include data on functional limitations in the HEI reward, we would need national data at the beneficiary level, which the MCBS does not provide.

Comment: A few commenters stated that there were many changes proposed to the Star Ratings and recommended more incremental change. A commenter requested that CMS consider distributing the implementation of the proposed changes to the Star Ratings over the next three years.

Response: As discussed in section I.B.1. of this final rule, not all of the proposed changes to the Star Ratings regulations in the December 2022 proposed rule are being finalized at this time. Also, as proposed and finalized, the HEI reward will be implemented beginning with the 2027 Star Ratings, whereas most of the other Star Ratings changes finalized in this rule will be implemented beginning with the 2026 Star Ratings.

Comment: 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.

Response: There are already existing adjustments in the Star Ratings program to account for contracts serving enrollees with SRFs. Some Star Ratings measures are case-mix adjusted, and this is accounted for in the HEI reward methodology. As discussed earlier in this preamble, the CAI also accounts for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. CMS does not believe contracts will avoid enrolling dually eligible beneficiaries, as enrolling duals would lead to a greater likelihood of meeting the percentage enrollment thresholds for contracts to be eligible for the HEI reward. If contracts increase their enrollment of LIS/DE and disabled enrollees, they must also do well serving this population to receive the HEI reward.

Comment: A commenter expressed concern that the HEI reward could conceal overall quality shortcomings and noted that implementation of the HEI reward must be carefully monitored. Another commenter encouraged CMS to study the use of the HEI reward and modify it based on experience.

Response: CMS does not believe the HEI reward will conceal overall quality shortcomings, as overall quality will continue to be assessed by the measure-level Star Ratings and contracts will not be able to receive high overall Star Ratings without performing well overall. CMS will evaluate the HEI reward over time as it does with the entire Star Ratings methodology and would propose any potential modifications through notice-and-comment rulemaking.

Comment: A commenter recommended CMS consider allowing plans to rely upon one year of data to encourage earlier adoption of HEI reward and in order to avoid penalizing new contracts from earning HEI rewards.

Response: CMS appreciates this suggestion. Use of two years of data is designed to ensure that smaller contracts have sufficient data to produce reliable results and that smaller contracts are not excluded from the HEI. We will explore other options, such as the commenter's recommendation to use only one year of data for contracts that would have enough enrollees to calculate reliable measure scores; however, we will need to consider whether HEI scores for contracts using one year of data are comparable to the scores for contracts using two years of data and whether using one year of data advantages or disadvantages contracts in any way. Any changes related to the HEI methodology would have to be proposed through future notice-and-comment rulemaking.

Commenter: A commenter stated that quality measures should be evaluated carefully to ensure they do not inadvertently create biases and mask or worsen health disparities that lead to care stinting. The commenter also stated that measures should also be appropriately stratified or adjusted to recognize population differences.

Response: CMS is committed to accurately measuring and calculating scores and stars to reflect true performance in the Star Ratings. Some Star Ratings measures are case-mix adjusted, and this is accounted for in the HEI reward methodology. As discussed earlier in this preamble, the CAI accounts for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. Beginning with the 2022 Star Ratings, CMS also began providing contracts with confidential stratified reports through HPMS that include the Star Ratings measures stratified by LIS/DE and disability status that plans can use for quality improvement purposes. Further, the HEI reward specifically focuses on performance among enrollees with the specified SRFs.

Comment: A commenter suggested CMS stratify health outcomes by five-digit zip codes in order to help understand SRFs based in particular localities.

Response: CMS appreciates this suggestion. It is not possible to stratify the Star Ratings measures by zip code because the sample sizes would be insufficient to provide reliable data.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the removal of the reward factor and addition of the HEI reward to the 2027 Star Ratings as proposed, with 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. We are finalizing changes to the following sections to revise references to the reward factor or to limit application of the current reward factor to the Star Ratings through the 2026 Star Ratings: §§ 422.166(c)(1), 422.166(d)(1) 422.166(f)(1), 422.166(f)(2)(i), 422.166(g)(1), 423.186(c)(1), 423.186(d)(1) 423.186(f)(1), 423.186(f)(2)(i), and 423.186(g)(1). We are also finalizing the addition of the HEI reward at §§ 422.166(f)(3) and 423.186(f)(3).

G. Extreme and Uncontrollable Circumstances (§§ 422.166(i) and 423.186(i))

1. 60 Percent Rule

Currently, the Star Rating for each non-CAHPS measure score is determined by applying a clustering algorithm to the numeric value scores from all contracts required to submit the measure. The cut points for non-CAHPS measures are derived from this clustering algorithm. As discussed in the April 2019 final rule and described at §§ 422.166(i)(9), 422.166(i)(10),

423.186(i)(7), and 423.186(i)(8), we exclude from this clustering algorithm and from the reward factor calculations (under §§ 422.166(f)(1) and 423.186(f)(1)) the numeric values for affected contracts with 60 percent or more of their enrollees in Federal Emergency Management Agency (FEMA) designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance (84 FR 15776-15777). Affected contracts are contracts that meet all of the criteria in §§ 422.166(i)(1) and 423.166(i)(1). We generally call this the “60 percent rule” to distinguish it from the adjustments provided under §§ 422.166(i) and 423.186(i) for affected contracts with 25 percent or more of their enrollment residing in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

This exclusion ensures that any impact of the extreme and uncontrollable circumstance on certain affected contracts’ measure-level scores does not have an impact on the cut points or reward factor for other contracts. When this rule was first implemented, the concern was that a contract impacted by an extreme and uncontrollable circumstance would have significantly different scores than other contracts and that these significantly different scores would shift the cut points and/or reward factor thresholds for non-affected contracts. Our analyses since the rule was implemented show the measure scores for affected contracts do not tend to be outliers and that this 60 percent rule can have adverse effects when extreme and uncontrollable circumstances affect nearly all contracts, as we saw with the COVID-19 PHE.

We proposed to limit to the 2025 and earlier Star Ratings, application of the rule at §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) that excludes numeric values for affected contracts with 60 percent or more of their enrollees residing in FEMA-designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance from cut point calculations and reward factor determinations. During the COVID-19 pandemic, we adopted a change to remove these rules temporarily since all contracts qualified for the extreme and uncontrollable circumstances policy as a result of COVID-19 in 2020; this change was adopted in the interim final rule titled “Medicare and Medicaid Programs, Clinical

Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” which appeared in the **Federal Register** and was effective on September 2, 2020, and the final rule titled “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” which appeared in the **Federal Register** on May 9, 2022 and was effective on June 28, 2022 (hereinafter referred to as the May 2022 final rule). The removal of the 60 percent rule was necessary to calculate measure stars for most measures for the 2022 Star Ratings and for HEDIS measures that are based on the Health Outcomes Survey (HOS) (HEDIS-HOS measures) for the 2023 Star Ratings. Without the removal of the rule, CMS would not have been able to calculate stars for most measures for 2022 Star Ratings and for the HEDIS-HOS measures for the 2023 Star Ratings because all contracts qualified for the extreme and uncontrollable circumstances policy as a result of COVID-19 in 2020.

Beginning with the 2024 Star Ratings, measure scores that are extreme outliers will be removed through Tukey outlier deletion, a standard statistical method to remove extreme outliers, as codified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), prior to applying the clustering methodology to determine the cut points. The combination of mean resampling (implemented with the 2022 Star Ratings and described at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i)) and Tukey outlier deletion will alleviate the impact of any extreme outliers. Thus, if a contract is impacted by an extreme and uncontrollable circumstance and as a result has a significantly lower score on a measure, the score will be removed if it is an extreme outlier. Removing extreme outliers will eliminate the concern that other contracts are inappropriately impacted by changes in scores for contracts impacted by disasters. By removing the 60 percent rule, we will also simplify the Star

Ratings calculations and continue to allow measure-level Star Ratings to be calculated if all or most contracts qualify for an extreme or uncontrollable circumstance in the future.

We proposed to amend §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) to remove the 60 percent rule beginning with the 2026 Star Ratings for non-CAHPS measures, including the HOS measures, even though the measurement period is slightly different for these measures. We solicited comments on this proposal.

Comment: Most commenters supported the removal of the 60 percent rule.

Response: CMS appreciates the support.

Comment: A commenter recommended delaying implementation of the 60 percent rule until Tukey outlier deletion is implemented.

Response: Starting with the 2024 Star Ratings, CMS will be including Tukey outlier deletion. Removing the 60 percent rule will begin with the 2026 Star Ratings. See section V.H. later in this rule for a discussion of the codification of the Tukey outlier deletion provision.

Comment: A commenter was concerned that enrollees in affected contracts would be impacted by this change.

Response: The removal of the 60 percent rule will only impact which contracts are included when we 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.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing 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 as proposed without modification.

2. Health Outcomes Survey (HOS) Measures

We adopted regulations for how Star Ratings would be calculated in the event of extreme and uncontrollable circumstances in the April 2019 final rule. We explained in the April 2019 final rule (CMS-4185-F) that for most measures, the extreme and uncontrollable circumstance adjustment applies for disasters from 2 years prior to the Star Ratings year (that is, a disaster that begins¹⁶⁸ during the 2020 measurement period results in a disaster adjustment for the 2022 Star Ratings). For Part C measures derived from HOS, the disaster adjustment is delayed an additional year due to the timing of the survey and 1-year recall period. That is, for measures derived from the HOS, the disaster policy adjustment is for 3 years after the extreme and uncontrollable circumstance. For example, we noted at 84 FR 15772-15773 that the 2023 Star Ratings would adjust measures derived from the HOS for 2020 extreme and uncontrollable circumstances. We proposed to clarify in § 422.166(i)(3)(iv) the timing for HOS measure adjustments for extreme and uncontrollable circumstances.

We solicited comments on this proposal.

Comment: All commenters supported our proposal to clarify the timing for HOS disaster adjustments.

Response: CMS appreciates the support for clarifying the timing of the HOS measure adjustments for extreme and uncontrollable circumstances at § 422.166(i)(3)(iv).

Comment: A commenter suggested that CMS provide additional clarification on the recall period for HOS measures and the “hold harmless” timing for the adjustment for extreme and uncontrollable circumstances.

¹⁶⁸We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

Response: The measurement period or “recall period” is defined by the measure steward. NCQA is the measure steward for the three HEDIS-HOS measures derived from the HOS. As noted by the title of NCQA’s technical manual for the 2021 HOS data collection, *HEDIS MY 2020 Volume 6: Specifications for the Medicare Health Outcomes Survey*, the measurement period is one year prior to data collection. Since 2020, HOS survey administration occurs in late summer through fall. HOS is currently fielded from late July through early November.

For Part C measures derived from HOS, the disaster adjustment is three years after the extreme and uncontrollable circumstance. That is, contracts affected by an extreme and uncontrollable circumstance in the year prior to data collection are essentially “held harmless” and receive the higher of the previous or current year’s Star Rating for each HOS and HEDIS-HOS measure (and corresponding measure score) for the Star Ratings 3 years after the eligible extreme and uncontrollable circumstance. For example, contracts affected by an extreme and uncontrollable circumstance in 2021 will receive the higher of their 2023 or 2024 measure-level Star Rating (and corresponding measure score) for each HOS and HEDIS-HOS measure in the 2024 Star Ratings as described at § 422.166(i)(3)(iv).

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the clarification at § 422.166(i)(3)(iv) as proposed without modification.

H. Calculation of Star Ratings (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the June 2020 final rule, we finalized use of Tukey outlier deletion effective for the Star Ratings issued in October 2023 and subsequent years. (85 FR 33833-36). In the rulemakings since that time, we have not proposed to eliminate the Tukey outlier deletion aspect of the Star Ratings methodology. In a final rule that appeared in the Federal Register on January 19, 2021, we noted how the Tukey outlier deletion provision had been adopted for the Part C and Part D Quality Star Ratings. (86 FR 5917). As we stated in May 2022 final rule (87 FR 27766), we will implement Tukey outlier deletion beginning with the 2024 Star Ratings to help improve

stability of cut points and prevent cut points from being influenced by outliers. We further stated that with Tukey outlier deletion, extreme outliers will be removed from measure scores prior to clustering to prevent outliers from impacting cut points for all contracts. However, it appears that the sentence in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) (“Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchical clustering, Tukey outer fence outliers are removed.”) was inadvertently removed from the codified regulation text. At no point did CMS propose removal of the Tukey outlier provision and CMS has, since its adoption in the June 2020 final rule, discussed implementation and application of the Tukey outlier provision when applicable. We proposed a technical amendment to fix this codification error from the May 2022 final rule. In addition, although the provision regarding application of the Tukey outlier deletion policy was originally at the end of paragraph (a)(2)(i) in each regulation, we also proposed a non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) since Tukey outlier deletion is applied prior to the other steps. We believe that this makes the regulation text clearer.

We solicited comments on this proposal.

Comment: Some commenters were concerned that Tukey outlier deletion would result in disproportionate losses of QBPs among D-SNPs. They cite an analysis performed by ZAHealth that found that the outlier policy would result in 14 percent of D-SNP contracts losing their QBPs compared to 7 percent of non-D-SNPs, and 27 percent of D-SNPs losing rebate dollars compared to 20 percent of non-D-SNPs.

Response: We are unable to replicate the findings of ZAHealth. Based on our simulations, we do not believe that contracts with D-SNPs will be disproportionately impacted by Tukey outlier deletion. Using the 2023 Star Ratings data, we examined the impact of introducing Tukey outlier deletion assuming no guardrails. In the simulation, approximately 8.2 percent of contracts with D-SNPs and 9.5 percent of contracts without D-SNPs would lose a

QBP by their overall rating decreasing from 4 to 3.5 stars overall with Tukey outlier deletion compared to without Tukey outlier deletion. The percentage of contracts losing a QBP is slightly higher for non-D-SNP contracts. In the simulation, 13.6 percent of contracts with D-SNPs would have a decrease in rebates or lose rebates compared to 10.5 percent of contracts without D-SNPs, a very small difference.

Comment: A commenter stated that CMS should withdraw its proposed Tukey outlier deletion for the 2024 Star Ratings as it will create new hurdles for plans that are trying to improve their ratings. Another commenter supported Tukey outlier deletion but raised challenges in the industry implementing multiple changes in the Star Ratings over the next few years, while another commenter suggested CMS delay implementation.

Response: Tukey outlier deletion is the only methodological enhancement to the 2024 Star Ratings. The only other changes for the 2024 Star Ratings are the addition of two new measures, Transitions of Care and Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions measures, to the Part C Star Ratings that have been on the display page since the 2020 Star Ratings (2018 measurement year) finalized in the January 2021 final rule (86 FR 5921-26) and the return of the updated Plan All-Cause Readmissions measure finalized in the April 2019 final rule,¹⁶⁹ a measure that has been included in the Star Ratings program since the 2012 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. The primary goal of setting cut points is to disaggregate the distribution of scores into discrete categories such that each grouping accurately reflects true performance. (85 FR 15752). Tukey outlier deletion supports this goal by helping stabilize measure-level cut points

¹⁶⁹ See the Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, page 97, which delayed the return of the Plan All-Cause Readmissions measure to the Star Ratings for an additional year due to the disruption to data collection posed by the COVID-19 pandemic.

since they will not be influenced by one or more contracts with outlier scores. Tukey outlier deletion does not change what contracts need to do to improve. 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 we do not believe that the implementation of Tukey outlier deletion needs to be delayed.

Comment: A commenter stated that an agency must use the same procedures when they amend or repeal a rule as they used to issue the rule. Additionally, this commenter noted that CMS cannot make a change in the substantive rules that apply to Star Ratings without undertaking rulemaking and cannot rely on the Regulatory Impact Analysis used in 2020, given that other policies related to the mechanism for calculating the Star Ratings continue to evolve.

Response: CMS proposed and provided public notice and an opportunity to comment on revising §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to include the Tukey outlier deletion provision that was inadvertently removed from the regulation text in a May 2022 final rule. The commenter responded to that proposal and had the opportunity to submit comments on the substance of the Tukey outlier deletion. Comments on the proposed correction were submitted and are being addressed in this final rule. After the adoption of the Tukey outlier deletion provision in the June 2022 final rule (85 FR 33833-36), CMS would need additional rulemaking to change that policy and change the Star Ratings methodology to eliminate that provision, which did not happen.

In addition, the June 2020 final rule adopting the Tukey outlier deletion step in the Star Ratings methodology (85 FR 33891-33893) adequately discussed the cost estimates for the implementation of Tukey outlier deletion. Those estimates were projected based on initial implementation for the 2024 Star Ratings, which the regulation text adopted in this rule at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) provides for, so the projected cost analysis remains relevant and accurate. We still measure performance in the same way at the measure-level and calculate the Star Ratings in a similar manner. We believe more recent data from 2020 and 2021

performance years would be less useful to simulate the impact of the Tukey outlier deletion process in future years. First, the performance data from the early years of the pandemic have been more impacted by COVID-19, and we would expect that there would be more fluctuations in scores during this time, including potentially more outliers. Second, some of the changes we made to the Star Ratings to account for the uncertainties caused by COVID-19, including expanding the existing hold harmless provision for the Part C and D improvement measures to include all contracts for the 2022 Star Ratings,¹⁷⁰ and all contracts qualifying for the disaster adjustment for the 2022 Star Ratings, make it difficult to use more recent data to predict future performance.

Comment: A commenter claimed there would be significant impact on 3, 4, and 5-star cut points.

Response: Outlier deletion does not significantly impact 3, 4, and 5-star cut points for most measures. For example, we examined the 2023 Star Ratings data with no guardrails to focus on the effect of Tukey outlier deletion at the measure level. While we note that the 2023 Star Ratings data may still show some impacts of the COVID-19 pandemic and therefore may have more outliers than data not impacted by the pandemic, we still found that outlier deletion did not significantly impact 3, 4, and 5-star cut points for most measures. In our analyses, 8 Part C measures (40 percent of the non-CAHPS measures) have no changes across all Star Rating thresholds. Similarly, for Part D measures, there are 4 measures (44 percent of the non-CAHPS measures) with no changes for MA-PD contracts and 4 measures (44 percent) with no changes for PDP contracts. Of the remaining measures, most of the changes were for the 1-2 star cut points, with most measures having no significant impact at the 3, 4, and 5-star cut points. The Tukey outlier approach lessens the influence of a few outliers on cut point formation, leading to more reliable and stable thresholds, especially for the 1-2 star cut points. This analysis is based on data available at <https://www.cms.gov/Medicare/Prescription-Drug->

¹⁷⁰ See COVID-19 interim final rule (IFC) (CMS-1744-IFC) issued on March 31, 2020.

[Coverage/PrescriptionDrugCovGenIn/PerformanceData](#) in the Downloads section under the Tukey Outlier Deletion Simulations.

Comment: A couple of commenters claimed that Tukey outlier deletion will decrease predictability and stability of cut points. A commenter gave as an example the Plan Makes Timely Decisions about Appeals measure where there would have been more significant changes to cut points with outliers removed for the 2023 Star Ratings.

Response: The primary effect of Tukey outlier deletion is to make thresholds more accurate, reliable, and stable. Outlying contract scores can have undue influence on cut points, and this can lead to a single contract having a major influence on cut point values used to assign stars for all contracts. Removing outliers means the thresholds are more stable since they are not influenced by scores on either extreme of the distribution. The commenter cited the Plan Makes Timely Decisions about Appeals measure where there were more significant changes to the thresholds in CMS's simulation using 2023 Star Ratings; this is an extreme example of how outliers influence cut points and is rare in nature. For Part C measures in the 2023 simulations, 8 measures (40 percent of the non-CAHPS measures) had no observed outliers, while only 2 measures (10 percent), including Plan Makes Timely Decisions about Appeals, had greater than 4 percent of contracts being classified as outliers, and the remaining 50 percent of measures had 3.5 percent or less (and generally less than 1 percent) of contracts being classified as outliers; similar trends were observed for Part D measures.

Additionally, we compared year over year stability of thresholds between simulations that included outlier deletion and simulations that did not remove outliers (without guardrails). The changes in thresholds between 2022 and 2023 were much smaller when outliers were removed as compared to when they were not removed. For 10 of the 20 non-CAHPS Part C measures, there were thresholds that changed by more than 5 percentage points if outliers were not removed, whereas only 5 measures had this property when outliers were removed. Outlier deletion does stabilize Part C cut points, and results in more year-to-year stability when outliers are deleted

compared to simulations that do not use outlier deletion. For MA-PD contracts, 4 of 9 Part D measures had thresholds that change by more than 5 percentage points if outliers are not removed compared to only 2 measures with thresholds that change by more than 5 percentage points if outliers were removed. Outlier deletion stabilizes Part D cut points for MA-PD contracts, and results in more year-to-year stability when outliers are deleted compared to simulations that do not use outlier deletion. Outlier deletion had a smaller effect on Part D thresholds for PDP contracts.

Comment: A couple of commenters claimed that outlier deletion will increase all cut points significantly and move them closer together, decreasing reliability.

Response: Outlier deletion may increase or decrease cut point thresholds, depending on the shape of the measure's score distribution. Closer cut points do not necessarily imply lower reliability or lessen the ability to distinguish between contracts. Tukey outlier deletion does not increase thresholds for all measures. In a simulation using the 2023 Star Ratings data, we calculated Tukey outlier deletion before applying guardrails as will be done when Tukey outlier deletion is implemented. This also allows us to distinguish the impact of Tukey outlier deletion from the impact of applying guardrails. In this simulation, there were 8 Part C measures (40 percent of measures) that had no change at all in the thresholds. For Part D there were 4 measures (44 percent of measures) with no changes for MA-PD contracts and 4 measures (44 percent) with no changes for PDP contracts.

Tukey outlier deletion refines measurement by ensuring cut points reflect true variation in performance and are not unduly influenced by low or high performance of a few outlying contracts. Lessening the influence of outliers on cut point formation leads to more reliable and stable cut points.

Comment: A commenter claimed that Tukey outlier removal will harm plans performing at lower star levels.

Response: Tukey outlier removal's primary effect is to make thresholds (that is, cut points) more accurate, reliable, and stable. Removing outliers means the thresholds are more stable and more accurately categorize performance across the industry into measure-level Star Ratings, especially at lower levels, since they are not influenced by outlier scores, and means that a single contract has limited impact on thresholds. These are desirable properties of thresholds. Contracts performing at the lower level are still incentivized to improve performance through the improvement measure, which is highly weighted in the calculation of Star Ratings. Additionally, the more such contracts improve their performance on any given measure, the higher their measure rating can be.

Comment: A commenter recommended replacing the clustering methodology with percentile thresholds.

Response: The Star Ratings system uses the clustering methodology for non-CAHPS measures because this groups contracts into natural clusters based on the distribution of performance, whereas percentile thresholds would force a certain percent of contracts to receive each star level, regardless of how similar or different those contracts perform. There are situations where it would not make sense to force a fixed percent of contracts into the highest star level, and other contracts into lower star levels, because there may not be meaningful differences between the top group of contracts based on percentile ranking and the next few contracts. The clustering methodology avoids the need to specify percentile thresholds and instead places contracts into their natural groupings based on actual plan performance.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are 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 outlier 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.

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

A. Contract Year Definition (§ 460.6)

Sections 1894(a)(9) and 1934(a)(9) of the Act define the trial period for PACE organizations as the first 3 contract years operating a PACE program under a PACE program agreement. Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency, to conduct a comprehensive annual review of the PACE organization's operation of the PACE program during the trial period to assure compliance with all significant requirements. The rule titled "Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)", which appeared in the November 24, 1999 issue of the **Federal Register** (64 FR 66234) (hereinafter referred to as the 1999 PACE interim final rule) defined a contract year at § 460.6 as the term of the PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS. This enables CMS to adjust the length of the initial contract year so that it always ends on December 31 and subsequent contract years align with a standard annual calendar year consisting of 12 months (64 FR 66236).

As discussed in the proposed rule (87 FR 79635), CMS is required to conduct comprehensive reviews during a PACE organization's trial period to assess all significant regulatory requirements, and these reviews must be conducted on an annual basis for the first 3 contract years. CMS must conduct the first trial period review (for example, audit) within the first contract year in order to comply with the statutory and regulatory requirements. However, CMS's ability to schedule and conduct the first trial period audit is limited by when a PACE organization enters into a program agreement, when the PACE organization begins enrolling participants during their first contract year, and the initial contract year timeframe in the current contract year definition in § 460.6. The timing of the initial contract year audit impacts the timing of subsequent audits, leaving CMS with increasingly narrow timeframes to audit within statutory and regulatory requirements.

We proposed to amend the definition of contract year at § 460.6 to state that a PACE organization's initial contract year may be 19 to 30 months, as determined by CMS, but in any event will end on December 31. Under the proposed contract year definition, although the duration of the initial contract year of the trial period would change, the initial contract year would continue to begin when the program agreement goes into effect on the first day of the relevant month and end on December 31 to ensure subsequent contract years follow the standard annual calendar year cycle. For PACE organizations with an initial contract year start date of January 1 through June 1, CMS would extend the initial contract year through the following year, and for PACE organizations with an initial contract year start date of July 1 through December 1, CMS would extend the initial contract year through the second succeeding year.

The proposed rule solicited comment on whether we should consider a different timeframe for the initial contract year, such as 25 to 36 months..

As explained in the proposed rule at 87 FR 79636, we do not believe revising the definition of contract year as proposed would create any additional burden for PACE organizations, as the effect of the proposed change would be to provide CMS with more flexibility when scheduling initial trial period audits without placing new requirements on CMS or PACE organizations, and we do not anticipate that the proposed change would have an impact on the Medicare Trust Fund.

Comment: Comments on CMS's proposal to amend the contract year definition at § 460.6 varied. A commenter supported the contract year definition change as proposed. Another commenter agreed with CMS's need for greater flexibility with scheduling PACE organizations' first year trial period audits, , but recommended a longer initial contract year timeframe of 25 to 36 months to allow for even more flexibility with scheduling PACE organizations' first trial period audits than the 19 to 30 month timeframe. However, the majority of commenters expressed concern with the proposal to amend the definition of contract year § 460.6 to state that a PACE organization's initial contract year may be 19 to 30 months, as determined by CMS, but

in any event will end on December 31. These commenters agreed with CMS's rationale for the proposed changes to the contract year definition, particularly CMS's concern that PACE organizations should have sufficient time to operate before their first trial period audit, which must take place during the initial contract year. However, most of these commenters recommended that CMS keep the current contract year definition, which has an initial contract year timeframe of 12 to 23 months, as determined by CMS, and utilize current administrative flexibilities to schedule trial year audits. They expressed concern that the proposed contract year definition's longer initial contract year could delay service area expansions, since PACE organizations must successfully complete their first trial period audit and implement acceptable corrective action plans, if applicable, before CMS and the State administering agency will approve a service area expansion or PACE center site expansion, as required at § 460.12(d). Another commenter suggested that CMS should amend the contract year definition to allow PACE organizations to choose their initial contract year timeframe, either the codified timeframe of 12 to 23 months, as determined by CMS, or the proposed timeframe of 19 to 30 months, as determined by CMS, and ending on December 31. This commenter recommended providing both options to PACE organizations for reasons similar to those discussed by other commenters. They suggested that the proposed initial contract year definition timeframe may give PACE organizations more time to stabilize operations before their first trial period audit, but expressed concern about the longer timeframe's consequences for PACE organizations' growth and expansion.

Response: Although a majority of commenters expressed support for flexibility when scheduling PACE organizations' first trial period audit, they also expressed concern that amending the definition of contract year at § 460.6 to lengthen the initial contract year timeframe to 19 to 30 months, as proposed, could affect the timing of the first trial period audit, and subsequently, the PACE organizations' ability to expand their service areas. As a result, the commenters recommended that CMS maintain the current initial contract year timeframe of 12 to

23 months to balance the timing of the first trial period audit, such that PACE organizations have sufficient time to operate before their first trial period audit, with consideration for services area expansions. We are not persuaded to maintain the current initial contract year timeframe of 12 to 23 months, as the majority of commenters recommended. As discussed in the proposed rule, CMS has limited flexibility when scheduling audits under the current contract year definition at § 460.6. This presents significant operational challenges for CMS, since CMS must review PACE organizations within the timeframes required by statute and regulation. These operational challenges are especially prevalent for shorter initial contract year durations, such as 12 to 18 months, which would be alleviated under the proposed longer initial contract year timeframe of 19 to 30 months. As stated in the proposed rule, we understand how the timing of the first trial period audit affects service area and PACE center site expansion applications, and we reiterate our commitment to ensuring timely completion of PACE organizations' first trial year audit in order to balance the impact on those applications with CMS's responsibilities related to program integrity and ensuring the wellbeing of PACE participants. Although our proposal, if finalized, would lengthen the initial contract year timeframe to 19 to 30 months, we still intend to promptly schedule first year reviews taking into consideration when organizations begin enrolling participants and whether an organization has had sufficient time to operate. We are also not persuaded to modify the proposal to lengthen the initial contract year timeframe to 25 to 36 months, as suggested by a commenter. Although the commenter expressed general support for the flexibility of a longer initial contract year timeframe, the commenter did not provide a specific justification for lengthening the initial contract year timeframe to 25 to 36 months. We do not believe this additional time is necessary to ensure that PACE organizations have sufficient time to operate before their first year trial period audits, nor that it is necessary in order for CMS to have sufficient flexibility in scheduling first year trial period audits. Additionally, since the current contract year definition and initial contract year timeframe do not offer CMS necessary flexibility for scheduling PACE organization's first trial period annual review, we are unable to

provide PACE organizations with the option to choose their preferred timeframe between the current and proposed initial contract timeframes. Therefore, we are finalizing our proposed changes to the definition of contract year at § 460.6 without modification.

B. Clarification of PACE Enforcement Authority for Civil Money Penalties and Intermediate Sanctions (§ 460.40(b))

In the final rule titled “Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)” (84 FR 25610), which appeared in the June 3, 2019 issue of the **Federal Register**, CMS amended § 460.40 by adding paragraph (b), which establishes that CMS has the discretion to take alternative enforcement actions in the form of civil money penalties (CMP) or a suspension of enrollment of Medicare beneficiaries by, or payment to, a PACE organization if CMS makes a determination that could lead to a termination of a PACE program agreement under § 460.50. In order to terminate a contract under paragraph (b) of § 460.50, CMS or the State administering agency must determine that both of the following circumstances exist: (1) there are significant deficiencies in the quality of care furnished to participants; or the PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2; and (2) within 30 days of the date of the receipt of written notice of a determination made under paragraph § 460.50(b)(1), the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies, or failed to continue implementation of the plan of correction.

In circumstances where CMS has made a determination under § 460.50 that could lead to termination, CMS would likely impose a CMP or suspension of enrollment and/or payment on a PACE organization prior to terminating the PACE organization, as authorized by § 460.40(b) (unless there was imminent risk to a PACE participant). This is because CMS views CMPs and suspensions of enrollment and/or payment as corrective in nature, since they are imposed when the PACE organization has been found noncompliant, and they provide time for the PACE

organization to correct the issue(s) that led to the noncompliance with the ultimate goal of mitigating any actual or potential harm for PACE participants.

As previously stated, in order for CMS to take any enforcement action (CMP, suspension of enrollment or payment, termination) on a PACE organization based on the grounds for termination set forth in § 460.50(b), the PACE organization must fail to develop and successfully initiate a plan to correct the deficiencies, or fail to continue implementation of the plan of correction within 30 days of receiving notice. Given that CMPs and suspensions of enrollment and/or payment are corrective in nature and imposed prior to termination, CMS believes that providing PACE organizations an opportunity to correct prior to imposing a CMP or suspensions of enrollment and/or payment is unnecessary and most importantly an impediment to CMS' ability to protect PACE participants from potential harm.

For these reasons, we proposed to revise § 460.40(b) by adding the following: "If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administering agency has to determine that the circumstances in 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension."

Comment: A few commenters suggested that this proposal would shift from a collaborative process of informing and providing PACE organizations an opportunity to self-disclose and self-correct deficiencies to a process that is overly punitive and has the potential to affect PACE organizations' ability to render services due to the financial risk of CMPs and suspension of enrollment and/or payments.

Response: We disagree with this comment. CMS has spent considerable time over the years increasing the amount of collaboration between CMS and PACE organizations before determining whether an enforcement action is warranted. This due diligence occurs both during the audit process, as well when CMS is reviewing a violation for a potential enforcement action. In addition, the proposal if finalized would not negatively impact PACE organizations' ability to self-disclose and self-correct compliance deficiencies to CMS at any time, including during the

audit and enforcement analysis stages. PACE organizations will continue to be permitted, and encouraged to self-disclose and self-correct issues found before or during audits, as well as issues discovered by PACE organizations outside of the audit. CMS considers such self-disclosure and self-correction as potential mitigating factors for violations/failures of the PACE program agreement and/or requirements. CMS also considers the financial condition of PACE organizations when determining whether to impose an enforcement action.

Comment: A few commenters incorrectly stated that current regulations require CMS to provide PACE organizations 30 days to correct deficiencies prior to imposing a CMP or suspension of enrollment and/or payment in all cases.

Response: We would like to clarify that CMS has the authority to impose enforcement actions without first providing a 30-day notice to PACE organizations under § 460.40.

We received comments on the following topics which were outside the scope of our proposal and to which we are therefore not responding: (1) the circumstances that exist prior to CMS imposing an enforcement action; and (2) the thresholds CMS uses in determining whether to impose an enforcement action.

After consideration of the comments received, we are finalizing our proposed changes to § 460.40(b) without modification.

C. PACE Contracted Services (§ 460.70)

As discussed in the proposed rule at 87 FR 79646, CMS originally included a list of required medical specialties at § 460.92 as part of the 1999 PACE interim final rule. The proposed rule explained that, in the 2006 final rule, CMS removed the list of medical specialties that appeared at § 460.92 based on the rationale that it was not possible to include an exhaustive list of all required services in PACE in the regulation and that PACE organizations might misconstrue the omission of any medical specialty from the list of required services at § 460.92 to mean that that type of specialty service was not required (*Id.*). The proposed rule further explained how, in the 2006 final rule, CMS revised § 460.92 to state that PACE organizations

are required to cover all Medicare-covered services, all Medicaid-covered services included in the State plan, and any other services determined necessary by the IDT (*Id.*). The proposed rule noted that, when CMS removed the list of medical specialties from § 460.92, we stressed that PACE organizations were still expected to have contractual arrangements with primary care physicians (PCPs) and specialists to meet the needs of their participants (*Id.*).

As explained in the proposed rule, we have seen through our monitoring and oversight efforts that some PACE organizations are not providing timely access to medical specialists (87 FR 79646). The proposed rule noted that we have found through our oversight activities that delays in accessing medical specialists sometimes occur as a result of PACE organizations not having contracts in effect for the medical specialties commonly utilized by PACE participants (*Id.*). We believe the delays experienced by participants may be reduced by PACE organizations effectuating contracts with medical specialists before a participant needs a particular medical specialty service. To address this issue, we proposed to add back into the PACE regulations the list of medical specialty services identified in the original PACE protocol as services that PACE organizations must ensure access to as a minimum requirement. Specifically, we proposed to amend § 460.70(a) to specify that the written contracts that PACE organizations are required to have with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization must include, at a minimum, the medical specialties listed in § 460.70(a)(1). We proposed to establish at new § 460.70(a)(1) that, at minimum, except as provided for in § 460.70(a)(4), PACE organizations must have contracts in place for the following medical specialties: anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, general surgery, thoracic and vascular surgery, and urology. We considered adding this list of medical specialties to § 460.92, where it was originally located; however, as explained in the

proposed rule, the requirement is better suited in § 460.70(a)(1) for several reasons. First, most, if not all, medical specialists do not work directly for the PACE organization, and rather are contracted providers that would need to adhere to the other requirements in § 460.70. Second, by adding this requirement into the contracted services provision of the regulation, we believe it will allow CMS and State administering agencies to better assess PACE organizations' readiness to enroll by ensuring these contracts are in place prior to participants enrolling in the organization.

While we proposed to add a list of medical specialty services back into the PACE regulations, we continue to maintain that this is not an exhaustive list of all medical specialists that the PACE organization may be required to provide access to. For example, if the IDT determines that a participant needs to see a hematologist, the PACE organization would be required to provide access to that specialist in a timely manner. The specialties we proposed to add in § 460.70(a)(1) would represent a minimum requirement for all PACE organizations; each PACE organization should consider the needs of its participants to determine what additional medical specialists may be necessary for its network to be sufficient. While we proposed to add back into regulation the 25 medical specialty services identified in the original PACE protocol, we solicited comment on whether CMS should include the following additional specialty services in the list of minimum required services: endocrinology, hematology, immunology, neurology, colorectal surgery, palliative medicine, infectious disease, physical medicine and rehabilitation. Additionally, we solicited comment on whether the proposed list of medical specialties should include any types of behavioral health specialties in addition to psychiatry such as psychologists or licensed clinical social workers. When submitting comments on this proposal, we requested that commenters indicate whether they have any concerns with CMS adding any or all of the previously discussed specialty services to the list, and that commenters describe any such concerns with specificity to help us understand the nature and basis of those concerns. We believe a PACE organization must be able to provide access to all of these

specialty services when a participant needs them and, based on our oversight experience, that additional specialty services are often necessary for the PACE population.

We proposed at new § 460.70(a)(2) to require a PACE organization to execute contracts with specialists prior to enrollment of participants, and to require the PACE organization to maintain such contracts on an ongoing basis to ensure participants receive appropriate and timely access to all necessary care and services. We clarified that we are not requiring PACE organizations to contract with individual specialists in situations where the PACE organization has contracted with a provider or practice that offers multiple specialties. In an instance of a medical provider or practice offering multiple specialties, the contract between the practice or provider, such as a hospital group, and the PACE organization would meet the requirement to have contracts in place for whatever specialties are included under the contract between the practice or provider group and the PACE organization. In the event a hospital group only contracts with a PACE organization to provide some of the specialty services it offers within its practice, the PACE organization would be expected to contract separately for any services not covered under the contract.

We believe it is appropriate for PACE organizations to be able to demonstrate that they have contracts in place that provide participants with sufficient and direct access to these commonly needed specialists prior to participants enrolling in the organization, and that PACE organizations maintain sufficient and direct access to these commonly needed specialists for enrolled participants on an ongoing basis. Through our auditing and oversight efforts, we have seen lengthy delays in specialist referrals when an organization has to contract with a new specialist, and waiting until a participant enrolls or has need of the specialist may create unreasonable delays in the participant being able to access that specialist. Additionally, as we noted in the 2006 PACE final rule (71 FR 71296), PACE organizations are financially responsible for all of their participants' health care needs, and delays in referrals for specialist services may have a significant impact on the PACE organization's financial viability. Failure to

provide timely specialist referrals may lead to more expensive care, including the need for institutionalization, which can drive up operating costs for a PACE organization.

We proposed to establish at § 460.70(a)(3) that a PACE organization must make reasonable and timely attempts to contract with medical specialists. PACE organizations are responsible for ensuring that participants have reasonable and timely access to medical specialty services, and that PACE organizations are responsible for taking appropriate steps in ensuring that they have suitable contracts in place in order to facilitate timely access to medical specialty services. We did not propose to establish specific criteria for determining whether “reasonable” attempts have been made for purposes of proposed § 460.70(a)(3), as what is reasonable would depend on the facts and circumstances of the case. For example, in an area with multiple providers in a specific medical specialty, it would not be reasonable to only attempt to contract with a single provider, if that provider indicated they were unwilling to contract with the PACE organization.

We further proposed to establish at § 460.70(a)(3)(i) that if at any time a PACE organization is unable to directly contract with a specific entity to provide specialist services to participants, the PACE organization must still ensure ongoing access to necessary care and services that would otherwise be provided to participants by a contracted specialist, and that the participant’s needs are met, through a different mechanism which may include hospitalization. As noted in the 2006 PACE final rule (71 FR 71296), we understand that in certain circumstances executing multiple contracts for a specific specialty may be difficult due, in part, to a limited number of specialists in certain geographic areas; however, we stress that PACE organizations continue to be responsible for meeting all of the participant’s needs, even if there is not a direct contract in place. Additionally, under our proposal at § 460.70(a)(3)(ii) we expect an organization to promptly report any contracting problems to CMS and the SAA, and include information on what attempts were made, the reason why a contract was not effectuated, and the PACE organization’s plan to provide access to the necessary services. This reporting

may be initiated by the PACE organization when reasonable attempts to contract have been made, and were unsuccessful; or it may be done in response to CMS or the SAA inquiring as to the status of the contracts. For example, during the State readiness review, the SAA may inquire as to the status of the PACE organization's contracts with medical specialists. When reporting these contracting issues to CMS or the SAA, the PACE organization should be prepared to describe its attempt(s) to contract with medical specialists, why a contract was not able to be effectuated, and how the PACE organization plans to ensure participants' needs are met. For example, if there is only one specialist in a service area, and they are not accepting new participants, the PACE organization must show it attempted to contract and how it will ensure participants are able to receive the services that the specialist would have provided. In other words, in this example, the PACE organization must show that it reached out to the one specialist in the area, attempted to contract with that specialist, and was unsuccessful.

Finally, in order to account for PACE organizations that may choose to employ some medical specialists directly, such as dentists and podiatrists, proposed § 460.70(a)(4) exempts a PACE organization from the contract requirements in § 460.70(a)(1) and (2) with respect to a particular medical specialty if a PACE organization employs one or more individuals prior to contracting who are legally authorized and, if applicable, board certified, in that medical specialty. While we generally expect that PACE organizations would have contracts in place for most of the specialties in this list, we understand that there are times when a PACE organization may directly employ a provider in one of the listed specialties. In those instances, assuming the participants have sufficient access to the type of specialist that is employed by the PACE organization, the PACE organization would not be required to contract with additional providers in that specialty. However, the organization must have the specialist actively employed prior to enrollment of participants in order for the exception to be met and cannot rely on future employment to satisfy this requirement. We believe that by modifying this provision as

proposed we would not increase the burden on PACE organizations as they are already required to either obtain and maintain contracts with or employ medical specialists.

Comment: The majority of commenters supported the proposal to add the 25 specialty types back into regulation under § 460.70(a)(1), but requested that CMS consider ways PACE organizations can meet the requirement to contract with the specialties listed. Methods suggested include contracting with telehealth providers and/or contracting for a specified duration of time with an out-of-network specialist to provide a limited service (or services) to a participant when that specialty provider is not immediately available in the PACE organization's network. Commenters specifically quoted § 422.116(d)(5), which allows MA organizations 10 percentage point credits for telehealth when the plans contract with certain specified providers to meet network adequacy requirements. These commenters indicated that § 422.116(d)(5) supports the spirit of allowing telehealth providers into contracted networks as a tool to provide benefits.

Response: We thank commenters for their support for our proposal to add the list of 25 medical specialties for which PACE organizations must have written contracts in place prior to enrolling participants. PACE organizations are already permitted flexibility in providing required services with specialists via alternative methods. Nothing in current regulation prohibits PACE organizations from contracting with telehealth specialists, contracting with providers outside of the service area, or creating temporary contracts to meet participant needs. PACE is distinctive from Medicare Advantage because PACE covers more than the Medicare benefit under § 460.92, which requires PACE to cover all Medicare-covered services, all Medicaid-covered services per the State's approved Medicaid plan, and any other necessary services approved by the IDT. Additionally, § 460.90(a) states that Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

While we do not believe that telehealth services are prohibited in PACE, PACE organizations must ensure that all other regulatory requirements are met when providing services in that manner. For example, decisions to provide a service must be based on the participant's current medical, physical, emotional, and social needs as required under § 460.92(b)(1). When considering the participant's condition, the IDT should also consider the service in question. The IDT may determine telehealth is appropriate for one participant in one situation, but not another participant based on the participant's condition. For example, a dental visit would very rarely be appropriate for telehealth services; however, a behavioral health visit may be appropriate depending on the participant's condition. Additionally, the PACE organization would have to ensure all other regulatory requirements are met, including contracting requirements for telehealth providers, and the PACE organization would not be able to utilize telehealth for services that are specifically required to be in-person per the regulations, such as routine assessments under § 460.104.

Additionally, if a PACE organization determines that a participant needs a service, and the PACE organization does not have a long-term contract in place, organizations may utilize flexibilities such as Letters of Agreement or Memoranda of Understanding with out-of-network providers, in order to ensure participants have access to the care and services they need.

Comment: Numerous commenters requested that CMS add palliative medicine to the list of contracted services in response to our solicitation for comment. Several commenters also requested that CMS consider adding other specialties to the proposed list of 25 medical specialties, including physical medicine and rehabilitation, infectious disease, and neurology. Another commenter requested that the list of required medical specialties include other behavioral health specialties in addition to psychiatry, as well as all eight specialties for which we solicited comment, namely: endocrinology, hematology, immunology, neurology, colorectal surgery, palliative medicine, infectious disease, physical medicine and rehabilitation.

Response: We agree with the addition of palliative medicine to the list of required specialties based on the needs of the population in PACE, and we are modifying the proposed regulation to include palliative medicine. We are not persuaded to require any of the additional proposed specialties at this time due to the often-limited availability of specialty providers, particularly in rural areas. However, as we stated in the proposed rule, the specialties included at § 460.70 are not an exhaustive list of all medical specialties that the PACE organization may be required to provide access to (87 FR 79647). While we are not including endocrinology, hematology, immunology, neurology, colorectal surgery, infectious disease, physical medicine and rehabilitation, or additional behavioral health specialties in the required contracted services, nothing precludes the PACE organization from contracting with any specialty, nor does this provision eliminate or change the requirement for a PACE organization to have in place a written contract for a specialty service when the IDT has deemed the service necessary to meet the needs of participants. Ultimately, PACE organizations are required to provide services that are necessary for participants, even if the PACE organization does not have a specific contract in place for that service.

Additionally, in the proposed rule, we identified neurosurgery as one of the 25 required medical specialties; however, it was inadvertently left out of the proposed regulation text. We are therefore adding it back in to the regulation text at § 460.70(a)(1)(x).

Comment: Another commenter suggested that CMS define “reasonable and timely attempts to contract” and “timely access to services”.

Response: As we stated in the proposed rule, we specifically chose not to include language defining reasonable and timely attempts to contract “as what is reasonable would depend on the facts and circumstances of the case” (87 FR 79647). It is not possible for CMS to anticipate every circumstance that may arise which may prevent or substantially impact a PACE organization’s ability to contract with one of the required specialties. Our intent is to work with PACE organizations and review their efforts to contract with the required specialties, as well as

their ability to provide medically necessary services to meet participant needs in the event the PACE organization is unable to contract with one of the required specialty services.

The meaning of “timely access to services” also depends on the facts and circumstances of each case and the participant’s condition and assessed needs. The PACE organization will need to consider the nature of the participant’s condition and the urgency with which it must be treated when determining what constitutes “timely access to services.”

Comment: A commenter did not support the proposed requirements for PACE organizations to have contracts in place for the listed 25 medical specialties because the commenter did not believe the proposal addressed the issue of ensuring timely access to services identified as necessary. The commenter noted that even enrollees of larger insurers with broad and diverse networks have struggled to obtain necessary specialist appointments in a timely manner.

Response: While we acknowledge that not all cited instances of a PACE organization failing to provide medically necessary services in a timely manner were a direct result of not having contracts with specialists, the proposed requirement is meant to mitigate situations where not having an executed contract in place with specialists caused significant delay in participants accessing necessary services. For instance, we have seen on audit where PACE organizations did not have a contract with a specialty service prior to enrollment, and delays in obtaining services for participants were exacerbated because of a lack of a contract. We believe the failure to execute contracts until the need for the service arises substantially contributes to the delay in participants receiving medically necessary care.

We also acknowledge that specialty provider availability continues to be a struggle across some health care settings. However, because of the time and effort required in negotiating contracts, we believe it is best practice to complete contract negotiations prior to participant enrollment to reduce additional delays in receiving services and that it is imperative for PACE

organizations to maintain contracts on an ongoing basis to mitigate delays in participants receiving timely care.

Comment: Several commenters expressed concern regarding CMS's reliance on 2021 audit data when determining to include the list of 25 medical specialties in the contracted services provision. These commenters noted that this audit data was collected during the COVID-19 pandemic which impacted medical specialty services on a national level and, therefore, is not an accurate reflection of failures on the part of PACE organizations but evidence of a broader issue in health care nationally.

Response: The discussion of the approximately 70 percent of organizations that were cited during the 2021 audit cycle for a failure to provide necessary services was meant to serve as the most recent example of concerning trends seen as part of our oversight and monitoring efforts where participants experienced delays in access to necessary care. It was not intended to be understood as the only data CMS reviewed when determining to engage in rulemaking and deciding which medical specialties to include in the required contracted services provision. We considered all oversight efforts, including audits, when drafting these provisions. We have seen through those oversight efforts that a lack of contracts with medical specialists have resulted in unnecessary delays in participants receiving medically necessary care. While we recognize the difficulties PACE organizations and other health care providers experienced during the COVID-19 pandemic, the delays in access to medically necessary services caused by a lack of contracts with medical specialists were occurring prior to the pandemic.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes at § 460.70(a)(2), (3), and (4) as proposed. We are finalizing the changes at § 460.70(a)(1) with two slight modifications: first, by adding neurosurgery, which was inadvertently left out of the proposed regulation text, and second, by adding palliative medicine to the list of required contracted services.

D. Service Determination Request (§ 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. Along with the regulations at § 460.120 related to grievances, and § 460.122 related to appeals, CMS created a process for service determination requests, the first stage of an appeal, at § 460.121, including the extension requirements as specified in § 460.121(i)(1). In the February 2020 proposed rule (85 FR 9002), CMS proposed to add a requirement at §460.121(i)(2) that required, in part, that the IDT notify the participant or the designated representative of a service determination request extension in writing. The proposed requirement was based on the MA organization determination requirements in § 422.568, which require written notification when an extension is taken. In response to our proposal, PACE organizations and industry advocacy groups recommended we modify the proposal to allow either oral or written notification when the IDT extends the timeframe for a service determination request, rather than requiring written notification only. When CMS responded to these comments in the January 2021 final rule, we expressed that we were not persuaded to modify the requirement to allow PACE organizations to notify participants orally instead of in writing, because we believed written notification of the extension was important in order to ensure the participant received a full explanation (86 FR 6022), and as a result, we finalized our proposal to require that the IDT notify the participant or their designated representative in writing when the IDT extends the timeframe for a service determination request.

As discussed in the December 2022 proposed rule preamble (87 FR 79670), since finalizing this requirement in the January 2021 final rule (86 FR 5864), CMS has received additional feedback from PACE organizations, particularly regarding their experiences engaging and communicating with participants in different ways during the COVID-19 pandemic. In light of that feedback and experience, CMS has determined that allowing the IDT to provide either oral or written notice of service determination request extensions should not adversely impact

participants, as both oral and written communication can be an effective means of communication when providing notice of a service determination request extension.

Therefore, we proposed to revise the requirement at § 460.121(i)(2) to allow the IDT to provide notification either orally or in writing to the participant or their designated representative when the IDT extends the timeframe for a service determination request, as permitted under § 460.121(i)(1) (87 FR 79670). Additionally, the proposed rule discussed that allowing the IDT to provide either oral or written notice of service determination request extensions increases operational flexibility for PACE organizations (87 FR 79670).

As stated in the proposed rule (87 FR 79670), in order to ensure participants are fully informed of the reason(s) for an extension, CMS would expect oral notice of the service determination request extensions to meet the same requirements as written notice, including the expectations that notices will explain the reason(s) for the delay and be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe. CMS would expect that PACE organizations document the content of oral notifications of service determination request extensions in accordance with § 460.121(m). An IDT may choose to provide the extension notification both orally and in writing if it believes that is necessary to ensure the participant's understanding.

We estimate ongoing burden reduction due to the expected decrease in written notifications of service determination request extensions in favor of oral notification. We discuss and account for the burden reduction resulting from the expected decrease in written notification of service determination request extensions in the Collection of Information Requirements section. We will submit these changes to OMB for approval under control number 0938-0790 (CMS-R-244).

Comment: All commenters that addressed the proposed change to § 460.121(i)(2) supported allowing the IDT to provide either oral or written notice of service determination

request extensions. They noted that this provision would increase operational flexibility, which would reduce burden for PACE organizations.

Response: We thank the commenters for their support of this provision and are finalizing this requirement as proposed.

E. PACE Maintenance of Records (§§ 460.200 and 460.210)

Under sections 1894(b) and 1934(b) of the Act, PACE organizations are required to provide all items and services covered under Medicare and Medicaid, and all additional items and services specified in regulations and determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status. Currently, PACE organizations are required to safeguard data and records in accordance with § 460.200(d). PACE organizations must also maintain a single comprehensive medical record for each participant in accordance with accepted professional standards (§ 460.210(a)(1)).

In the February 2020 proposed rule (85 FR 9002), CMS proposed to add a new requirement at § 460.200(d)(2) for PACE organizations to maintain in the medical record all written communications received from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6). We explained in that proposed rule that we had found through our monitoring of PACE organizations that they do not always maintain and safeguard important records such as communications related to a participant's care from family members, caregivers, and the participant's community (85 FR 9134). We stated that maintaining a comprehensive, complete, and accurate medical record allows a PACE organization to remain alert to all information that is relevant to a participant's care, health and safety, and to provide appropriate and timely care to the participant (85 FR 9140). Therefore, we also proposed a new requirement at § 460.210(b)(6) for PACE organizations to maintain in a participant's medical record original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not

limited to (i) communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both; and (ii) communications from an advocacy or governmental agency such as State-based Adult Protective Services.

In the January 2021 final rule, CMS summarized and responded to the comments received on these proposed record maintenance requirements (86 FR 6039 through 6040). We noted that some commenters recommended we allow PACE organizations to maintain original communications *outside* of the medical record systems, as they believed that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format *in* the medical record would compromise the usefulness of the medical record, due to the quantity of information that would be required to be stored (86 FR 6040). Based on these comments, we contemplated allowing original documentation of communications to be summarized in the medical record, so long as PACE organizations maintained the original documentation of the communication in a separate system. Ultimately, we chose not to modify our proposal with the contemplated change of permitting PACE organizations to summarize written communications relating to the care, health, or safety of a participant in the medical record. We did, however, modify our original proposal to allow PACE organizations to maintain in a participant's medical record original documentation, or an electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant. In finalizing this provision, we explained that we were not establishing specific requirements governing where affected communications must be stored within a participant's medical record. We also explained that PACE organizations may operationalize these requirements in accordance with the capabilities of their medical record systems (86 FR 6040).

Participants, their family members, and representatives have a longstanding right to file a grievance expressing dissatisfaction with the delivery of PACE services or the quality of care furnished as part of the PACE benefit package (see §§ 460.112(g)(1) and 460.120). A PACE

organization must have a formal written process to evaluate and resolve medical and non-medical grievances by PACE participants (§ 460.120(a)). A PACE organization's grievance process must include a written procedure for maintaining the confidentiality of a participant's grievance (§ 460.120(c)(4)).

PACE participants routinely file grievances with a PACE organization under the assumption that the details of their grievance will be kept confidential. This is especially important to PACE participants when a grievance involves a particular staff member of the PACE organization (for example, a home care aide, a driver, or a specific member of the interdisciplinary team). PACE organizations have typically maintained confidentiality of this information by only allowing access to the information, that is, the details of the complaint, to a limited number of PACE organization staff and/or by storing this information outside of the medical record in a secure location (for example, a separate electronic application or paper-based system).

Since we finalized the January 2021 final rule, PACE organizations have had an opportunity to implement this provision, and we have continued to receive questions related to maintaining original communications in the medical record. These questions and comments indicate that as PACE organizations have begun to operationalize this requirement, they have been challenged with maintaining the confidentiality of grievances and managing the volume of these communications in the medical record. Other inquiries include whether it would be permissible for PACE organizations to scan communications and store them electronically in the medical record.

In addition to the concerns around maintaining the confidentiality of grievances, PACE organizations have also pointed out that there are instances when written communications sent to the PACE organization by the individuals and entities listed at § 460.210(b)(6)(i) and (ii) may contain sensitive information about a PACE participant, their caregivers, and/or family members, and that these communications are often accompanied by a request to keep the information

private. For example, information shared with a PACE organization may pertain to a caregiver's health, and may have implications for the participant's care, and the caregiver may only want the details of this information shared among employees and contractors who need to know the information rather than all individuals with access to the participant's medical record. There are also instances when the communications include contents or language that may be inappropriate for inclusion in the medical record, such as vulgar comments directed towards individual PACE staff. PACE organization staff have indicated that maintaining written communications related to participant grievances in the medical record allows access to the information by all PACE organization staff, thereby jeopardizing the confidentiality of such communications, and have therefore requested clarification from CMS on how to adhere to comply with the requirement in § 460.210(b)(6) when the original communication is part of a participant grievance and contains sensitive or confidential information.

Sections 1894(f)(3) and 1934(f)(3) of the Act provide authority for the establishment of certain additional beneficiary and program protections applicable to MA and Medicaid managed care programs under prepaid capitation agreements under section 1903(m) of the Act. Sections 1894(b)(2) and 1934(b)(2) of the Act require that the PACE program agreement have written safeguards of the rights of enrolled participants, including a bill of rights and procedures for grievances and appeals, in accordance with regulations and with other Federal and State laws designed for the protection of beneficiaries. This authority allows CMS to implement regulations to ensure that PACE participants' rights are protected, including the right to file a grievance anonymously.

To uphold participant rights and help PACE organizations to safeguard anonymity to the extent possible during the grievance process and in other circumstances that involve sensitive information, CMS proposed, using the authority at sections 1894(f)(3) and 1934(f)(3) of the Act, to amend the PACE regulations at §§ 460.200(d)(2) and 460.210(b)(6) to allow for more

administrative flexibility in how PACE organizations maintain written communications relating to the care, health, or safety of a participant.

Specifically, we proposed to amend § 460.200(d)(2) to require that a PACE organization must maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety, including, but not limited to, the following: (i) communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's care, health or safety; and (ii) communications from an advocacy or governmental agency, such as Adult Protective Services. This proposal moves and revises language located at § 460.210(b)(6) that requires PACE organizations to maintain original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format. By moving this language to § 460.200(d)(2), with the proposed modifications, we retained the requirement for PACE organizations to maintain these important communications in their original form, while removing the requirement that these communications be stored in the participant's medical record. At § 460.210(b)(6), we proposed to replace the current language with a new requirement that states that original documentation or an unaltered electronic copy, of any written communication as described in § 460.200(d)(2), must be maintained in the participant's medical record unless the following requirements are met: (i) the medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication, (ii) original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and (iii) original documentation of the communication is available to CMS and the SAA upon request. This provision continues to require PACE organizations ensure that these important communications relating to the care, health, or safety of a participant are included in the medical

record, but it allows PACE organizations operational flexibility on how these communications are included. PACE organizations would be permitted, under this proposal, to summarize the information in the medical record, as long as the summary is accurate and thorough, and the original documentation of the communication is maintained outside the medical record and is accessible by the PACE organization's employees and contractors as needed, and available to CMS and the SAA upon request. We believe this proposal balances CMS' interest in ensuring these communications are safeguarded with PACE organizations' interest in ensuring the medical record is usable and that confidential information is protected to the extent possible. A PACE organization would be able to include a summary of the information but could now choose to exclude names or other potentially sensitive information, provided the requirements under proposed § 460.210(b)(6)(i) through (iii) are met.

We summarize the comments received on the proposals at §§ 460.200(d)(2) and 460.210(b)(6) and provide our responses to those comments in this section of this rule.

Comment: CMS received several comments expressing overwhelming support for our proposals at §§ 460.200(d)(2) and 460.210(b)(6), allowing for more administrative flexibility in how PACE organizations maintain written communications relating to the care, health, or safety of PACE participants. Commenters conveyed their appreciation and believed that the ability to maintain these communications in a more appropriate location will help to safeguard participant anonymity during the grievance process and reduce burden on PACE organizations.

Response: CMS appreciates the comments and agrees that this flexibility will safeguard participant anonymity and sensitive information, and help PACE organizations more easily comply with the requirements at the new 460.200(d)(2) to maintain all written communications received in any format from participants or other parties in their original form when the communications relate to a participant's care, health, or safety.

Comment: CMS received a comment stating that they were not supportive of our proposals at §§ 460.200(d)(2) and 460.210(b)(6) as they believed this flexibility was unnecessary and could lead to confusion and variation amongst the industry regarding practices for medical record access and storage.

Response: CMS appreciates the comment, however disagrees that this will lead to variation and confusion in the industry regarding medical record access and storage practices. As described in the proposed rule, when the January 2021 final rule became effective, CMS received concerns from PACE organizations regarding the requirement to maintain original communications in the medical record, due to the challenges associated with maintaining the confidentiality of grievances, and managing the volume of communications in the medical record. Furthermore, PACE organizations indicated that maintaining written communications related to participant grievances in the medical record allows access to the information by all PACE organization staff, thereby jeopardizing the confidentiality of such communications, especially when confidentially is requested by a participant and/or caregiver, and requested that CMS provide clarification on how to adhere to the requirements at the former § 460.210(b)(6), while maintaining the confidentiality of participant grievances, as required at § 460.120(c)(4).

CMS believes that allowing these communications be stored outside of the medical record, when certain conditions are met, balances the need to keep grievance and sensitive information confidential, while appropriately maintaining communications related to participant care, health or safety, as part of the medical record. CMS also points out that PACE organizations may choose to maintain these communications outside of the medical record in a secure location when certain conditions are met, however, they can also choose to maintain the communications in the medical record in accordance with the new § 460.200(d)(2). PACE organizations have the option to exercise this flexibility, but are not required to do so. Lastly, CMS believes these changes will be welcomed by the industry.

After consideration of the comments received, we are finalizing our proposed changes to §§ 460.200(d)(2) and 460.210(b)(6) without modification.

F. Out of Scope Comments and Summary

We received comments on the following topics which were out of scope of our proposal and to which we are therefore not responding: (1) The passage of the 117th Congress' proposed legislation entitled "PACE Plus Act" (S. 1162/H.R. 6770) , "PACE Part D Choice Act" (S. 5106/H.R. 4941), and "Improving Senior's Timely Access to Care Act" (S. 3018/H.R. 3173); and (2) Allowing the PACE program to utilize gift cards in marketing.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information,” as defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

On December 27, 2022 (87 FR 79452) we solicited public comment on each of these issues for the following sections of the proposed rule (CMS-4201-P, RIN 0938-AU96) that contained information collection requirements. Such comments were received as indicated under ICR #5 (Regarding [the] Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization) and ICR #11 (Regarding the PACE Service Determination Process) in this rule. This final rule is only finalizing some of the provisions of the proposed rule. The remaining provisions may be finalized in subsequent rulemaking.

A. Wage Data

1. Wage Changes

For the provisions being finalized in this rule, the proposed rule’s burden estimates are being carried over without change except that the beneficiary’s wage is

adjusted from \$28.01/hr to \$20.71/hr. The adjustment is based on internal review as we changed the source of the wage figure from BLS at \$28.01/hr to HHS at \$20.71/hr. See “Wage for Beneficiaries” and ICR #2, in this rule.

2. Private Sector Wages

To derive average costs, we are using data from the most current U.S. Bureau of Labor Statistics’ (BLS’s) National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 5 presents BLS’ mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 5: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business operations specialists (all others)	13-1199	38.1	38.1	76.20
Compliance officers	13-1041	36.45	36.45	72.90
Computer programmer	15-1251	46.46	46.46	92.92
Healthcare Social workers	21-1022	29.96	29.96	59.92
Pharmacists	29-1051	60.43	60.43	120.86
Software developer	15-1252	58.17	58.17	116.34

As indicated, except for enrollees, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

3. Wage for Beneficiaries

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of \$20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of \$998, divided by 40 hours to calculate an hourly pre-tax wage rate of \$24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of \$20.71/hr. Unlike our private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II. through VI.) of this final rule.

1. ICRs Regarding Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments (§ 422.514)

This rule adds a new paragraph at § 422.514(g) to clarify that the D-SNP look-alike contracting limitations at § 422.514(d) through (f) apply to segments of the MA plan. This new paragraph will address instances we have seen since adopting § 422.514(d) through (f) where a specific segment of an MA plan looks like a D-SNP look-alike and would be subject to the

contracting prohibitions in § 422.514(d) if the segment were treated as an MA plan. We believe that by applying the D-SNP look-alike contracting limitations only at the MA plan level without applying it to segments of plans, our existing regulation has an unintended and unforeseen loophole through which D-SNP look-alikes could persist, contrary to the stated objectives in our prior rulemaking.

Based on January 2022 Monthly Membership Report data, we expect that this rule will result in three MA plan segments being identified as D-SNP look-alikes, and these D-SNP look-alikes would likely transition the approximately 3,000 current enrollees into another MA-PD plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization) using the transition process described in § 422.514(e). Based on our analysis of proposed D-SNP look-alike transitions for contract year 2023, two D-SNP look-alikes in contract year 2022 are proposing to transition a combined total of approximately 7,000 D-SNP look-alike enrollees into two new non-SNP MA plan segments, which could create two new D-SNP look-alikes for contract year 2023.

In the June 2020 final rule (85 FR 33877 through 33880), we estimated each D-SNP look-alike would take a one-time effort of 2 hours for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. We also stated that, after the prohibition on D-SNP look-alikes was implemented, at most five plans per year would be identified as D-SNP look-alikes under § 422.514(d) due to meeting the enrollment threshold for dually eligible individuals or operating in a State that will begin contracting with D-SNPs or other integrated plans. In association with our June 2020 final rule, the requirement and burden estimates (5 respondents, 5 total responses, and 10 total hours) were approved by OMB under control number 0938-0753 (CMS-R-267).

This rule's clarification under § 422.514(g) does not change the transition process nor our currently approved burden estimates. Similarly, the addition of non-SNP MA plan segments to the contracting limitations at § 422.514 has no impact on our currently approved burden

estimates that at most five plans (including PBP segments) per year would be identified as D-SNP look-alikes; therefore, the currently approved number of respondents and burden estimates in control number 0938-0753 would not change.

2. ICRs Regarding Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the LI NET Program (§ 423.2500 through § 423.2536)

The following changes will be submitted to OMB for approval under control number 0938-1441 (CMS-10831). OMB will set out an expiration date upon their approval of this final rule's new collection of information request. The issuance of the expiration date can be monitored at reginfo.gov.

We did not receive any comments specific to the private sector proposed ICRs and, therefore, are finalizing the proposed private sector requirements and burden estimates as is. As previously indicated under Wage Data, we have adjusted the proposed beneficiary wage resulting in adjusted cost estimates under this final rule.

As described in section II.D.2 of this final rule, we expect that some beneficiaries will enroll in LI NET using methods that may entail providing information. Some beneficiaries may enroll in LI NET at the point-of-sale (POS) at a pharmacy because: 1) they are likely eligible for the low-income subsidy (LIS), have immediate need for their prescription, and do not have Part D coverage or 2) present documentation with their LIS status at the pharmacy and do not have Part D coverage. Some beneficiaries submit receipts for reimbursement for claims paid out of pocket; if they are eligible for LI NET they will be retroactively enrolled into the LI NET program by the LI NET sponsor. Another way for beneficiaries to potentially enroll into LI NET is by completing an LI NET application form.

To estimate the total burden, we consider the burden for enrollees, pharmacists, and Part D sponsors separately. Each consideration entails counting the number of

documents arising from point of sale enrollments, direct reimbursement forms, and LI NET application forms.

a. Beneficiaries

To estimate the information collection burden for beneficiaries, we have estimated the number of beneficiaries submitting information to LI NET and time related to handling the information. We have not included burden estimates for individuals who would not be providing documentation, such as those CMS automatically enrolls into LI NET, individuals whose eligibility for LI NET is confirmed independently by the LI NET sponsor, or for those who opt not to provide evidence.

When enrolling in LI NET at POS, possible forms of evidence for LIS eligibility include but are not limited to, a Medicaid card or a letter from the State or SSA showing LIS or “Extra Help” status. We estimate that it would take an individual approximately 15 minutes (0.25 hr) to gather supporting documentation. There are 36,722 individuals enrolled in the LI NET demonstration at POS in 2021 who applied at the point of sale. Based on our experience with the LI NET demonstration, we estimate approximately 250 beneficiaries would submit receipts for reimbursement for claims paid out of pocket. These beneficiaries may complete a direct reimbursement request form available online, and return by mail, e-mail, or fax, together with their receipt, to the LI NET sponsor. In the LI NET demonstration, approximately ten beneficiaries per year completed the LI NET application form, which is available online, and returned it to the LI NET sponsor by mail, e-mail, or fax. Thus, in total we expect 36,982 beneficiaries (36,722 at point of sale plus 250 through direct reimbursement plus 10 applying via the LI NET application form) to spend 15 minutes (0.25 hr) resulting in an aggregate burden of 9,246 hours (36,982 enrollees * 0.25 hr) at an aggregate cost of \$191,485 (9,246 hr * \$20.71/hr).

b. Private Sector (Pharmacists)

We estimate that it will take 2 minutes (0.0333 hr) for a pharmacy to fax the documentation to the LI NET sponsor. However, pharmacists will not process the forms

of enrollees who use direct reimbursement or the LI NET application form. Thus, pharmacists will only process the 36,722 enrollees at point of sale. Thus, the aggregate burden for pharmacists is 1,223 hours (36,722 enrollees * 0.0333 hr) at an aggregate cost of \$147,812 (1,223 hr * \$120.86/hr).

c. Part D Sponsors

The Part D sponsors will process the documents received from all 36,982 enrollees. Part D sponsors are estimated to spend about 2 minutes (0.0333 hr) to process information from point of sale, direct reimbursement requests, and application forms. Thus, the aggregate burden for Part D sponsors is 1,232 hours (36,982 enrollees * 0.0333 hr) at an aggregate cost of \$93,878 (1,232 hr * \$76.20/hr).

3. ICRs Regarding Adding New Behavioral Health Specialty Types Subject to Network Adequacy Evaluation (§ 422.116)

The following changes will be submitted to OMB for approval under control number 0938-1346 (CMS-10636).

To ensure that MA enrollees have access to provider networks sufficient to provide covered services, including behavioral health service providers, this rule adds new specialty types that will be subject to network adequacy evaluation under § 422.116. This rule adds Clinical Psychology and Clinical Social Work under § 422.116(b)(1). However, we are not finalizing our proposed addition of the Prescribers of Medication for Opioid Use Disorder specialty type.

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 from SAMHSA and the DEA to administer, dispense, or prescribe MOUD. Therefore, we will not be finalizing this portion of our proposal. Because we planned to use SAMHSA's list of waived providers to populate the

Provider Supply file, we are no longer able to accurately track the providers that prescribe medications like buprenorphine in order to create and maintain a network adequacy standard.

We have determined that there is no cost for MA organizations in regards to reporting new specialty types to CMS for their network adequacy reviews as this rule requires. However, we have determined that there is a minimal one-time cost for MA organizations to update their policies and procedures associated with this rule.

First, regarding reporting the proposed new specialty types to CMS, MA organizations are already conducting ongoing work related to network adequacy reviews that happen during the initial or service area application, or every three years for the triennial review. Further, organizations should already have these specialty provider types within network, as these are services covered by Medicare Part A and B and which are furnished by these specialty types, so there is no burden related to contracting with new provider types. This will only require that the specialty types be added to the Health Services Delivery (HSD) tables during any network adequacy evaluation requested by CMS. As determined by our contractors, the time to conduct tasks related to adding additional specialty types on the HSD tables is negligible.

We understand that MA organizations will need to update their policies and procedures related to submission of HSD tables to ensure that the new required behavioral health specialty types are included. We estimate that a business operations specialist working at an hourly wage of \$76.20/hr will take 5 minutes (0.0833 hr) for a one-time update of policies and procedures related to this task, at a cost of \$6.35 (0.0833 hr * \$76.20/hr). The aggregate burden is 62 hours (742 MA contracts * 0.0833) at a cost \$4,724 (62 hr. * 76.20/hr).

We did not receive any comments specific to the proposed ICRs and, therefore, are finalizing the proposed requirements and burden estimates as is.

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

The following changes were submitted to OMB for review under control number 0938-0753 (CMS-R-267).

As described in section III.D. of this final rule, we are revising: (1) § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur; and (2) § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination. We are finalizing this provision as proposed with some modifications based on public comment. We are modifying the proposed changes to § 422.111(e) by requiring only one telephonic notice attempt to enrollees who have not opted out of plan calls and by specifying a three-year lookback period to determine which enrollees of terminating primary care and behavioral health providers must be notified. However, these modifications have no impact on our proposed burden estimates.

This amendment to §§ 422.111(e) and 422.2267(e)(12) impacts MA organizations in terms of the burden required to identify those enrollees who must be notified of provider contract terminations per CMS requirements, to develop and send the required written notices, to develop the scripts for the required telephonic notices, and to make the required enrollee telephone calls. However, CMS does not currently collect data regarding the widely variable number of provider contract terminations an MA organization undergoes in a given contract year, nor the number of enrollees affected by each termination. Therefore, in the proposed rule, we did not have information that would have allowed us to estimate the extent of MA provider contract terminations, how many enrollees are affected and need to be notified per § 422.111(e), or how the MA program will be impacted as we see the effects of this regulation. Although we solicited comment, we received no comments to help us derive such estimates.

The actual direct burden of this provision arises from MA organization staff hours spent, resources purchased, and enrollee notifications provided. MA organizations may also differ in

how their spending for the requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation.

Despite our inability to quantify certain burden for this provision, we were able to estimate the one-time burden on MA organizations to update their existing written provider termination notice in compliance with the new required notice content that we are finalizing at § 422.2267(e)(12)(ii). We stated in the proposed rule that we expect MA organizations to engage in some routine software development to update their notice template and related systems to incorporate the new requirements, which will be delineated in a provider termination model document developed by CMS staff (thus not incurring COI burden). This proposed model was posted for public review and comment in conjunction with the proposed rule's 0938-0753 ICR. We estimated that one or two software developers working at a wage of \$92.92/hr will spend a total of 8 hours updating an MA organization's existing provider termination notice template and related systems based on CMS's model. With approximately 697 MA organizations impacted by this change, this results in a total of 5,576 hours (697 MA organizations * 8 hours), at an aggregate cost across all MA organizations of \$518,122 (5,576 hours * \$92.92/hr). In the proposed rule, we were unable to estimate the burden for the telephonic notice requirement at §§ 422.111(e)(1)(i) and 422.2267(e)(12)(iii) because the number of primary care and behavioral health provider contract terminations an MA organization undergoes in a given contract year is unknown, as are the number of affected enrollees per termination. We did not receive any comments related to our projected burden estimates for this provision, therefore, we are finalizing the proposed burden without change.

5. ICRs Regarding Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization (§ 422.101)

The following changes be submitted to OMB for approval under control number (0938-0753) (CMS-R-267).

As explained in section III.E. of this rule, MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations when making medical necessity determinations. Under this rule, MA plans must follow Traditional Medicare coverage criteria as specified in NCDs, LCD, or Medicare laws (that is, in Medicare statutes and regulations).

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

This rule also provides that when creating these internal policies, MA organizations must provide in a publicly accessible way: the internal coverage criteria in use and a 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 an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination, which includes, when applicable, identifying the general provisions that are being supplemented or interpreted and explaining how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

We expect that each plan will have new policies that they create annually.

We believe that the public accessibility of a plan's internal coverage criteria, a summary of evidence that was considered; a list of the sources of such evidence; and an explanation of the rationale that supports the adoption of the coverage criteria will require 16 hours per contract. We believe this is an adequate estimate of time needed for a business operations specialist to make all postings. Thus the per contract burden is 16 hours at a cost of \$1,219 (16 hr * \$76.20)

and the aggregate burden over 697 contracts is 11,152 hours (697 contracts * 16 hr /contract) at a cost of \$849,782 (11,152 hr * \$76.20/hr)

We invited stakeholder comment on all aspects of this proposal. More specifically, we questioned (1) is our assumption that plans are already complying with the requirement of creating new guidance correct? (2) is our assumption of 16 hours annually sufficient? (3) Are there any other aspects of this proposal or its estimates upon which stakeholders have comments?

Comments were received. Some commenters stated that publicly posting a summary of evidence considered during the development of the criteria would require significant administrative effort. However, we did not receive specific comments on our estimates and are therefore finalizing our burden estimates for public posting of guidance as proposed. However, the stakeholder comments of increased administrative burden are consistent with our statement in the preamble and RIA, that due to its complexity and many unknowns we cannot quantify the burden of the requirement to create new policies when existing guidance does not exist.

6. ICRs Regarding Utilization Management (UM) Committee (§ 422.137)

The following changes will be submitted to OMB for approval under control number 0938-0964 (CMS-10141) (reference to this package was inadvertently left out of the proposed rule). We are correcting that oversight in this final rule.

This rule adds protections to help ensure that beneficiaries maintain access to medically necessary Part A and B services and drugs, while permitting MA plans to use utilization management tools, such as prior authorization. This rule requires that MA plans establish and use a committee (similar to a P&T committee) that reviews UM policies annually to ensure the policies are consistent with current traditional Medicare coverage and guidelines in Medicare statutes and regulations, NCDs, and LCDs. This final rule also requires that the committee review all medical services that require PA and other utilization management policies, at least on an annual basis and to document their findings. Additionally, the committee will be responsible for revising and updating the MA plan's utilization management policies as needed.

In this rule, 422.137 (c)(1) through (4) specifies that the UM committee must clearly articulate and document processes to determine that the committee membership requirements under 422.137(c)(1) through (4) have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. We estimate it would take 1 hour at \$76.20/hr for an UM Committee business specialist to perform the tasks enumerated in the previous paragraph and review and retain documentation and information on an annual basis. Additionally, at § 422.137(d)(4) and (5) specifies that the committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. We estimate that it will take 2 hours at \$ 76.20/hr for a UM Committee business specialist to capture and retain this required documentation on an annual basis.

In aggregate, the burden for 697 MA plans is 2,091 hours (697 plans * 3 hr) at a cost of \$159,334 (2,091 hr * \$76.20/hr).

We did not receive any comments related to our proposed provisions and projected burden estimates. Consequently, we are finalizing the proposed provisions and burden without change.

7. ICRs Regarding Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service (§§ 422.566 and 422.629)

The following changes will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267).

In section III.G. of this final rule, we are finalizing the proposal to strengthen the current requirement at §§ 422.566(d) and 422.629(k)(3) for who must review an organization determination or an integrated organization determination when the MA organization or AIP expects to issue a partially or fully adverse medical necessity decision.

Under this new requirement, the reviewing physician or health care professional must have expertise in the field appropriate to the requested service. This requirement will also apply to coverage denials from section 1876 cost plans and healthcare prepayment plans because §§ 417.600 and 417.840 require those plans to comply with the requirements in the MA regulations regarding organization determinations.

As stated in the proposed rule, we do not believe this requirement imposes additional staffing burden on plans. In light of existing review requirements applicable to organization determinations and integrated organization determinations, coupled with the requirements at § 422.152 for MA plans (including AIPs) to engage in ongoing quality improvement (including in processing requests for initial or continued authorization of services) and the contract requirement provisions at § 422.504, we believe plans already have the requisite expertise in staffing to satisfy this requirement. The requirement that the physician or other appropriate health care professional have expertise in the field appropriate to the requested service may at most result in plans reallocating staff resources in certain cases to ensure that someone with appropriate expertise is reviewing the request; however, we don't believe that this requirement will require additional staffing for MA organizations and AIPs.

This requirement is expected to yield savings due to fewer denied organization determinations getting into the appeals process as a result of enhanced medical necessity review by appropriate experts.

TABLE 6: EXPECTED IMPACT OF REQUIREMENT ON APPEALS

Row ID	Item	CMS-R-267, 2022 Version	CMS-R-267, CMS-4201-F	Changes
A	Number of pre-service decisions	31,346,194	31,346,194	No change
B	Percent of unfavorable pre-service organization determinations	0.057	0.0285	We assume a savings of 50% in unfavorable decisions
C	Number of unfavorable pre-service organization determinations	1,786,733	893,367	Product of previous two rows, A*B, (-893,366 or roughly 50% savings)
D	Percent of unfavorable pre-service organization determinations that are appealed	0.09*	0.09	No change
E	Number of unfavorable pre-service organization determinations that are appealed	160,806	80,403	Product of previous two rows, C*D, (-80,403 or 50% savings)
F	Percent of appeals resulting in an overturn	0.81**	0.81	No change
G	Number of appeals resulting in an overturn	130,253	65,126	Product of previous two rows, E*F, (-65,127 or roughly 50% savings)
H	Time for a single appeal notifications (hr)	0.25***	0.25	No change

I	Savings: Total Time (hr)	32,563	16,282	Product of previous two rows, G*H, (-16,281 or roughly 50% savings)
J	Wage of business operations specialist	\$76.20/hr	\$76.20/hr	No change
K	Total Cost	\$2,481,301	\$1,240,688	Product of previous two rows, I*J
L	Savings, (Dollars)		1,240,688	Difference of columns in row K (\$2,481,301 - \$1,240,688). (The rounding reflects that both cost and savings use the same wage and should therefore be identical)

*This percentage is not used in the CMS-R-267, 2022 package which arrives at 242,795 The documentation for these numbers is not presented and we believe it inaccurate. See the narrative for complete details.

**The CMS-R-267, 2022 package uses 75 percent. This has been corrected to 81 percent based on a re-examination of the underlying data. See the narrative for complete details.

*** The CMS-R-267, 2022 package uses 4 hours for the total time of processing an appeal without ear-marking the time needed specifically for notification. We believe 15 minutes (0.25 hr) to be a reasonable time for notification and consistent with the 4 hour estimate of CMS-R-267. See the narrative for complete details.

To estimate these savings we considered the following:

- Number of unfavorable pre-service organization determinations: The 2022 CMS-R-267 reports 1,786,733 (Row C of Table 6) which equals 5.7 percent (Row B), (the percent of unfavorable pre-service organization determinations), times 31,346,194 (Row A) (the total number of pre-service organization determinations.) We re-examined the underlying 2020 MA plan reported data and still believe this to be correct. You can find this computation in rows A - C of Table 6.

- Number of unfavorable pre-service organization determinations that are appealed. The 2022 CMS-R-267 comes up with 431 per plan or 242,653 appealed pre-service organization determinations. This number appeared excessively low to us. Additionally, this number was derived in the 2022 CMS-R-267 by taking 5% * 20% * 24,279,575. There is no documentation explaining the percentages or the number. Accordingly, we re-examined the underlying 2020 MA plan data. The aggregate percentage of unfavorable pre-service organization determinations that are appealed is 9 percent (Row D). Using this we calculate 160,806 (Row E) appealed unfavorable decisions (0.09 * 1,786,733). We note that 160,806 is in the ballpark of the 242,795 used in the 2022 CMS-R-267 package but as noted the documentation for the calculations is not presented and a reexamination of the data gives 160,806. Accordingly, we are correcting that number from the CMS-R-267 package in the base we use for impact. These calculations are also conveniently summarized in Table 6 in rows C – E.

- Percent of appeals resulting in an overturn: The CMS-R-267 package uses a figure of 75 percent. However, upon reexamination of the same underlying data we found the percentage to be 81 percent (Row F). We believe the 81 percent is more accurate and are therefore correcting the base figures on which we base our impact. We note that in this Collection of Information Section we are basing all numbers on aggregate percentages from total appeals rather than the approach used in the CMS-R-267 package which was based on the per-plan percentage. The process of using per-plan may result in unintended approximations which may account for some of the inaccuracies discovered.

- Time for a single appeal notification: The CMS-R-267 package lists 4 hours as the time necessary to totally process an appeal including notification. The amount of time from this 4 hours targeted specifically to notification is not listed in the package. We believe 15 minutes (Row H) (0.25 hr) is an adequate and reasonable allocation of time for notification. This requirement has no impact on the time required for an appeal notification. The calculations are summarized in Table 6 and are summarized as follows.

As just explained, according to 2020 MA plan reported data, 1,786,733 (5.7 percent of all 31,346,194 Medicare pre-service organization determination decisions) are unfavorable coverage decisions (the decision is fully or partially unfavorable to the enrollee). Of this universe of unfavorable pre-service organization determinations, 160,806 cases (9 percent * 1,786,733) are appealed and subject to reconsideration by the plan. Of the cases reviewed on appeal, 130,253 cases (81 percent * 160,806 cases) of the reconsiderations resulted in a plan overturning its unfavorable organization determination (Rows A – G of Table 6)..

Thus, the total burden is 32,563 hr (Row I) (130,253 cases * 0.25 hr/case) at a cost of \$2,481,317 (Row K) (32,563 hr * \$76.20/hr for a business operations specialist).

While we don't know with certainty what the reduction in existing denied organization determinations will be under this new requirement, we believe it is reasonable to estimate that 50 percent (Row B) of the existing volume of denials will result in a favorable decision given the

enhanced standard of review. In other words, having a physician or other health care professional with expertise in the field of medicine appropriate to the requested service will result in a favorable organization determination decision, thereby reducing the number of cases potentially subject to appeal. In the absence of further information, we believe this a reasonable assumption. We also explicitly note that given that a decision is still unfavorable, even with an expert review, we believe the other percentages (such as the overturn rate and rate of appeals) remains unchanged.

Savings: To estimate savings associated with this finalized rulemaking, we note that Table 6 estimates 50 percent of the burden of the current practice and hence the savings is also 50 percent. That is, the numbers in Table 6 in the column with this rule's burden estimates are numerically equal to the savings: 16,281 hours (32,563 hr - 16,282 hr) and \$1,240,688 (\$2,481,301 - \$1,240,688) (Row L).

We received no comments on our proposed requirement and burden estimates and are finalizing them as is.

8. ICRs Regarding Strengthening Translation Requirements for Medicare Advantage, Part D, and D-SNP Enrollee Marketing and Communication Materials: Standing Request for Translated Materials or Materials in Alternate Formats (§§ 422.2267 and 423.2267)

This rule requires that FIDE SNPs, HIDE SNPs, and AIPs translate materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

This rule slightly modifies existing policy, so the impact to FIDE SNPs, HIDE SNPs, and AIPs depends upon whether, and to what extent, these plans are already translating materials in ways that would meet this rule's requirements. We note that translation requirements vary by State. Therefore, we expect no impact in States where the applicable Medicare and Medicaid translation requirements result in the same outcome. We expect marginal impacts where State requirements result in translation into languages not required by the current MA rules at §§

422.2267(a)(2) and 423.2267(a)(2). However, even in these States, FIDE SNPs, HIDE SNPs, and AIPs (in combination with their affiliated Medicaid managed care plans) have translators on staff or access them via contractors because of existing Medicare and Medicaid translation requirements.

Consistent with our April 15, 2011 final rule (76 FR 21536), (CMS-4144-F, RIN 0938-AQ00), we continue to claim that the Medicare translation requirement is exempt from the requirements of the PRA since the time, effort, and financial resources necessary to comply with this rule's translation requirements is a usual and customary business practice (see 5 CFR 1320.3(b)(2)). FIDE SNPs, HIDE SNPs, and AIPs are already required to translate all Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into language(s) required by the Medicare translation standard at § 422.2267(a) and meet obligations for translation or interpretation services under 45 CFR § 92.101. The requirements we are finalizing as proposed at §§ 422.2267(a)(4) and 423.2267(a)(4) would require that these Medicare materials also be translated into any additional languages required by Medicaid. Since FIDE SNPs, HIDE SNPs, and AIPs are already translating these Medicare materials for enrollees on their language preferences as part of their usual and customary business practice, the finalized requirements do not establish any new disclosure, information collection, or record keeping requirements. For a full accounting of the translation burden, please see section IX.D.3.b. of this final rule.

9. ICRs Regarding Medicare Advantage (MA) and Part D Communications and Marketing (Subpart V of Parts 422 and 423)

The following changes will be submitted to OMB for approval under control number 0938-1442 (CMS-10837). The control number and expiration date have yet to be issued. The issuance can be monitored at reginfo.gov.

The proposed rule mistakenly set out CMS-10260 (0938-1051) as the collection of information request's CMS and OMB identification numbers, respectively. We are correcting that oversight in this final rule.

This rule sets forth several changes to the marketing policies in subpart V of parts 422 and 423. Each of these changes will require updates to policies and procedures on the part of a business operations specialist, entailing the addition of a phrase or sentence and, as such, not requiring much time.

For this rule's reinstatement of the prohibition on MAOs and Part D sponsors marketing outside of their service areas (unless unavoidable), we estimate 30 minutes (0.5 hr) to implement the change to policies and procedures (0.5 hr x \$76.20/hr = \$38.10).

For our reinstatement of the prohibition on sales presentations following educational events, we estimate 15 minutes (0.25 hr) to implement the change to policies and procedures (0.25 hr x \$76.20/hr = \$19.05).

For our reinstatement of the prohibition on distribution and collection of Scope of Appointment and Business Reply Cards by agents at educational events, we estimate 0.25 hours to implement the change to policies and procedures (0.25 hr. x \$76.20/hr = \$19.05).

For our reinstatement of the prohibition on conducting a sales/marketing or enrollment meeting with a beneficiary before 48 hours after the beneficiary's initial consent to the meeting (via scope of appointment), we estimate 0.25 hours to implement the change to policies and procedures (0.25 hr x \$76.20/hr = \$19.05).

For the clarification of the requirement of a plan to notify CMS of any agent that fails to adhere to CMS requirements, we estimate 0.5 hours to implement the change to policies and procedures (0.5 hr x \$76.20/hr = \$38.10). We estimate that this policy change does have burden, however we have no way of estimating the number of agents and frequency of which they will violate CMS requirements. Therefore, we cannot estimate it.

For the requirement that agents/brokers inform beneficiaries that the beneficiaries can obtain complete Medicare information from 1-800-MEDICARE, SHIPs, or Medicare.gov, we estimate ½ hour to implement the change to policies and procedures (0.5 hr x \$76.20/hr = \$38.10).

For the requirement that agents/brokers ask a standardized list of questions prior to enrolling the beneficiary in a plan, we estimate 0.5 hours to implement the change to policies and procedures ($0.5 \text{ hr} \times \$76.20/\text{hr} = \38.10). CMS has already developed the questions as part of the Pre-Enrollment Check List. CMS does not require agents/brokers to develop the questions themselves. As the questions were already developed, and the development was by CMS staff, development of the questions does not incur COI burden.

For the requirement that agents/brokers inform beneficiaries of all the plans the agent/broker actually sells, we estimate 0.25 hours to implement the change to policies and procedures ($0.25 \text{ hr.} \times \$76.20/\text{hr.} = \$19.05$).

For the changes that clarify the prohibition of the use of the term “Medicare” or CMS’s logos in a way that is misleading or confusing or which misrepresents the plan, we estimate $\frac{1}{4}$ hour to implement the change to policies and procedures ($0.25 \text{ hr} \times \$76.20/\text{hr} = \19.05).

Thus, the total one-time burden per contract for these marketing provisions is 3.25 hours ($0.5 \text{ hr} + 0.25 \text{ hr} + 0.25 \text{ hr} + 0.25 \text{ hr} + 0.5 \text{ hr} + 0.5 \text{ hr} + 0.5 \text{ hr} + 0.25 \text{ hr} + 0.25 \text{ hr}$ for the time required to update policies and procedures on the prohibitions of marketing outside the service area, of sales following educational events, of distribution of business cards, as well as the required 48-hour wait time for agents, reporting to CMS delinquent agents, disclosing 800-Medicare, using a standardized list of questions, for agents to notify beneficiaries of all plans they represent, and to avoid misleading use of the Medicare log respectively) at $\$76.20/\text{hr}$ for a total of $\$247.65$. The aggregate burden across 697 contracts is 2,265 hr ($3.25 \text{ hr} * 697 \text{ contracts}$) at a cost of $\$172,593$ ($\$76.20/\text{hr} * 2,265 \text{ hr}$).

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

As discussed in section V. of this final rule, this rule adds, removes, and updates certain measures, replaces the current reward factor with a new HEI reward to further incentivize Part C and D plans to focus on improving care for enrollees with specific SRFs, reduces the weight of

patient experience/complaints and access measures, adds a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, and removes the 60 percent rule that is applied when adjusting Star Ratings for extreme and uncontrollable circumstances (for example, natural disasters like hurricanes or public health emergencies). The HEI is a different way for CMS to analyze existing data and will not increase plan burden. Most of the new measures will be calculated from administrative data and, as such, there will be no increase in plan burden. The other measure-level change we are finalizing in this rule entails moving an existing measure from the display page to Star Ratings, which also will have no impact on plan burden. This rule also sets out a series of technical clarifications related to adjusting Star Ratings for extreme and uncontrollable circumstances and consolidations. The provisions will not change any respondent requirements or burden pertaining to any of CMS's Star Ratings related PRA packages, including: OMB control number 0938-0732 for CAHPS (CMS-R-246), OMB control number 0938-0701 for HOS (CMS-10203), OMB control number 0938-1028 for HEDIS (CMS-10219), OMB control number 0938-1054 for Part C Reporting Requirements (CMS-10261), and OMB control number 0938-0992 for Part D Reporting Requirements (CMS-10185). Since the provisions will not impose any new or revised information collection requirements or burden, we are not making any changes under any of the aforementioned control numbers.

11. ICRs Regarding the PACE Service Determination Process (§ 460.121)

The following changes will be submitted to OMB for approval under control number 0938-0790 (CMS-R-244).

Section 460.121 currently includes the service determination process PACE organizations are required to follow and only allows PACE organizations to notify participants and/or their representatives of service determination extensions in writing. Per the burden estimate currently approved by OMB (CMS-R-244), we estimate the burden of the current extension notification requirements at § 460.121 to be 2,350 hours and \$140,812 in aggregate. As discussed in section

VI.E. of this final rule, we are finalizing our proposal to allow PACE organizations to notify the participant or their designated representative either orally or in writing when the PACE organization extends the timeframe for making a service determination. We expect that PACE organizations will prefer to provide oral notification more frequently than written notification, because oral notification is less time consuming. This belief is further supported by commenters on this proposal, who unanimously agreed the proposed change would reduce burden for PACE organizations. Due to PACE organizations' preference for oral notification over written notification and the 45 minutes per response reduction in burden oral notification offers, we estimate that the proposed change will reduce the burden of the extension notification requirements at § 460.121.

To estimate the decreased burden, we considered: (1) the annual number of extension notifications; (2) the estimated proportions of extension notifications that are provided orally or in writing; and (3) the estimated time required to complete oral and written notification.

First, we reviewed extended service determination requests (SDRs) from 2019 through 2021 and found that there were 6,564 total extended SDRs nationally (3,942 in 2019 + 773 in 2020 + 1,849 in 2021). Then we averaged the number of extended SDRs from 2019 – 2021 to calculate 2,188 extended SDRs annually (6,564 total extended SDRs / 3 years), which is about 15 extended SDRs per PACE organization annually (2,188 extended SDRs annually / 149 PACE organizations).

Secondly, we estimate, based on our experience with audits of similar areas of PACE requirements where PACE organizations have an option of oral or written notification, that 80 percent of extension notifications will be provided orally, at 15 minutes per notification, and 20 percent will be provided in writing at 1 hour per notification. The hourly wage for notification by an MSW in both cases is \$59.92/hr. In aggregate, the new burden is 875 hours ((2,188 extension notifications * 0.2 written notifications * 1 hr) + (2,188 extension notifications * 0.8 oral notifications * 0.25 hr)) at a cost of \$52,430 (875 hours * \$59.92/hr).

Thus, the aggregate annual time and cost savings for the change is minus 1,475 hours (2,350 hours under current provisions minus 875 hours as documented in the pending OMB package) and minus \$88,382 (\$140,812 cost under current provisions minus \$52,430 under the pending OMB package). Additionally, at the individual service determination request extension level, PACE organizations that choose to provide oral notification instead of written notification will save minus 0.75 hours and \$44.94 per extension notification.

We did not receive any comments related to our proposed provisions and burden estimates. Consequently, we are finalizing them without change.

12. ICRs Regarding Safeguarding Data and Records and Medical Record Requirements (§§ 460.200 and 460.210)

PACE organizations are currently required to retain original communications related to a participant's care, health, or safety in the medical record. In this proposal, we are removing the requirement that these communications be stored in the participant's medical record, provided certain conditions are met. Therefore, our burden estimates include costs incurred related to staff (1) training; (2) software development; (3) file cabinets for document storage; and (4) updating/maintaining the organizations' policies and procedures.

- Training: We estimate that a PACE organization will spend 40 hours at a cost of \$2,916 (40 hours × \$72.90/hr) for a compliance specialist to establish training materials. In aggregate, we estimate a one-time burden of 5,960 hours (40 hours x 149 POs) at a cost of \$434,484 (5,800960 hours x \$72.90/hr).

- Software development: We estimate that PACE organizations will spend 40 hours at a cost of \$4,654 (40 hours x \$116.34/hr) for a software developer to make the appropriate software updates. In aggregate, we estimate a one-time burden of 5,960 hours (40 hours x 149 POs) at a cost of \$693,386 (5,960 hours x \$116.34/hr).

- Storage: We estimate that a PACE organization will spend a total of \$300 (2 × \$150/each) for 2 four-drawer locking file cabinets. In aggregate, we estimate a one-time non-labor cost of \$44,700 (\$300 x 149 POs).

- Update policies and procedures: We estimate that PACE organizations will spend 10 hours at a cost of \$729 (10 hours x \$72.90/hr) for a compliance specialist to update and maintain related policies and procedures. In aggregate, we estimate a one-time burden of 1,490 hours (10 hours x 149 POs) at a cost of \$108,621 (1,490 hours x \$72.90/hr).

The aggregate of this provision is a one-time impact of 13,410 hours (5,960 hours (training materials) + 5,960 hours (software development) + 1,490 hours (policy updates) at a cost of \$1,282,191 (\$434,484 (training materials) + \$693,386 (software updates) + \$44,700 (nonlabor purchase of storage) + \$108,621 (policy updates).)

These changes will be submitted to OMB for approval under control number 0938-0790 (CMS-R-244). Since PACE organizations are already required to retain original communications related to a participant's care, health, or safety, and to make these communications accessible to CMS and the SAA upon request, this proposal does not impose any new information collection requirements for PACE organizations.

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

In this rule, we revise the Part D LIS income and resource standards at § 423.773 to expand eligibility for the full benefit to individuals who currently have the partial benefit and make a coordinating change in § 423.780. This will change the level of assistance that an individual could qualify for in paying their Part D premiums, copays and deductibles. While there will be no change in the number of individuals eligible for the Part D LIS, it will create a transition of people from partial subsidy status to full subsidy status.

The burden associated with determining eligibility for the Part D LIS is the time and effort for States or SSA to verify the income and resources and report eligibility to beneficiaries

and CMS annually. Most individuals who qualify for the Part D LIS do so because they qualify for Medicaid or other assistance in their State. The burden for States to determine and report eligibility is currently approved by OMB under control number 0938-0467 (CMS-R-74) at 54 respondents, 3,241 annual responses, a variable amount of time per response, and 1,082 estimated annual hours.

We did not receive any comments related to our proposed provisions and burden estimates. Consequently, we are not making any changes to any of the requirements or burden estimates that are currently approved by OMB under control number 0938-0467.

C. Summary of Information Collection Requirements and Associated Burden Estimates

TABLE 7: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN*

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Cost First Year (\$)	Total Cost Subsequent Years (\$)
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program	0938-1441 (CMS-10831)	Enrollees**	36982	0.25	9246	20.71	191,485	191,485
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program	0938-1441 (CMS-10831)	Pharmacists (on behalf of enrollees) ***	36,722	0.0333	1223	120.86	147,812	147,812
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program	0938-1441 (CMS-10831)	LI NET sponsor (on behalf of enrollees) ***	36982	0.0333	1232	76.20	93,878	93,878
422.116	New Behavioral Specialty Types	0938-1346	MA Organizations**	742	0.0833	62	76.20	4,724	-
422.111 and 422.2267	MA Provider Termination Notices	0938-0753 (CMS-R-267)	MA Organizations**	697	8	5576	92.92	518,122	
422.100 and 422.101	Posting New PA Guidance		MA Organizations**	697	16	11,152	76.20	849,782	849,782
422.137	Utilization Management Review Committee	0938-0964	MA Organizations**	697	3	2,091	76.20	159,334	159,334
422.566 and 422.629	Medical Necessity Decisions		MA Organizations & Section 1876 Cost plans (total overturned appeals) ***	65126	-0.25	(16,282)	76.20	(1,240,688)	(1,240,688)
422.2261, 422.2264, 422.2265, 422.2267, 422.2274, 423.2261, 423.2264, 423.2267, and 423.2274	Marketing Provisions	0938-1051 (CMS-10260)	MA Organizations**	697	3.25	2,265	76.20	172,593	172,593
460.121	PACE Service Determination Process	0938-0790 (CMS-R-244)	PACE Organizations (total extension notifications) ***	2,188	-0.674	(1,475.0)	59.92	(88,382)	(88,382)
460.200 and 460.210	Safeguarding data	0938-0790 (CMS-R-244)	PACE Organizations**	149	40	5960	72.90	434,484	0
460.200 and 460.210	Safeguarding data: Software updates	0938-0790 (CMS-R-244)	PACE Organizations**	149	40	5960	116.34	693,386	0
460.200 and 460.210	Safeguarding data: Storage	0938-0790 (CMS-R-244)	PACE Organizations**	149			300.00	44,700	0
460.200 and 460.210	Safeguarding data: Updating policies	0938-0790 (CMS-R-244)	PACE Organizations**	149	10	1490	72.90	108,621	0
Totals				<i>Varies</i>		28,500		2,089,851	285,814

*Blank cells in the “Total Cost Subsequent Years” column indicates no cost since the provision only has a first-year cost.

** For the cells marked with a double asterisk the number of respondents is equal to the number of responses.

*** For rows with three asterisks, calculations are not based on respondents but rather on the items indicated in parenthesis.

VIII. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this final rule is to amend the regulations for the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). This final rule, besides codifying existing Part C and Part D sub-regulatory guidance also includes a number of new policies from the Bipartisan Budget Act (BBA) of 2018., the Consolidated Appropriations Act, 2021 (CAA), and the Inflation Reduction Act of 2022 (IRA), that would improve these programs.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. § 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f)(1) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities ; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency;

(3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by having an annual effect of \$100 million or more in any 1 year, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately \$177 million. This final rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of \$177 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 795 contracts (which includes MA, MA-PD, and PDP contracts), 55 State Medicaid Agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major PBMs). We expect that each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is \$115.22 per hour, including fringe benefits, overhead, and other indirect costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 19 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore \$2,200 (19 hours x \$115.22). Therefore, we estimate that the maximum total cost of reviewing this final rule is \$ 5.3 million (\$2200 x 2,000 reviewers). However, we expect that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be \$ 0.5 million.

Note that this analysis assumes one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by OMB.

C. Impact on Small Businesses – Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

We proposed a wide range of policies in the proposed rule. These policies codify, modify, and update current guidance governing MA organization bid requirements.

This rule has several affected stakeholders. They include: (1) MA organizations such as HMOs, local and regional PPOs, MSAs, PFFS and Part D sponsors, PACE plans, and Stand Alone Part D plans (PDP) (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies; and (3) enrollees. Some descriptive data on these stakeholders are as follows:

- Pharmacies and Drug Stores, NAICS 446110, have a \$30 million threshold for “small size” with 88 percent of pharmacies, those with under 20 employees, considered small.

- Direct Health and Medical Insurance Carriers, NAICS 524114, have a \$41.5 million threshold for “small size,” with 75 percent of insurers having under 500 employees meeting the definition of small business. Several Medicare Advantage plans (about 30-40 percent) are not-for-profit resulting in a “small entity” status.

- Ambulatory Health Care Services, NAICS 621, including about 2 dozen subspecialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from \$8 to \$35 million (Dialysis Centers, NAICD 621492, have a \$41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed \$34 million.

- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, Specialty Hospitals have a \$41.5 million threshold for small size, with half of the hospitals (those with between 20-500 employees) considered small.

- Skilled Nursing Facilities (SNFs), NAICS 623110, have a \$30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this FC does not have a significant economic impact on a substantial number of small entities. To explain our position, we explain certain operational aspects of the Medicare program.

Each year, MA plans, including Part D sponsors, submit a bid for furnishing Part A and B benefits and the entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay basic premium, thus this percentage of plans is not "significant" as defined by the RFA and as justified in this section of this rule). The costs of stand-alone Part D plans, PDPs, is also covered by the Medicare Trust Fund. PACE plans have their costs covered by both the Medicare Trust Fund as well as the States they negotiate with.

MA plans and Part D Sponsors can also offer enhanced benefits, that is, benefits not covered under Original Medicare. These enhanced benefits are paid for through enrollee premiums, extra government payments or a combination. Under the statutory payment formula, if the bid submitted by an MA plan (including Part D sponsors) for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is, benefits not covered under Original Medicare) and or/low beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the government's payments to plans for the bid plus the rebate exceeds costs in Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original Medicare who do not have the additional health services available in many MA plans.

Part D plans, including MA-PD plans, submit bids and those amounts are paid to plans through a combination of Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries, Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by a variety of government funding and in some cases by enrollee premiums. As a result, MA plans, Part D plans, Prescription Drug Plans, and PACE plans are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this final rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For the insurance plans classified in category Direct Health and Medical Insurance Carriers, NAICS 524114, which include MA plans, Part D sponsors, standalone PDPs, and PACE plans, the plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either--(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

If an MA plan or Part D sponsor bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees a premium for that amount. Historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. Since the number of plans bidding above the benchmark is 2 percent, this is not considered substantial for purposes of the RFA. Note that PACE plans while not submitting bids (except for Part D) in the same sense as MA plans, estimate their costs and these amounts are covered by a combination of funding from the Trust Fund and the States in which they operate.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

Besides the direct costs, as previously discussed, are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of MA plans (including MA-PD plans) bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government. However, the government additionally pays the plan a “beneficiary rebate” amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan’s quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also partially be paid by enrollee premiums.) However, as noted previously, the number of plans bidding above the benchmark to whom this burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this rule would otherwise cause bids to increase, plans will reduce their profit margins, rather than substantially change their benefit package. This may be in part due to market forces; a plan lowering supplemental benefits even for 1 year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

We note that we do not have definitive data on this. Plans do not report to CMS the strategies behind their bids. More specifically, when supplemental benefits are reduced, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes. Notably, it may be inappropriate to consider the relevant regulatory impacts (and thus the profit considerations) as temporary because the issuance of a series of regulations

sustains the effects.¹⁷¹ As a result, changes in benefits packages may be plausible and we requested comment on the assessment of this outcome in association with this final rule.

We next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for: (1) Pharmacies and Drug Stores, NAICS 446110; (2) Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) SNFs, NAICS 623110.

If these providers are contracted with the plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments.

The rules for non-contracted providers servicing plan enrollees depends on the plan type involved. Non-contracted providers in both MA and MA PD plans are not expected to incur burden from a final rule because the regulations (42 CFR 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act) require they be paid at least the FFS Rate. PACE must provide only contracted providers to its participants (42 CFR 460.70(a)). Similarly non-contracted pharmacies are a sporadic issue in stand-alone drug plans which are encouraged to limit out of network access to those situations when it is required (42 CFR 423.124). PACE plan participants must obtain services either from the PACE organization or from its contracted providers (42 CFR 470(a)). Consequently, non-contracted providers have no additional cost burden above the already existing burden in original Medicare.

¹⁷¹Indeed, see similar discussion in previous regulatory impact analyses:
<https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and> and
<https://www.federalregister.gov/documents/2022/04/14/2022-07642/medicare-program-maximum-out-of-pocket-moop-limits-and-service-category-cost-sharing-standards>

Consequently, consistent with our conclusions stated earlier, the Secretary has certified that this final rule will not have a significant impact on a substantial number of small entities.

D. Anticipated Effects

Many provisions of this final rule have negligible impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact that cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when we estimated that provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions are estimated in section VIII of this final rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts from section VIII. of this final rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been experienced as a direct result of the statute. For further discussion of what is estimated in this Regulatory Impact Analysis, see Tables 13 and 14 and the discussion afterwards.

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

This rule implements section 118 of the CAA, which amends section 1860D-14 of the Act, to establish the Limited Income Newly Eligible Transition (LI NET) Program as a permanent part of Medicare Part D. This will ensure that the transitional drug coverage currently provided to low-income Medicare beneficiaries under the LI NET demonstration will continue indefinitely. Therefore, we anticipate this rule will advance health equity by improving low income individuals' access to continuous, affordable health coverage, consistent with Executive Order 13985, issued January 20, 2021, on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. We also believe it will improve the customer

service experience of low-income beneficiaries consistent with the goals of the Executive Order 14058, Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government.

Using drug cost data from 2021, the CMS Office of the Actuary (OACT) projects the following program costs (in millions of dollars) over the next 10 years:

TABLE 8: PROJECTED LI NET PROGRAM COSTS (\$ in MILLIONS)

	Fiscal Year									
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Costs	5	7	8	9	9	10	11	11	12	13

We note that OACT has provided cost/savings estimates each year under the LI NET demonstration, and it has not altered its methodology based on the program becoming permanent. Therefore, these projected costs are the same as what the government would have incurred if the demonstration continued. Further, the costs of the payments provided for under the LI NET program will continue, as under the demonstration, to be covered through the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance (SMI) Trust Fund. Also note that we are classifying these payments of the Medicare Trust Fund as transfers from the Trust Fund to the LI NET sponsor.

We received no comments on this section and therefore are finalizing this provision without modification.

2. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service (§§ 422.566 and 422.629)

The provision that a physician or other health professional with expertise in the field of medicine appropriate to the requested service review any decision about medical necessity before an MA plan may issue an adverse organization determination was intended to provide a more meaningful clinical review informed by specific expertise. As stated in the proposed rule, we

believe this enhanced level of review will reduce unnecessary appeals, delays in treatment and the potential for adverse outcomes.

In the proposed rule, we quantified the expected reduced appeals in the Collection of Information section, quantifying the costs of effects of delay in treatment and consequent possible adverse medical complications is not possible because we lack adequate data. In addition to requesting comment on these effects, we sought feedback on the opportunity cost of medical experts' time when reallocated for the purpose of compliance with this provision. We did not receive comments on this impact analysis. We are finalizing this provision without modification.

3. Strengthening Translation Requirements for Medicare Advantage and D-SNP Enrollee Marketing and Communication Materials: Require HIDE SNPs and FIDE SNPs to translate materials into the more stringent of the Medicare or Medicaid translation standards (§§ 422.2267 and 423.2267)

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

We proposed to specify in Medicare regulations that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a standing basis in an accessible format or any non-English languages that is the primary language of at least 5 percent of the individuals in a plan benefit package service area upon receiving a request for the materials or otherwise learning of the enrollee's preferred language. The proposal would also extend to individualized plans of care for special needs plans.

Our final rule clarifies existing policy. Therefore, the impact to MA organizations, cost plans, and Part D plan sponsors depends on whether, and to what extent, they currently have processes in place to note an enrollee's language preference and need for an alternate format. As described in this section of this final rule, we believe many plans would not incur significant cost from the proposed requirement because plans currently comply with the proposal.

Enrollees who need translated materials or materials in an accessible format who are enrolled in MA, cost, or Part D plans that do not currently create a standing request for these materials would likely spend less time contacting their plan to request these materials as a result of this proposal. Any MA, cost, or Part D plan that has not created a standing request for enrollees requiring translated materials or materials in an accessible format would likely reduce their efforts to accept requests and resend the translated materials or materials in an accessible format.

CMS received information from Medicare-Medicaid Plans (MMPs) in Ohio and California about their requests for translated materials in 2021 and 2022. We include our assumptions from these discussions, but we sought comment on additional information that may better inform our estimates. Of the five MMPs in Ohio in 2021, only one of the plans accepted standing requests for translated materials or materials in an accessible format. A higher proportion (86 percent) of seven California MMPs that responded had established standing requests due to State oversight ensuring California MMPs followed the State-specific marketing guidance; however, we believe the Ohio MMPs landscape better represents MA organizations as a whole. Therefore, we estimate that 20 percent or 171¹⁷² MA organization, cost plan, and Part D plan sponsor contracts are currently accepting standing requests and would not be impacted by this proposal. Therefore, an estimated 80 percent or 683 MA organization, cost plan, and Part D plan sponsor contracts would need to implement this proposed requirement. We believe our analysis of MMP plans, which cover Part C and Part D benefits, also applies to MA organization, cost plan, and Part D plan sponsors. We requested comment on whether MA organization, cost plan, and Part D plan sponsors accept standing requests for translated materials or materials in an accessible format at a greater or lesser extent than MMPs.

¹⁷²Based on 854 MA, cost, and Part D plan sponsor contracts in the May 2022 Monthly Contract and Enrollment Summary Report. Retrieved from <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldatamonthly/contract-summary-2022-05>

Based on the information we received from MMPs, we are uncertain if establishing a standing request for translated material or materials in an accessible format will increase or decrease administrative cost for the estimated 683 MA organization, cost plan, and Part D plan sponsor contracts impacted by our proposal. Based on information from MMPs who have implemented a standing request, we believe establishing a process for standing requests would require about 200 hours of business operations specialist¹⁷³ time during the first year or 136,600 hours (200 hr * 683 MA, cost, and Part D contracts) at a cost of \$10,408,920 (136,600 hr * \$76.20/hr wage for a business operations specialist).

We assume that this initial cost would be offset by a reduction in cost for MA organizations, cost plans, and Part D plan sponsors to resend materials in the correct translated or accessible format. We also expect that implementing a standing request process would reduce future costs to MA organizations, cost plans, and Part D sponsors by decreasing rework of sending two sets of information, one in the incorrect language or format and the other in the correct format. However, establishing a standing request for translated material or materials in an accessible format could result in more enrollees requesting to consistently receive these materials at an additional cost to MA organizations, cost plans, and Part D plan sponsors. We requested comment on our assumptions and the potential savings or costs to MA organizations, cost plans, and Part D plan sponsors.

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

We proposed to require that FIDE SNPs, HIDE SNPs, and AIPs translate materials into any languages required by the Medicare translation standard plus any additional languages

¹⁷³Based on the BLS wage information for business operations specialist (code 13–1199) whose wage we estimate at \$76.20 per hour, including fringe benefits and overhead costs (http://www.bls.gov/oes/current/oes_nat.htm).

required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

Our final rule slightly modifies existing policy, so the impact to FIDE SNPs, HIDE SNPs, and AIPs depends upon whether, and to what extent, these plans are already translating materials in ways that would meet our proposed requirements. We note that translation requirements vary by State. Therefore, we expect no impact in States where the applicable Medicaid and Medicaid translation requirements result in the same outcome. We expect marginal impacts where State requirements result in translation into languages not required by the current MA rules at §§ 422.2267(a)(2) and 423.2267(a)(2). However, even in these States, FIDE SNPs, HIDE SNPs, and AIPs (in combination with their affiliated Medicaid managed care plans) have translators on staff or access them via contractors because of existing translation requirements.

For contract year 2022, MA organizations sponsor 292 FIDE SNPs, HIDE SNPs, and AIPs. We expect that some portion of these FIDE SNPs, HIDE SNPs, and AIPs already translate their Medicare materials in ways that meet our proposed requirement, but we do not have a good estimate of how many. While HPMS identifies the Medicare translation requirements for each MA and Part D plan sponsor at the plan level, we do not have a good source of the State-specific Medicaid translation requirements since they differ by State and there is no one source of information outlining these requirements. For purposes of this analysis, we estimate that 75 percent of the FIDE SNPs, HIDE SNPs, and AIPs currently translate their Medicare materials in ways that would meet our proposed requirement and 25 percent or 73 of these FIDE SNPs, HIDE SNPs, and AIPs do not.

Section 422.2267(e) requires MA plans to provide 29 materials to current and prospective MA plan enrollees, as applicable and § 423.2267(e) requires Part D sponsors to provide an additional 18 materials to current and prospective enrollees for a total of 47 materials. We estimate that the proposed provision would require 73 FIDE SNPs, HIDE SNPs, and AIPs to translate 47 materials into one additional language. On average, we expect these plans to

translate materials into one additional language based on our experience with MMPs where, out of nine States, only two States (California and Rhode Island) required translation of materials into additional languages that exceeds the Medicare translation standard. California required MMPs to translate materials into nine additional languages in certain counties and Rhode Island required MMPs to translate materials into two additional languages. Collectively, these 47 materials include an estimated 253,311 words.¹⁷⁴ At a cost of \$56.16/hr,¹⁷⁵ we estimate a translator could translate 500 words/hr.¹⁷⁶ The aggregate cost is \$2,076,988, which is the product of the following:

- 253,311 words for one set of 47 materials.
- 500 words translated per hour.
- 73 FIDE SNPs, HIDE SNPs, and AIPs.
- \$56.16/hr wage.

Translating one set of 47 materials into one other language would cost an estimated \$28,452 (253,311 words /500 words/hr * \$28.08/hr * 2 (for 100 percent for fringe benefits)). Based on these assumptions, it would cost \$2,076,996 for 73 FIDE SNPs, HIDE SNPs, and AIPs to translate one set of materials into one other language. Any additional documents needing translation would be a one-time cost with a smaller cost to update the documents in future contract years.

Comment: A number of commenters expressed concern over the financial investment that would be needed in developing an organization-wide process for capturing language and

¹⁷⁴Extrapolated based on data from CMS-4144-F (76 CFR 21549) that estimated 91,623 words for translation of approximately 17 plan materials.

¹⁷⁵ Mean hourly wage for interpreters and translators, May 2021 retrieved from:

<https://www.bls.gov/oes/current/oes273091.htm> The mean rate of \$28.08 was doubled to include fringe benefits and overwork time.

¹⁷⁶Translation rates vary widely and also depend on the technical nature of what is translated as well as whether adequate review time is included. The consensus of multiple websources i)

https://www.proz.com/forum/money_matters/300163-words_per_hour.html ii)

<https://www.pactranz.com/translation-times/> iii) <https://www.getblend.com/blog/output-words-per-day/> iv)

<https://www.trainingfortranslators.com/2011/01/20/webinar-question-how-many-words-per-day/> provides ranges from 200 words /hour to 1000 words per hour. We have selected 500 as a reasonable average and invite stakeholder feedback on the reasonableness of this assumption.

alternate format preference and implementing the requirement on a standing basis, including an investment in IT and vendor contracts. Numerous commenters also noted that it would take time to implement these processes including the system updates, updating vendor contracts, staff training, etc., and requested that CMS delay implementation until CY 2025. A commenter also requested a delay in implementing this requirement since these materials are often prepared well in advance of open enrollment for the following plan year. A few commenters expressed concern over the cost of translating materials into several languages on a standing basis. A commenter believed the proposed requirement would necessitate plans translating materials into more than 30 languages. Another commenter noted that they will still have to provide English versions of the materials for providers, even when enrollees request information in other languages.

Response: We appreciate the commenters' concerns regarding the infrastructure updates that will be needed to capture an enrollee's preference for receiving materials in non-English languages and/or accessible formats and then using this information to send out materials in the requested format on a standing basis.

We also understand that some commenters are concerned about the cost of translating materials into several languages on a standing basis. Each fall, we release an HPMS memorandum announcing that plans can access in the HPMS marketing review module a list of all languages that meet the 5 percent threshold for plan service areas, which is the threshold for translation.¹⁷⁷ For contract year 2023, the threshold requires few contracts to translate into languages that exceeds Spanish: 16 MA contracts meet the threshold that requires translating materials into Chinese, and 19 MA and PDPs meet the threshold that requires translating materials into other Asian languages. There are no other service areas with additional languages that currently meet the 5 percent threshold for translation. As a result, there are very few MA

¹⁷⁷CMS released the contract year 2023 version of this HPMS memorandum titled, "Contract Year 2023 Translated Model Materials Requirements and Language Data Analysis" on September 23, 2022. This memorandum can be retrieved at: <https://www.cms.gov/httpseditcmgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-memos-archive/hpms-memos-wk-4-september-19-23>

organizations or PDPs that will be required to translate required materials and, for MA SNPs, ICPs into more than one language. Therefore, we do not agree that plans will be required to translate materials into several languages. Also, the current regulations at §§ 422.2267(a)(2) and 423.2267(a)(2) already require plans to translate required materials into languages that meet the 5 percent threshold. We also remind MA organizations and Part D sponsors that, as recipients of Federal financial assistance, they have independent language access requirements under Title VI of the Civil Rights Act of 1964 and section 1557 of the Affordable Care Act and implementing regulations at 45 CFR Parts 80 and 92, respectively.

For auxiliary aids and services, section 504 of the Rehabilitation Act of 1973, section 1557 of the ACA, and the regulations at 45 CFR 92.102(b) already require plans to provide appropriate auxiliary aids and services in alternate formats to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. The requirement we are finalizing at §§ 422.2267(a)(3) and 423.2267(a)(3) only clarifies that plans must provide the materials based on the enrollee's preference on a standing basis.

While we understand that plans may need to make some adjustments to vendor contracts and make system updates, plans should already have resources in place to provide these materials translated into the languages required currently under §§ 422.2267(a)(2) and 423.2267(a)(2) and accessible formats. In addition, plans should have systems in place that can be adjusted to track standing requests since they are already required to track a request for hard copy materials as described in §§ 422.2267(d)(2)(i)(E) and 423.2267(d)(2)(i)(E). We believe the benefit of ensuring access to materials that can be easily understood by enrollees so that they can receive timely access to care outweighs any additional effort that plans may need to undertake. As stated earlier in this section and in the proposed rule at 87 FR 79522, we believe it is a substantial burden for enrollees to have to request each material in a non-English language or request accessible formats for each material and that requiring enrollees to do so could cause a

critical delay to timely access to care. Thus, we are finalizing the provisions at §§ 422.2267(a)(3) and 423.2267(a)(3) as proposed, without a delay in implementation.

4. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 423.182, 423.184, and 423.186)

We proposed to add, remove, and update certain measures and to make methodological clarifications (to codify current practice and policies) to the Part C and D Star Ratings program. These measure additions, removals, and updates and methodological clarifications are routine, and routine changes have historically had very little or no impact on the highest ratings (that is, overall rating for MA-PD contracts, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). Hence, we anticipate there will be no, or negligible, impact on the Medicare Trust Fund from these routine changes we are finalizing in this rule. Beyond the Trust Fund, there may be effects on supplemental benefits, premiums, and plan profits. These impacts will likely vary significantly from plan to plan (or contract to contract) based on the business strategies and the competitive landscape for each plan and contract.

We also proposed some methodological enhancements to the Star Ratings as follows: replacing the current reward factor with an HEI reward, reducing the weight of patient experience/complaints and access measures, adding a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, and removing the 60 percent rule that is applied when adjusting Star Ratings for extreme and uncontrollable circumstances (for example, natural disasters like hurricanes or public health emergencies). We anticipate that removing the 60 percent rule and adding a rule for subregulatory measure removal would each have a negligible impact on the highest ratings. Two of our enhancements have the potential to cause a contract's Star Rating to change: (1) decreasing the weight of patient experience, complaints, and access measures from four to two; and (2) replacing the current reward factor with an HEI that would reward contracts for doing well serving enrollees with specified social risk factors.

We also simulated the cumulative impact of the proposed changes to the overall rating by geographical area – specifically, by state, DC, and Puerto Rico. Since the service area of a contract can include multiple states, we assigned to each enrollee the rating of their MA contract and calculated the average rating across all enrollees residing in each state. The average change in the overall rating is a decrease of 0.099, with the changes ranging from 0.01 to -0.33 across geographic areas. Table 9 below shows the simulated changes by state, DC, and Puerto Rico. The second column is the number of MA enrollees in each state in contracts that received the 2021 overall rating. In most cases, but not all, there are larger declines in areas that had on average higher 2021 overall ratings.

TABLE 9: STAR RATINGS SIMULATIONS BY STATE, DC AND PUERTO RICO

State	Number of Enrollees	2021 Overall Rating	Simulated Overall Rating	Difference
AK	1,524	4.08	3.98	-0.10
AL	443,969	4.24	4.03	-0.22
AR	170,915	3.59	3.57	-0.03
AZ	521,901	3.76	3.73	-0.03
CA	2,657,281	4.46	4.45	-0.01
CO	367,021	4.30	4.14	-0.17
CT	271,820	4.07	3.97	-0.10
DC	19,146	4.32	4.14	-0.18
DE	34,468	3.95	3.89	-0.06
FL	2,111,559	4.11	3.99	-0.12
GA	697,263	3.92	3.81	-0.12
HI	127,315	4.05	3.92	-0.13
IA	131,963	3.97	3.89	-0.08
ID	113,540	3.80	3.78	-0.02
IL	548,385	4.11	3.90	-0.21
IN	402,282	3.98	3.88	-0.10
KS	97,754	3.85	3.73	-0.11
KY	313,488	3.90	3.82	-0.08
LA	339,228	4.24	4.00	-0.24
MA	309,105	4.55	4.22	-0.33
MD	127,039	4.28	4.02	-0.26
ME	119,565	4.43	4.15	-0.28
MI	819,565	3.76	3.72	-0.05
MN	458,194	4.31	4.18	-0.13
MO	445,550	4.12	3.86	-0.26
MS	123,683	3.70	3.59	-0.11
MT	44,284	4.00	3.98	-0.02
NC	746,214	4.13	3.98	-0.15
ND	23,931	4.02	4.01	-0.01
NE	56,025	4.13	3.91	-0.22
NH	55,680	3.98	3.89	-0.09

State	Number of Enrollees	2021 Overall Rating	Simulated Overall Rating	Difference
NJ	484,539	3.87	3.83	-0.04
NM	153,762	3.73	3.70	-0.03
NV	199,573	3.92	3.90	-0.02
NY	1,510,549	3.82	3.73	-0.09
OH	943,397	3.98	3.95	-0.03
OK	149,407	3.75	3.76	0.01
OR	391,460	4.13	3.89	-0.24
PA	1,157,687	4.10	3.99	-0.10
PR	592,702	4.03	4.03	0.00
RI	84,615	4.02	3.99	-0.02
SC	310,810	3.73	3.71	-0.03
SD	37,222	3.99	3.97	-0.02
TN	548,221	4.11	4.03	-0.08
TX	1,638,848	3.95	3.89	-0.06
UT	148,224	3.95	3.92	-0.03
VA	335,867	3.91	3.91	-0.01
VT	17,644	3.86	3.79	-0.07
WA	450,597	4.05	3.99	-0.06
WI	488,875	4.14	4.00	-0.14
WV	133,231	3.90	3.88	-0.03
WY	4,101	3.60	3.53	-0.08

We calculated the cost impacts summarized in Tables 10 and 11 due to these proposed Star Ratings updates by quantifying the difference in the MA organization's (including Part D for MA-PDs) final Star Rating with the proposed changes and without the proposed changes. We assume Medicare Trust Fund impacts due to the Star Ratings changes associated with these two revisions to the methodology. The first change, decreasing the weight of patient experience, complaints, and access measures, will be effective for the 2026 Star Ratings and will impact the 2027 plan payments and 2027 Quality Bonus Payments. The introduction of the HEI reward in lieu of the current reward factor will impact the 2027 Star Ratings and will impact the 2028 plan payments and 2028 Quality Bonus Payments.

These impacts are considered transfers, but we requested comment on the extent to which provision of goods or services would increase or decrease in association with the payment changes. The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those contracts that would have Star Ratings changes under this final rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

- A Star Rating of 4.0 or higher will result in a Quality Bonus Payment for the MA contract, which, in turn, leads to a higher benchmark for the MA plans offered by the MA organization under that contract. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a Quality Bonus Payment that is capped at 5 percent (or 10 percent for certain counties).

- The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, the Private Health Baseline assumptions are updated with the assumed Star Ratings changes described in this final rule. We first estimated the two changes to the Star Ratings calculations as independent of each other and, since there are likely overall Star Rating interactions between the two changes, the impacts, as shown in Table 10, should be viewed separately and should not be summed. The negative values in this section of this final rule represent net savings to the Medicare Trust Funds. The patient experience/complaints and access measure weight provision is expected to result in net savings of between \$330 million in 2027 and \$580 million in 2033, resulting in a 10 year savings estimate of \$3.28 billion. This amount equates to 0.05 percent of the Private Health Baseline for 2024 – 2033. The replacement of the current reward factor with the HEI reward is expected to result in net savings of between \$670 million in 2028 and \$1,050 million in 2033 resulting in a 10-year savings estimate of \$5.12 billion. \$5.12 billion represents 0.08 percent of the Private Health Baseline for the years 2024 – 2033. These projections are based on simulations using data from the 2020 and 2021 Star Ratings.

TABLE 10: NET IMPACTS (\$ Millions) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Patient Experience/Complaints/Access Measure Weight	Percent of Private Health Baseline	Health Equity Index Reward	Percent of Private Health Baseline
----------------------	------------------------------------------------------------	-------------------------------------------	-----------------------------------	-------------------------------------------

2024	-	0.00%	-	0.00%
2025	-	0.00%	-	0.00%
2026	-	0.00%	-	0.00%
2027	(330)	-0.06%	-	0.00%
2028	(380)	-0.06%	(670)	-0.11%
2029	(430)	-0.06%	(750)	-0.11%
2030	(480)	-0.07%	(820)	-0.11%
2031	(530)	-0.07%	(880)	-0.11%
2032	(550)	-0.06%	(950)	-0.11%
2033	(580)	-0.06%	(1,050)	-0.11%
Total	(3,280)	-0.05%	(5,120)	-0.08%

We also estimated the cumulative impact of the changes to the Star Ratings calculations we are finalizing in this rule since there are interactions between those changes. The impacts are showing in Table 11. The negative values represent net savings to the Medicare Trust Funds. For the Star Ratings updates, net savings are estimated to be between \$330 million in 2027 and \$1.24 billion in 2033, resulting in a 10-year savings estimate of \$6.41 billion, which equates to 0.10 percent of the Private Health Baseline for the years 2024 through 2033.

TABLE 11: NET IMPACTS (\$ Millions) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Net Impact Star Ratings Updates	Percent of Private Health Baseline
2024	-	0.00%
2025	-	0.00%
2026	-	0.00%
2027	(330)	-0.06%
2028	(800)	-0.13%
2029	(890)	-0.13%
2030	(970)	-0.13%
2031	(1,050)	-0.13%
2032	(1,130)	-0.13%
2033	(1,240)	-0.13%
Total	(6,410)	-0.10%

We did not received comments on our impact analysis and therefore are finalizing these provisions without modification.

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

In this final rule, we will revise the Part D LIS income and resource standards at § 423.773 to expand eligibility for the full benefit to individuals who currently have the partial benefit and make a coordinating change in § 423.780. This will change the level of assistance that an individual could qualify for in paying their Part D premiums, copays and deductibles. While there would be no change in the number of individuals eligible for the Part D LIS, it will create a transition of people from partial subsidy status to full subsidy status.

The result of this change is the Federal Government providing more subsidies to low income Medicare beneficiaries for Part D coverage, which would result in additional costs to the Medicare Trust Fund. The following table reflects the scored government costs for expanding the full low income subsidy to the current partly subsidized LIS beneficiaries starting January 1, 2024. Included in this table are the breakdown of increases for both the low income cost-sharing subsidy (LICS) and the low income premium subsidy (LIPS). OACT arrived at the cost estimate by assuming that the ratio of post-LICS-out-of-pocket as a percentage to the total drug cost for the partial subsidy beneficiaries would be close, possibly equal, to the drug cost of the full subsidy beneficiaries. Therefore, the impact analysis assumed that the ratio (plan benefits + LICS)/total drug cost for the partial subsidy beneficiaries was the same as the ratio for the full subsidy beneficiaries., We are classifying these payments of the Medicare Trust Fund as transfers from the Trust Fund to the LI NET sponsors. We received no comments on our regulatory impact analysis and are finalizing this impact as is.

TABLE 12: PROJECTED COSTS FOR EXPANDING LOW INCOME SUBSIDIES

	Calendar Year Incurred (\$ in millions)									
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
LIS total	\$169	\$180	\$193	\$207	\$221	\$237	\$253	\$269	\$286	\$304
LICS	\$135	\$144	\$155	\$166	\$178	\$191	\$205	\$218	\$232	\$247
LIPS	\$34	\$36	\$38	\$41	\$43	\$46	\$48	\$51	\$54	\$57

6. Adding New Behavioral Health Specialty Types Subject to Network Adequacy Evaluation (§ 422.116)

To ensure that MA enrollees have access to provider networks sufficient to provide covered services, including behavioral health service providers, this rule adds new specialty types that will be subject to network adequacy evaluation under § 422.116. This rule adds Clinical Psychology, Clinical Social Work and Prescribers of Medication for Opioid Use Disorder under § 422.116(b)(1). However, we are not finalizing our proposed addition of Prescribers of Medication for Opioid Use Disorder for the reasons presented in section VII.C.3.

To determine the potential burden regarding this proposal, we considered cost estimates for CMS making programming updates to the HPMS system, which is utilized to conduct automated reviews; additional burden, including updating policies and procedures, for CMS contractor; and additional burden, including updating policies and procedures, for MA organizations.

We have determined that there is a \$0 cost for programming HPMS with regard to this rule. Adding new specialty types to the automated review conducted by HPMS would be covered under funding currently in place for updating the system.

The CMS contractor does not indicate any additional or reduced costs to carry out the work required by this rule ; therefore, there is no impact.

E. Alternatives Considered

In this section, CMS includes discussions of Alternatives Considered for several provisions. Several provisions of this final rule reflect a codification of existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification of this existing policy would not affect compliance. In such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health. Also, in these cases, different enforcement methods and different levels of stringency, are not fully relevant since the provision

is already being complied with adequately. Alternative analysis is not provided for these provisions.

1. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.100, 422.101, 422.112, 422.137, 422.138).

Both the reasons for proposing the UM Committee requirement provisions and the alternatives they are intended to counteract are discussed in the respective preambles. Because we cannot quantify any of these we have not included a repetition of this analysis in the RIA. A brief summary is as follows:

- The finalized regulation adopts new and existing standards and requirements for coverage criteria for basic benefits by requiring MA plans to make medical necessity determinations based on Traditional Medicare coverage and benefit criteria as reflected in Medicare statutes and regulations, NCDs and LCDs and prohibiting the use of internal coverage criteria or additional medical necessity standards except in limited situations. This is major policy shift in which MA plans may only deny coverage for Medicare items and services based on Traditional Medicare coverage rules unless coverage criteria for the Part A or Part B benefit are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. . As stated elsewhere in this final rule, MA plans are still permitted to use utilization management policies, such as PA—within the scope of § 422.138(b)(1) through (3)—in situations where they are not permitted to use internal coverage criteria per 422.101(b)(2) and (b)(6). In situations where MA plans may not use internal coverage criteria, plans may still use PA to confirm criteria for determining whether an item or service is one for which benefits are available under Traditional Medicare. Additionally, while PA is still permitted, plans must use coverage criteria consistent with the rules being finalized at § 422.101(b)(2) and (b)(6) and plans must make medical necessity determinations consistent with the rules at 422.101(c). Finally, in regards to burden, we understand that this provision will create new burden which is difficult to quantify.

- The finalized regulation also requires plans to follow specific procedures as part of developing internal coverage policies and making these coverage policies publicly accessible including a public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations. We provided an impact analysis in section VII.C.4 of this final rule of one quantifiable aspect of this proposal. As part of this analysis, we took into account solicited stakeholder input on aspects of the proposal and its impact requested in the NPRM.

- The regulation requires a PA approval to be valid for as long as medically necessary pursuant to 422.101(c), to avoid disruptions in care. In combination with the requirements to limit when MA plans may deny coverage (or use internal coverage criteria that are not used in Traditional Medicare), this will limit an MA organization's ability to approve only part of what a provider has ordered or prescribed. In addition, the finalized requirements would minimize repetitive PA requirements for enrollees on an appropriate, chronic, stable therapy. It would be qualitatively beneficial for the enrollee.

- The finalized regulation establishes a minimum 90-day transition period when an enrollee switches to a new plan, or switches from FFS to an MA plan (including new MA plan members who are also new to Medicare as well) for any ongoing courses of treatment so that treatment may not be subjected to prior authorization. This was adopted from similar transition periods in Part D; we believe it is appropriate to align the transition period and scope with the current transition requirements in Part D. We lack adequate data to quantify this provision. Qualitatively, it may result, in certain cases, in more cost to plans; but the proposal is beneficial to the enrollee.

- The proposed regulation requires MA organizations to establish a committee (similar to a P&T committee), led by a plan's Medical Director, that reviews utilization management policies annually and keeps current of Medicare statutes and regulations, LCDs and NCDs. This is beneficial for the enrollee. It was modeled on similar committees used for Part B step therapy

programs and by Part D plans. Its major effect is to ask plans to review their utilization management policies.

We re-emphasize that we are not able to fully quantify all of these and the discussion of reasons is discussed in the preamble.

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

As an alternative to our proposal to have a tiered health equity index reward, we considered a non-tiered approach. We proposed a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified social risk factors (SRFs). We proposed that contracts that have percentages of enrollees with any of the specified SRFs in a given year that are greater than or equal to one-half of the contract-level median percentage of enrollees with the specified SRFs up to, but not including, the contract-level median would qualify for one-half of the HEI reward. Contracts that have percentages of enrollees with any of the specified SRFs greater than or equal to the contract-level median would qualify for the full HEI reward.

We have also considered and solicited comment on an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRF greater than or equal to one-half of the contract-level median would qualify for the full HEI reward. Both the tiered and non-tiered HEI reward structures align with our goal of not rewarding contracts that may do well among enrollees with SRFs but serve very few enrollees in this population, although the tiered HEI reward structure goes further in aligning with these goals. The non-tiered HEI reward structure aligns better with the goal of ease of use and understanding for contracts and other stakeholders. Although the non-tiered approach would slightly increase the mean HEI reward, it does not impact the number of contracts qualifying for the reward. We received a few comments related to the tiered versus non-tiered approach summarized in Section V. of this rule. Most commenters did not comment on the tiered versus non-tiered approach and

supported the HEI reward as proposed. For the reasons set forth in the proposed rule and our responses to the related comments summarized in Section V of this rule, we are finalizing the HEI reward as proposed without modification.

F. Accounting Statement and Table

The following Table 14 summarizes costs and transfers by provision. As required by OMB Circular A-4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Table 13, we have prepared an accounting statement showing the costs and transfers associated with the provisions of this final rule for calendar years 2024 through 2033. Table 13 is based on Table 14 which lists transfers and costs by provision and year. Tables 13 and 14 are expressed in millions of dollars with costs listed as positive numbers and transfers of savings (reduction in dollar spending) to the Medicare Trust Fund listed as a savings. As can be seen, the net annualized cost of this rule is about \$2 million per year. This cost is offset by a reduction in dollar spending (savings) to the Medicare Trust Fund of about \$0.35 billion per year. Minor seeming discrepancies in totals in Tables 13 reflects use of underlying spreadsheets, rather than intermediate rounded amounts. A breakdown of these costs of this final rule by provision may be found in Table 14.

TABLE 13: ACCOUNTING TABLE (MILLIONS \$)*

Item	Annualized at 7%	Annualized at 3%	Period	Who is Impacted
Net Annualized Monetized Cost in 2023 dollars	2.2	1.9	2024-2033	Federal Government, MA organizations, and Part D sponsors
Transfers to the Medicare Trust Fund	(319.1)	(364.4)	2024-2033	The transfers are between MA plans and Part D Sponsors (including LI NET sponsors) and the Medicare Trust Fund. The Star Ratings provisions reduce dollar spending while the low income subsidy and LI NET sponsor provisions increase dollar spending.

* Cost is expressed as a positive number. The net savings (reductions in dollar spending) to the Medicare Trust Fund is expressed as a negative number.

The following Table 13 summarizes costs, and transfers by provision and year and forms a basis for the accounting Table 13. In Table 14, costs are expressed as positive numbers while savings to the Medicare Trust Fund (reduced dollar spending) are expressed as negative numbers. All numbers are in millions. The costs in this table are true costs reflecting increased consumption of services and goods. However, the savings (reduced dollar spending) to the Medicare Trust Funds reflect a transfer from MA plans, Part D sponsors, and enrollees, who increase their spending, to the Trust Fund.

Table 14 combines related provisions. For example, all PACE provisions in the COI summary table are combined into one-line item. Similarly, all provisions dealing with prior authorization have been combined into one-line item in the summary table. Table 14, also combines the three provisions with transfers: The Star Ratings provisions reduce spending by the Trust Fund (TF) to MA plans; the low-income NET provision and the expansion of low-income subsidy provision both increase dollar spending by the TF to cover assistance through the LI NET sponsors to low-income beneficiaries who would otherwise have to pay for Prescription Drugs. Since the aggregate transfer over all three provisions is a reduction in dollar spending, Table H6, lists this transfer as a savings.

TABLE 14: SUMMARY OF COST AND TRANSFERS BY PROVISION AND YEAR*

	2024 Cost	2024 Transfers	2025 Cost	2025 Transfers	2026 Cost	2026 Transfers	2027 Cost	2027 Transfers	2028 Cost	2028 Transfers	2029 Costs	2029 Transfers	2030 Cost	2030 Transfers	2031 Cost	2031 Transfers	2032 Cost	2032 Transfers	2033 Cost	2033 Transfers	Raw 10 Year Totals
Total Costs	14.6		0.3		0.3		0.3		0.3		0.3		0.3		0.3		0.3		0.3		17.1
Savings of the Medicare Trust Fund		174.0		187.0		201.0		(114.0)		(570.0)		(643.0)		(706.0)		(770.0)		(832.0)		(923.0)	(3996.0)
Translation (FIDE, HIDE SNPS)	2.1				0.0		0.0		0.0		0.0		0.0		0.0		0.0		0.0		2.1
Translation (Standing request)	10.4																				10.4
Low Income NET program (PRA)	0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		0.4		4.3
Low Income NET Program (TF)		5.0		7.0		8.0		9.0		9.0		10.0		11.0		11.0		12.0		13.0	95.0
Prior Authorization Provisions	1.0		1.0		1.0		1.0		1.0		1.0		1.0		1.0		1.0		1.0		10.1
Star Ratings								(330.0)		(800.0)		(890.0)		(970.0)		(1,050.0)		(1,130.0)		(1,240.0)	(6,410.0)
PACE Provisions	1.2		(0.1)		(0.1)		(0.1)		(0.1)		(0.1)		(0.1)		(0.1)		(0.1)		(0.1)		0.4
Marketing Provisions	0.2		0.2		0.2		0.2		0.2		0.2		0.2		0.2		0.2		0.2		1.7
Medical Necessity Decisions	(1.2)		(1.2)		(1.2)		(1.2)		(1.2)		(1.2)		(1.2)		(1.2)		(1.2)		(1.2)		(12.4)
Expansion of low income subsidies		169.0		180.0		193.0		207.0		221.0		237.0		253.0		269.0		286.0		304.0	2319.0
MA Provider Termination Notices	0.5																				0.5

*Numbers are in millions. Costs are positive numbers while savings (reduced dollar spending) of the Medicare Trust Fund are expressed as negative numbers.

Notes to the summary table:

*Raw 10-year totals are found in the right most column. Monetized annual amounts are found in the accounting table.

**Almost all individual entries are costs. However, the medical necessity decisions as well as the PACE provisions (after the first year) are a savings. Since these are the only items that are savings it was not believed necessary to create a new column of savings. Consequently, these savings are listed with the costs but are listed as negative numbers. The actual computations were presented in the section VII. of this rule.

***There are 3 provisions that impact the Medicare Trust Fund:

(i) The Star Ratings provisions are estimated to save \$6.4 billion over 10 years. These savings are transfers.

(ii) The LI NET program will cost (increase spending of) the Medicare Trust Fund \$95 million over 10 years.

(iii) The expansion of low-income subsidies will cost (increase spending of the Medicare Trust Fund) \$2.3 billion over 10 years.

Although items (ii) and (iii) may involve cases of health inequity – that is, cases where without the provisions the beneficiary would not have joined a health plan and/or avoided necessary prescription drugs – we have classified the expenditures as a transfer, since in many cases the Trust Fund is paying for prescription drugs that otherwise would have been paid for by the beneficiaries themselves

(iv) The aggregate impact on the Trust Fund over 10 years is a reduced spending of \$4.0 billion as displayed in the top rows of the Summary Table.

G. Conclusion

As indicated in Table 13 the finalized provisions of this rule in aggregate reduce dollar spending of the Medicare Trust Fund by \$4.0 billion over 10 years, with the Star Ratings provisions being the primary driver of savings. Contrastively, the aggregate paperwork burden of this rule is small, in aggregate, \$17.1 million over 10 years. Except for 2024, the annual cost is \$0.3 million. The major driver of costs are the translation requirements, which although taking place in 2025, will probably be prepared for by most plans in 2024. Over an infinite horizon the aggregate costs of this rule expressed in 2016 dollars is \$0.8 million per year. In accordance with requirements, this major rule has been reviewed by OMB.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 29, 2023.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health Insurance, Health maintenance organizations (HMO), Loan programs-health Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV and the Department of Health and Human Services amends 45 CFR part 170 as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

Subpart K - Enrollment, Entitlement, and Disenrollment under Medicare Contract

1. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e-5, and 300e-9, and 31 U.S.C. 9701.

2. Section 417.454 is amended by revising paragraph (e)(4) to read as follows:

§ 417.454 Charges to Medicare Enrollees.

* * * * *

(e) * * *

(4) A COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

PART 422—MEDICARE ADVANTAGE PROGRAM

3. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

4. Section 422.62 is amended by:

a. Removing and reserving paragraph (b)(18); and

b. Redesignating paragraph (b)(26) as paragraph (b)(27) and adding new paragraph

(b)(26) to read as follows:

§ 422.62 Election of coverage under an MA plan

(b) * * *

(26) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR 406.27 and 407.23. The SEP begins when the individual

submits their application for premium-Part A and Part B, or Part B only, if the individual is already entitled to Part A (or is enrolling in premium-free Part A within the timeframe for use of this SEP), and continues for the first 2 months beyond the premium-Part A and/or Part B entitlement date. The MA plan enrollment is effective the first of the month following the month the MA plan receives the enrollment request.

* * * * *

5. Section 422.100 is amended by adding paragraph (n) to read as follows:

§ 422.100 General requirements

* * * * *

(n) *Digital health education program.* MA organizations must establish procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135.

(1) The MA organization must make information about its digital health literacy screening and digital health education programs available to CMS upon request. Requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of this section.

(2) [Reserved].

6. Section 422.101 is amended by:

- a. Revising paragraph (b)(2);
- b. Adding paragraph (b)(6); and
- c. Revising paragraph (c).

The revisions and addition read as follows:

§ 422.101 Requirements relating to basic benefits

* * * * *

(b) * * *

(2) General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. For example, this includes payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a)(3).

* * * * *

(6) MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

(i) *Coverage criteria not fully established.* Coverage criteria are not fully established when:

(A) additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. The MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;(B) NCDs or

LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or

(C) There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.

(ii) *Publicly accessible*. For internal coverage policies, the MA organization must provide in a publicly accessible way the following:

(A) The internal coverage criteria in use and a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;

(B) A list of the sources of such evidence; and

(C) An explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. When coverage criteria are not fully established as described in paragraph (6)(i)(A), the MA organization must identify the general provisions that are being supplemented or interpreted and explain how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

(c) Medical necessity determinations and special coverage provisions— (1) *Medical necessity determinations*. (i) MA organizations must make medical necessity determinations based on all of the following:

(A) Coverage and benefit criteria as specified at paragraphs (b) and (c) of this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) or (c) of this section.

(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.

(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.

(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

(ii) [Reserved]

(2) *Exception for qualifying hospital stay.* MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

7. Section 422.109 is amended by revising the section heading and adding paragraphs (e) and (f) to read as follows:

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials

* * * * *

(e) *Clinical trials specified in NCD 310.1.* (1) With the exception specified in paragraph (e)(3) of this section, original Medicare is responsible for coverage of MA enrollees participating in CMS-approved clinical trials to include routine costs, as specified in NCD 310.1, and any coverage for the diagnosis or treatment of complications related to the clinical trial.

(2) MA enrollees are not charged traditional Medicare Part A and B deductibles for clinical trial coverage.

(3) MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services.

(4) An enrollee's in-network cost-sharing portion must be included in the MA plan's maximum out-of-pocket calculation.

(5) MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial.

(f) *A and B IDE trials.* (1) MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies that are covered under § 405.211(a) of this chapter.

(2) MA plans are responsible for coverage of CMS-approved Category B devices that are covered under § 405.211(b) of this chapter.

8. Section 422.111 is amended by revising paragraphs (b)(3)(i) and (e) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(3) * * *

(i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; each provider’s cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider’s office; any out-of-network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

* * * * *

(e) *Changes to provider network.* The MA organization must provide enrollees notice of a termination of a contracted provider, irrespective of whether the termination was for cause or without cause, in accordance with § 422.2267(e)(12). The MA organization must make a good faith effort to provide enrollees notice of a for-cause termination of a contracted provider within the timeframes required by this paragraph (e). For all terminations, the MA organization must meet the following requirements:

(1) For contract terminations that involve a primary care or behavioral health provider:

(i) Provide written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have not opted out of calls regarding plan business as described in § 422.2264(b),

(ii) At least 45 calendar days before the termination effective date, and

(iii) To all enrollees who are currently assigned to that primary care provider and to enrollees who have been patients of that primary care or behavioral health provider within the past three years.

(2) For contract terminations that involve specialty types other than primary care or behavioral health:

(i) Provide written notice,

(ii) At least 30 calendar days before the termination effective date, and

(iii) To all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The phrase “enrollees who are patients seen on a regular basis by the provider whose contract is terminating” means enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated.

* * * * *

9. Section 422.112 is amended by—

a. Adding a sentence at the end of paragraph (a)(1)(i);

b. Adding paragraph (a)(1)(iii);

c. Removing the last sentence of paragraph (a)(3);

d. Revising paragraphs (a)(6)(i), (a)(8) and (b)(3); and

e. Adding paragraph (b)(8).

The additions and revisions read as follows:

§ 422.112 Access to services.

(a) * * *

(1) * * *

(i) * * * The network must include providers that specialize in behavioral health services.

* * * *

(iii) Arrange for 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.

* * * *

(6) * * *

(i) Timeliness of access to care and member services that meet or exceed standards in this paragraph. The MA organization must continuously monitor access to care and member services and must take corrective action as necessary to ensure that appointment wait times in the provider network comply with these standards. The minimum standards for appointment wait times for primary care and behavioral health services are as follows for appointments:

(A) Urgently needed services or emergency—immediately;

(B) Services that are not emergency or urgently needed, but the enrollee requires medical attention—within 7 business days; and

(C) Routine and preventive care—within 30 business days.

* * * *

(8) *Ensuring equitable access to Medicare Advantage (MA) Services.* Ensure that services are provided in a culturally competent manner and to promote equitable access to all enrollees, including the following:

(i) People with limited English proficiency or reading skills.

(ii) People of ethnic, cultural, racial, or religious minorities.

(iii) People with disabilities.

(iv) People who identify as lesbian, gay, bisexual, or other diverse sexual orientations.

(v) People who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex.

(vi) People living in rural areas and other areas with high levels of deprivation.

(vii) People otherwise adversely affected by persistent poverty or inequality.

* * * * *

(b) * * *

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the MA plan, including nursing home and community-based services, and behavioral health services; and

* * * * *

(8)(i) With respect to basic benefits, policies for using prior authorization that at a minimum include that for enrollees undergoing an active course of treatment—

(A) Approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the individual patient’s medical history, and the treating provider’s recommendation; and

(B) A minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. This includes enrollees new to a plan and enrollees new to Medicare. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

(ii) For purposes of this paragraph (b)(8), the following definitions apply:

(A) *Course of treatment* means as a prescribed order or ordered course of treatment for a specific individual with a specific condition is outlined and decided upon ahead of time with the patient and provider. A course of treatment may but is not required to be part of a treatment plan.

(B) *Active course of treatment* means a course of treatment in which a patient is actively seeing the provider and following the course of treatment.

* * * * *

10. Section 422.113 is amended by revising paragraph (b)(1)(i) introductory text to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(1) * * *

(i) *Emergency medical condition* means a medical condition, mental or physical, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in –

* * * * *

11. Section 422.116 is amended by —

- a. In paragraph (a)(1)(i), removing “§ 422.114(a)(3)(ii)” and adding “§ 422.2” in its place;
- b. Adding paragraphs (b)(1)(xxviii) and (xxix);
- c. Adding in alphabetical order entries for “Clinical Psychology”, and “Licensed Clinical Social Work” to Table 1 to Paragraph (d)(2);
- d. Adding paragraphs (d)(5)(xiii) and (xxiv); and
- e. Adding in alphabetical order entries for “Clinical Psychology”, and “Clinical Social Work” to Table 2 to Paragraph (e)(3)(i)(C).

The revisions and additions read as follows:

§ 422.116 Network adequacy.

* * * * *

(b) * * *

(1) * * *

(xxviii) Clinical Psychology.

(xxix) Clinical Social Work.

* * * * *

(d) * * *

(2) * * *

Table 1 to Paragraph (d)(2)

Provider/Facility Type	Large Metro		Metro		Micro		Rural		CEAC	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
*	*	*	*	*	*	*				
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
*	*	*	*	*	*	*				
Licensed Clinical Social Work	20	10	30	20	50	35	75	60	125	110
*	*	*	*	*	*	*				

* * * * *

(5) * * *

(xiii) Clinical Psychology.

(xxiv) Clinical Social Work.

* * * * *

(e) * * *

(3) * * *

(i) * * *

(C) * * *

Table 2 to Paragraph (e)(3)(i)(C)

Minimum Ratio	Large Metro	Metro	Micro	Rural	CEAC
* *	*	*	*	*	*
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
* *	*	*	*	*	*

12. Section 422.137 is added to read as follows:

§ 422.137 Medicare Advantage Utilization Management Committee

(a) *General.* An MA organization that uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan’s medical director (described in § 422.562(a)(4)).

(b) *Limit on use of UM policies and procedures.* An MA plan may not use any UM policies and procedures for basic or supplemental benefits on or after January 1, 2024 unless those policies and procedures have been reviewed and approved by the UM committee.

(c) *Utilization Management Committee Composition.* The UM committee must—

- (1) Include a majority of members who are practicing physicians.
- (2) Include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan.
- (3) Include at least one practicing physician who is an expert regarding care of elderly or disabled individuals.
- (4) Include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan’s utilization management policies.

(d) *Utilization Management Committee Responsibilities.* The UM committee must—

- (1) At least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. Such review must consider:
 - (i) The services to which the utilization management applies;
 - (ii) Coverage decisions and guidelines for Traditional Medicare, including NCDs, LCDs, and laws; and
 - (iii) Relevant current clinical guidelines.
- (2) Approve only utilization management policies and procedures that:

(i) Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);

(ii) For prior authorization policies, comply with requirements and standards at § 422.138;

(iii) Comply with the standards in § 422.202(b)(1); and

(iv) Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

(3) Revise the utilization management policies and procedures as necessary to comply with the standards in this regulation, including removing requirements for UM for services and items that no longer warrant UM.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

13. Section 422.138 is added to read as follows:

§ 422.138 Prior authorization.

(a) *Requirement.* When a coordinated care plan, as specified in § 422.4(a)(iii) (including MSA network plans), uses prior authorization processes in connection with basic benefits or supplemental benefits, the MA organization must comply with the requirements in this section. (MA PFFS are not permitted to use prior authorization policies or “prior notification” policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS plan in advance that services will be furnished). Prior authorization processes include all policies and procedures used in prior authorization unless otherwise noted.

(b) *Application.* Prior authorization processes for coordinated care plans may only be used for one or more the following purposes:

(1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or

(2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1), or

(3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) *Effect of prior authorization or pre-service approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The definitions of the terms “reliable evidence” and “similar fault” in § 405.902 of this chapter apply to this provision.

14. Section 422.152 is amended by adding paragraph (a)(5) to read as follows:

§ 422.152 Quality Improvement Program.

(a) * * *

(5) Incorporate one or more activities that reduce disparities in health and health care.

These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.

* * * * *

15. Section 422.162 is amended by –

a. In paragraph (a) adding in alphabetical order a definition for “health equity index” and a revision to the definition of “highly-rated contract”; and

b. Revising paragraphs (b)(1) and (b)(3)(iv)(A)(I).

The addition and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

* * *

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments in § 422.166(f).

* * * * *

(b) * * * (1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA-PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with § 422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 422.166(c), with the applicable adjustments provided in paragraph (f) of this section. Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 422.166(d), with the applicable adjustments provided in paragraph (f) of this section. CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

* * * * *

(3) * * *

(iv) * * *

(A)(I) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving

contracts for all measures, except survey-based measures, call center measures, and improvement measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures will use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

* * * * *

16. Section 422.164 is amended by adding paragraph (e)(1)(iii) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(e) * * *

(1) * * *

(iii) The measure steward other than CMS retires a measure.

* * * * *

17. Section 422.166 is amended by—

a. Revising paragraphs (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii) and (iv), (f)(1) introductory text, and (f)(2)(i) introductory text;

b. Adding paragraph (f)(3); and

c. Revising paragraphs (g)(1), (i)(3)(iv), (i)(9)(i), and (i)(10)(i).

The revisions and addition read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are

removed. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchical clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(c) * * *

(1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(d) * * *

(1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

* * * * *

(f) * * *

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

* * * * *

(2) * * *

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

* * * * *

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA-PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA-PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA-PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings are adjusted using all standard case-mix adjustors for the measure except for those

adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjuster to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. 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.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA-PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the HEI. CMS will announce the measures being evaluated for inclusion in the calculation of the HEI under this paragraph (f)(3) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's HEI score, the measure must meet both of the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees in the contract with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each eligible measure for the subset of enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median

enrollment percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.4 if the contract receives a score of 1 on the HEI. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.2 if the contract receives a score of 1 on the HEI. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have an HEI score calculated (that is, contracts that are not scored on at least half of the measures included in the index) will not receive an HEI reward.

(ix) The HEI reward is calculated separately for, and then added to, the overall rating, Part C rating for MA-PDs and MA-only contracts (and cost contracts), Part D rating for MA-PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in

paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

(g) * * *

(1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA-PD contracts and Part C summary rating for MA-only contracts), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

* * * * *

(i) * * *

(3) * * *

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS-HOS measure. The adjustment is for 3 years after the extreme and uncontrollable circumstance.

* * * * *

(9) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

* * * * *

(10) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

* * * * *

18. Section 422.202 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 422.202 Participation procedures.

(b) * * *

(1) * * *

(i) Are based on current evidence in widely used treatment guidelines or clinical literature;

* * * * *

19. Section 422.503 is amended by revising paragraphs (e)(1) and (2) to read as follows:

§ 422.503 General provisions.

* * * * *

(e) * * *

(1) The contract will be amended to exclude any MA plan, MA plan segment, or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan, segment, or entity will be deemed to be in place when such a request is made.

20. Section 422.504 is amended by adding paragraph (a)(19) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(19) Not to establish a segment of an MA plan that meets the criteria in § 422.514(d), as determined in the procedures described in § 422.514(e)(3), with the addition of the newly enrolled individuals.

* * * * *

21. Section 422.510 is amended by adding paragraph (a)(4)(xvi) to read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(a) * * *

(4) * * *

(xvi) Meets the criteria in § 422.514(d)(1) or (2).

* * * * *

22. Section 422.514 is amended by revising paragraph (d)(1) and adding paragraph (g) to read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(d) * * *

(1) Enter into or renew a contract under this subpart, for plan year 2024 and subsequent years, for a MA plan that –

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Projects enrollment in its bid submitted under § 422.254 that 80 percent or more enrollees of the plan's total enrollment are enrollees entitled to medical assistance under a State plan under title XIX.

* * * * *

(g) *Applicability to segments.* The rules under paragraphs (d) through (f) of this section also apply to segments of the MA plan as provided for local MA plans under § 422.262(c)(2).

23. Section 422.566 is amended by revising paragraph (d) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

24. Section 422.590 is amended by revising paragraph (b)(1) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(b) * * *

(1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)(2)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

* * * * *

25. Section 422.629 is amended by revising paragraph (k)(3) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(k) * * *

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

* * * * *

26. Section 422.2261 is amended by revising paragraph (a)(2) and removing paragraph (a)(3).

The revision reads as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) * * *

(2) Materials must be submitted to the HPMS Marketing Module by the MA organization or, where materials have been developed by a Third Party Marketing Organization for multiple MA organizations or plans, by a Third Party Marketing Organization with prior review of each MA organization on whose behalf the materials were created or will be used.

* * * * *

27. Section 422.2262 is amended by revising paragraph (a)(1)(ii) and adding paragraph (a)(1)(xix) to read as follows:

§ 422.2262 General communications materials and activity requirements.

* * * * *

(a) * * *

(1) * * *

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that applies to the current or prior contract year.

(A) Including data older than the prior contract year is permitted provided the current and prior contract year data are specifically identified.

(B) [Reserved]

* * * * *

(xix) Use the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card, in a misleading way. Use of the Medicare card image is permitted only with authorization from CMS.

* * * * *

28. Section 422.2263 is amended by adding paragraphs (b)(8) through (10) to read as follows:

§ 422.2263 General marketing requirements.

* * * * *

(b) * * *

(8) Advertise benefits that are not available to beneficiaries in the service area(s) where the marketing appears, unless the advertisement is in local media that serves the service area(s) where the benefits are available and reaching beneficiaries who reside in other service areas is unavoidable.

(9) Market any products or plans, benefits, or costs, unless the MA organization or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) MA organization or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or fine print.

(ii) For television, online, or social media, the MA organization or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number, contact information, or benefits.

(iii) For radio or other voice-based advertisements, MA organization or marketing names must be read at the same pace as the advertised phone numbers or other contact information.

(10) MA organizations may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

* * * * *

29. Section 422.2264 is amended by –

a. Adding paragraphs (a)(2)(i)(A) and (B);

b. Revising paragraph (b)(2);

c. Removing paragraph (c)(1)(ii)(C).

d. Redesignating paragraphs (c)(1)(ii)(D) and (E) as paragraphs (c)(1)(ii)(C) and (D) and revising newly redesignated (c)(1)(ii)(D);

f. Revising paragraphs (c)(2)(i), (c)(3)(i), and (c)(3)(iii)(A) and (B).

The additions and revisions read as follows:

§ 422.2264 Beneficiary contact.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(A) Contact is unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable date and time, was previously scheduled.

(B) [Reserved].

(b) * * *

(2) If the MA organization reaches out to beneficiaries regarding plan business, as outlined in this section, the MA organization must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

(c) * * *

(1) * * *

(ii) * * * * *

(D) Make available and receive beneficiary contact information, including Business Reply Cards, but not including Scope of Appointment forms

(c) * * *

(2) * * *

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

* * * * *

(3) * * *

(i) At least 48 hours prior to the scheduled personal marketing, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies), except for:

(A) SOAs that are completed during the last four days of a valid election period for the beneficiary.

(B) Unscheduled in person meetings (walk-ins) initiated by the beneficiary.

* * * * *

(iii) * * *

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 12 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment, identifying the additional lines of business to be discussed; such Scope of Appointment is valid for 12 months following the beneficiary's signature date.

* * * * *

30. Section 422.2265 is amended by revising paragraph (b)(4) to read as follows:

§ 422.2265 Websites.

* * * * *

(b) * * *

(4) A provider directory searchable by every element required in the model provider directory, such as name, location, specialty.

* * * * *

31. Section 422.2267 is amended by –

a. Redesignating paragraph (a)(3) as paragraph (a)(5);

b. Adding new paragraphs (a)(3) and (4);

c. Revising paragraph (e)(4) introductory text;

d. Adding paragraph (e)(4)(viii);

e. Revising paragraphs (e)(5)(ii)(A) introductory text, (e)(10) introductory text, (e)(12), (e)(30)(vi) and (e)(41).

The additions and revisions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(a) * * *

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section or accessible format upon receiving a request for the materials in anon-English language or accessible format or when otherwise learning of the enrollee’s primary language or need for an accessible format. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan, as defined at § 422.2, or applicable integrated plan, as defined at § 422.561, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

(5) * * *

(e) * * *

(4) *Pre-Enrollment checklist (PECL)*. The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments, the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

* * * * *

(viii) Effect on current coverage.

(5) * * *

(ii) * * *

(A) Information on the following medical benefits, starting in the top half of the first page and in the order as identified in paragraphs (A)(1) through (A)(10), including--

* * * * *

(10) *Non-renewal Notice*. This is a standardized communications material through which plans must provide the information required under § 422.506.

* * * * *

(12) *Provider Termination Notice*. This is a model communications material through which plans must provide the information required under § 422.111(e).

(i) The written Provider Termination Notice must be provided in hard copy via U.S. mail (first class postage is recommended, but not required).

(ii) The written Provider Termination Notice must do all of the following:

(A) Inform the enrollee that the provider will no longer be in the network and the date the provider will leave the network.

(B) Include names and phone numbers of in-network providers that the enrollee may access for continued care (this information may be supplemented with information for accessing a current provider directory, including both online and direct mail options).

(C) Explain how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider.

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is impacted by the provider termination may contact 1-800-MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period, as specified in § 422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP.

(E) Include the MA organization's call center telephone number, TTY number, and hours and days of operation.

(iii) The telephonic Provider Termination Notice specified in § 422.111(e)(1)(i) must relay the same information as the written Provider Termination Notice as described in paragraph (e)(12)(ii) of this section.

* * * * *

(30) * * *

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all MA organizations in the service area the disclaimer consists of the statement: “We do not offer every plan available in your area. 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 to get information on all of your options.” If the TPMO sells for all MA organizations in the service area the disclaimer consists of the statement: “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 for help with plan choices.” The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

32. Section 422.2272 is amended by adding paragraph (e) to read as follows:

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

33. Section 422.2274 is amended by adding paragraph (c)(12) and revising paragraph (g)(2)(ii) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.

* * * * *

(g) * * *

(2) * * *

(ii) Record all marketing, sales, and enrollment calls, including the audio portion of calls via web-based technology, in their entirety.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

34. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

35. Section 423.4 is amended by adding in alphabetical order definitions for “Immediate need individual”, and “Limited Income Newly Eligible Transition (LI NET) sponsor” to read as follows:

§ 423.4 Definitions.

* * * * *

Immediate need individual means a beneficiary whose enrollment into LI NET is on the basis of presumed low income subsidy eligibility and immediate need of a Part D drug.

* * * * *

Limited Income Newly Eligible Transition (LI NET) sponsor means a Part D sponsor selected by CMS to administer the LI NET program.

* * * * *

36. Section 423.38 is amended by—

- a. Revising paragraph (c)(16).
- b. Redesignating paragraph (c)(34) as paragraph (c)(35); and
- c. Adding new paragraph (c)(34).

The revision and addition read as follows:

§ 423.38 Enrollment periods

(c) * * *

* * * * *

(16) The individual who is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B that starts January 1, 2023, is eligible to request enrollment in a Part D plan. The special enrollment period begins when the individual submits their Part B application and continues for the first 2 months of Part B enrollment. The Part D

plan enrollment is effective the first of the month following the month the Part D sponsor receives the enrollment request.

* * * * *

(34) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR parts 406.27 and 407.23. The SEP begins when the individual submits their premium-Part A or Part B application and continues for the first 2 months of enrollment in premium Part A or Part B. The Part D plan enrollment is effective the first of the month following the month the Part D plan receives the enrollment request.

* * * * *

37. Section 423.154 is amended by revising paragraph (c) to read as follows:

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA-PD plans

* * * * *

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section, except paragraphs (a)(2) and (3) of this section, for pharmacies when they service intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

* * * * *

38. Section 423.182 is amended by –

a. In paragraph (a) adding in alphabetical order a definition for “health equity index” and revising the definition of “highly-rated contract”; and

b. Revising paragraphs (b)(1) and (b)(3)(ii)(A)(I).

The addition and revisions read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

* * *

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments in § 423.186(f).

* * * * *

(b) * * *

(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA-PD contract and a Part D summary rating for each PDP contract using the 5-star rating system described in this subpart. For PDP contracts, the Part D summary rating is the highest rating. Measures are assigned stars at the contract level and weighted in accordance with § 423.186(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 423.186(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 423.186(c), with the applicable adjustments provided in paragraph (f) of this section. Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 423.186(d), with the applicable adjustments provided in paragraph (f) of this section. CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

* * * * *

(3) * * *

(ii) * * *

(A)(I) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures, call center measures, and improvement

measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures will use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

* * * * *

39. Section 423.184 is amended by adding paragraph (e)(1)(iii) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(e) * * *

(1) * * *

(iii) The measure steward other than CMS retires a measure.

* * * * *

40. Section 423.186 is amended by—

- a. Revising paragraphs (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii) and (iv), (f)(1) introductory text, and (f)(2)(i) introductory text;
- b. Adding paragraph (f)(3); and
- c. Revising paragraphs (g)(1), (i)(7)(i), and (i)(8)(i).

The revisions and addition read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will

add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap).

New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(c) * * *

(1) CMS will calculate the Part D summary ratings using the weighted mean of the measure-level Star Ratings for Part D, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(d) * * *

(1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

* * * * *

(f) * * *

(1) *Reward factor*. Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

* * * * *

(2) * * *

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

* * * * *

(3) *Health equity index*. Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA-PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA-PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA-PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings are adjusted using all standard case-mix adjustors for the measure except for those

adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjuster to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Measure-level scores are used for contracts that have data for only the most recent of the 2 years, but measure-level scores are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA-PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the HEI. CMS will announce the measures being evaluated for inclusion in the calculation of the HEI under this paragraph (f)(3) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's HEI score, the measure must meet both of the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each eligible measure for the subset of enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median

enrollment percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.4 if the contract receives a score of 1 on the HEI. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.2 if the contract receives a score of 1 on the HEI. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have a HEI score calculated (that is, contracts that are not scored on at least half of the measures included in the index) will not receive an HEI reward.

(ix) The HEI reward is calculated separately for, and then added to, the overall rating, Part C rating for MA-PDs and MA-only contracts (and cost contracts), Part D rating for MA-PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in

paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

(g) * * *

(1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA-PD contracts and Part D summary rating for PDPs), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

* * * * *

(i) * * *

(7) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

* * * * *

(8) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

* * * * *

41. Section 423.265 is amended by

a. Redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;

b. Adding new paragraph (b)(2).

c. Adding a paragraph heading to the newly redesignated paragraph (b)(4); and

The additions read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Substantial differences between bids*—(i) *General rule.* Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered “substantially different,” each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(ii) *Exception.* A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions.

* * * * *

(4) *Bid acceptance.* * * *

* * * * *

42. In § 423.308 amend the definition of “Gross covered prescription drug costs” by revising the introductory text and paragraph (1) to read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of actual costs (as defined by § 423.100 of this part) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.

* * * * *

43. Section 423.505 is amended by revising paragraph (b)(22) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Through the CMS complaint tracking system, address and resolve complaints received by CMS against the Part D sponsor.

* * * * *

44. Section 423.773 is amended by:

- a. Revising paragraph (b)(1);
- b. In paragraph (b)(2)(ii) removing the phrase "For subsequent years," and adding in its place the phrase "For years 2007 through 2023,";
- c. Adding paragraph (b)(2)(iii); and
- d. Revising paragraph (d) introductory text.

The revisions and addition read as follows:

§ 423.773 Requirements for eligibility.

* * * * *

(b) * * *

(1) Has income below 135 percent of the FPL applicable to the individual's family size or, with respect to a plan year beginning on or after January 1, 2024, has income below 150 percent of the FPL applicable to the individual's family size; and

(2) * * *

(iii) For plan years beginning on or after January 1, 2024, the amount of resources specified at paragraph (d)(2) of this section.

* * * * *

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who, for plan years beginning before January 1, 2024—

* * * * *

45. Section 423.780 is amended by revising paragraph (d) introductory text to read as follows:

§ 423.780 Premium subsidy.

* * * * *

(d) *Other low-income subsidy eligible individuals - sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy for plan years beginning before January 1, 2024, based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

* * * * *

46. Section 423.2261 is amended by revising paragraph (a)(2) and removing paragraph (a)(3).

The revision reads as follows:

§ 423.2261 Submission, review, and distribution of materials.

* * * * *

(a) * * *

(2) Materials must be submitted to the HPMS Marketing Module by the Part D sponsor or, where materials have been developed by a Third Party Marketing Organization for multiple Part D sponsors or plans, by a Third Party Marketing Organization with prior review of each Part D sponsor on whose behalf the materials were created or will be used.

* * * * *

47. Section 423.2262 is amended by revising paragraph (a)(1)(ii) and adding paragraph (a)(1)(xviii) to read as follows:

§ 423.2262 General communications materials and activity requirements.

* * * * *

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that applies to the current contract year or prior contract year.

(A) Including data older than the prior contract year is permitted provided the current and prior contract year data are specifically identified.

(B) [Reserved]

* * * * *

(xviii) Use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card in a misleading way. Use of the Medicare card image is permitted only with authorization from CMS.

* * * * *

48. Section 423.2263 is amended by adding paragraphs (b)(8) through (10) to read as follows:

§ 423.2263 General marketing requirements.

* * * * *

(b) * * *

(8) Advertise benefits that are not available to beneficiaries in the service area(s) where the marketing appears, unless the advertisement is in local media that serves the service area(s) where the benefits are available and reaching beneficiaries who reside in other service areas is unavoidable.

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

(i) Part D sponsor or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or in fine print.

(ii) For television, online, or social media, the Part D sponsor or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number, contact information or benefits.

(iii) For radio or other voice-based advertisements, Part D sponsor or marketing names must be read at the same pace as phone numbers or contact information.

(10) Part D sponsors may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

* * * *

49. Section 423.2264 is amended by:

- a. Adding paragraphs (a)(2)(i)(A) and (B);
- b. Revising paragraphs (b)(2);
- c. Removing paragraph (c)(1)(ii)(C);
- d. Redesignating paragraphs (c)(1)(ii)(D) and E as paragraphs (c)(1)(ii)(C) and (D);
- e. Revising newly redesignated paragraph (c)(1)(ii)(D); and
- f. Revising paragraphs (c)(2)(i), (c)(3)(i), and (c)(3)(iii)(A) and (B).

The addition additions and revisions read as follows:

§ 423.2264 Beneficiary contact.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(A) Contact is unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable time and date, was previously scheduled.

(B) [Reserved]

* * * * *

(b) * * *

(2) If the Part D sponsor reaches out to beneficiaries regarding plan business, as outlined in this section, the Part D sponsor must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

(c) * * *

(1) * * *

(ii) * * * * *

(D) Make available and receive beneficiary contact information, including Business Reply Cards, but not including Scope of Appointment forms

(c) * * *

(2) * * *

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

* * * * *

(3) * * *

(i) At least 48 hours prior to the scheduled personal marketing appointment, the Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies), except for:

(A) SOAs that are completed during the last four days prior of a valid election period for the beneficiary.

(B) Unscheduled in person visits (walk-ins) initiated by the beneficiary.

* * * * *

(iii) * * *

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 12 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment, identifying the additional lines of business to be discussed; such Scope of Appointment is valid for 12 months following the beneficiary's signature date.

* * * * *

50. Section 423.2267 is amended by –

- a. Redesignating paragraph (a)(3) as paragraph (a)(5);
- b. Adding new paragraphs (a)(3) and (4);
- c. Revising paragraph (e)(4) introductory text;
- d. Adding paragraph (e)(4)(viii);
- e. Revising paragraphs (e)(13) introductory text, (e)(32)(vi), and (e)(41); and
- f. Adding new paragraphs (e)(42) through (e)(44).

The revisions and additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(a) * * *

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section and/or accessible format using auxiliary aids and services upon receiving a request for the materials in a non-English language or accessible format or when otherwise learning of the enrollee's primary language and/or need for an accessible format. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) of this chapter for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan as defined at § 422.2 of this chapter, or applicable integrated plan as defined at § 422.561 of this chapter, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

* * * * *

(e) * * *

(4) *Pre-enrollment checklist (PECL)*. The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

* * * * *

(viii) Effect on current coverage.

* * * * *

(13) *Non-renewal notice.* This is a standardized communications material through which plans must provide the information required under § 423.507.

* * * * *

(32) * * *

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all Part D sponsors in the service area the disclaimer consists of the statement: “We do not offer every plan available in your area. 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 to get information on all of your options.” If the TPMO sells for all Part D sponsors in the service area the disclaimer consists of the statement: “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 for help with plan choices.” The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

(42) [Reserved]

(43) *Comprehensive medication review - written summary.* This is the standardized communications material Part D sponsors must provide to all MTM program enrollees who receive a comprehensive medication review, as required under § 423.153(d)(1)(vii)(B).

(44) *Safe disposal information.* This is model communications material Part D sponsors must provide to all enrollees targeted for its MTM program, as required under § 423.153(d)(1)(vii)(E).

51. Section 423.2272 is amended by adding paragraph (e) to read as follows:

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

52. Section 423.2274 is amended by adding paragraph (c)(12) and revising paragraph (g)(2)(ii):

§ 423.2274 Required materials and content.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), premiums, and other services or incentives.

* * * * *

(g) * * *

(2) * * *

(ii) Record all marketing, sales, and enrollment calls, including the audio portion of calls occurring via web-based technology, in their entirety.

* * * * *

53. Subpart Y is added to read as follows:

Subpart Y – Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

Sec.

423.2500 Basis and scope.

423.2504 LI NET eligibility and enrollment.

423.2508 LI NET benefits and beneficiary protections.

423.2512 LI NET sponsor requirements.

423.2516 Selection of LI NET sponsor and contracting provisions.

423.2518 Intermediate sanctions for the LI NET sponsor.

423.2520 Non-renewal or termination of appointment.

423.2524 Bidding and payments to LI NET sponsor.

423.2536 Waiver of Part D program requirements.

Subpart Y – Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

§ 423.2500 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D-14 of the Social Security Act.

(b) *Scope.* This subpart sets forth the requirements for the Limited Income Newly Eligible Transition (LI NET) program that begins no later than January 1, 2024. Under this program, eligible individuals are provided transitional coverage for Part D drugs.

§ 423.2504 LI NET eligibility and enrollment.

(a) *Eligibility.* An individual is eligible for LI NET coverage if they satisfy the criteria at paragraph (a)(1) or (2) of this section.

(1) *LIS-eligible.* The individual is a low-income subsidy eligible individual as defined at § 423.773 and—

(i) Has not yet enrolled in a prescription drug plan or an MA-PD plan; or

(ii) Has enrolled in a prescription drug plan or MA-PD plan but their coverage has not yet taken effect.

(2) *Immediate need individuals.* An individual who states their eligibility for LIS and immediate need for their prescription, but whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale, will be granted immediate need LI NET coverage.

(3) *Documentation of LIS eligibility.* Individuals may provide documentation to the LI NET sponsor to demonstrate LIS eligibility. Documentation may include, but is not limited to:

(i) A copy of the beneficiary's Medicaid card that includes their name and the eligibility date;

(ii) A copy of a letter from the State or SSA showing LIS or "Extra Help" status;

(iii) The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call;

(iv) A copy of a State document that confirms active Medicaid status;

(v) A screen-print from the State's Medicaid systems showing Medicaid status; or

(vi) Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy's patient profile.

(4) *Confirmation of LIS eligibility.* CMS uses documentation submitted under paragraph (a)(3) of this section to confirm LIS eligibility.

(5) *Inability to confirmation of eligibility.* 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.

(b) *Enrollment.* Individuals who are eligible for LI NET as defined in § 423.2504 are enrolled into the LI NET program as follows:

(1) *Automatic enrollment.* Beneficiaries who are LIS-eligible and whose auto-enrollment into a Part D plan (as outlined in § 423.34(d)(1)) has not taken effect will be automatically enrolled by CMS into the LI NET program unless the beneficiary has affirmatively declined enrollment in Part D per § 423.34(e);

(2) *Point-of-sale enrollment.* An individual 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; or

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

(4) *LI NET application form.* An individual who is not enrolled through one of the methods in paragraphs (b)(1) through (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) of this section). If no documentation is submitted and accepted, the LI NET sponsor will periodically check for eligibility and enroll applicants once LIS eligibility is confirmed.

(c) *Duration of LI NET enrollment.* (1) Enrollment begins on the first day of the month an individual is identified as eligible under this section and ends after 2 months, with a longer LI NET enrollment for those with retroactive coverage per paragraph (c)(2) of this section.

(2) Retroactive LI NET coverage begins on the date an individual is identified as eligible for a low-income subsidy as a full-benefit dual eligible or an SSI benefit recipient, or 36 months

prior to the date such individual enrolls in (or opts out of) Part D coverage, whichever is later. LI NET coverage ends with enrollment into a Part D plan or opting out of Part D coverage.

(d) *Ending LI NET enrollment.* An individual's enrollment in the LI NET program ends when:

(1) The individual is auto-enrolled into a standalone Part D plan in accordance with the guidelines at § 423.34(d) and that coverage has taken effect.

(2) The individual elects another Part D plan and that coverage has taken effect.

(3) The individual voluntarily disenrolls from the LI NET program.

(4) The individual is involuntarily disenrolled under § 423.44(b).

(5) LIS eligibility for an individual in LI NET due to an immediate need cannot be confirmed within the period of LI NET coverage.

§ 423.2508 LI NET benefits and beneficiary protections.

(a) *Formulary.* The LI NET program provides access to all Part D drugs under an open formulary.

(b) *Network.* The LI NET sponsor must allow its network and out-of-network pharmacies that are in good standing to process claims under the program. Licensed pharmacies are considered to be in good standing for the LI NET program so long as they: are not revoked from Medicare under § 424.535; do not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act or from Medicare and State health care programs under section 1156 of the Act (unless waived by the OIG); do not appear on the preclusion list as defined at § 423.100; and do not have a determination by the LI NET sponsor of a credible allegation of fraud as defined at § 423.4.

(c) *Safety.* The following provisions necessary to improve patient safety and ensure appropriate dispensing of medication apply to the LI NET program and LI NET sponsor, as applicable:

(1) Sections 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Cost sharing.* (1) LI NET beneficiaries under § 423.2504(a)(1) will pay the applicable cost sharing for their low-income category as established for each year in the Rate Announcement publication specified in § 422.312 of this chapter.

(2) LI NET beneficiaries under § 423.2504(a)(2) will pay the cost sharing associated with the category of non-institutionalized full-benefit dual eligible individuals with incomes above 100% of the Federal poverty level and full-subsidy-non-FBDE individuals. If the beneficiary is later confirmed to belong to a different LIS category, the LI NET sponsor must reimburse the beneficiary for the difference between the cost sharing they paid versus what they would have paid in their LIS category.

(e) *Appeals.* LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of this part.

§ 423.2512 LI NET sponsor requirements.

The LI NET program is administered by one or more Part D sponsor(s) that meet all of the requirements in paragraphs (a) through (c) of this section.

(a) *Pharmacies and access to Part D drugs.* (1) The LI NET sponsor must be a PDP sponsor that has an established contracted pharmacy network in all geographic areas of the United States in which low-income subsidies are available.

(2) The LI NET sponsor must meet the requirements for providing access to Part D drugs under § 423.120(a), (c), and (d).

(b) *Experience.* The LI NET sponsor must have a minimum of two consecutive years contracting with CMS as a Part D sponsor.

(c) *Other LI NET sponsor requirements.* The LI NET sponsor must:

(1) Have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees;

(2) Have the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees.

(3) Identify, develop, and conduct outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program.

(4) Establish and manage a toll-free customer call center per § 423.128(d)(1) and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf, for purposes that include but are not limited to: handling inquiries about services under the LI NET program, providing the status of eligibility or claims, and having the ability to accept supporting documentation.

(5) Timely respond to beneficiary requests for reimbursement of claims by issuing reimbursement for eligible claims submitted by beneficiaries no later than 30 days after receipt, or, if the drug is not covered, the LI NET sponsor has 14 days to send communication to the beneficiary with a reason for the denial.

(6) Adjudicate claims from out-of-network pharmacies that are in good standing (as defined in § 423.2508(b)) according to the LI NET sponsor's standard reimbursement for their network pharmacies.

§ 423.2516 Selection of LI NET sponsor and contracting provisions.

(a) *Appointment by CMS.* CMS appoints a Part D sponsor that meets the requirements at § 423.2512 to serve as the LI NET sponsor.

(b) *Selection criteria.* In appointing a LI NET sponsor, CMS evaluates the following:

(1) Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.34;

(2) Pharmacy access as outlined in § 423.120;

(3) Past performance, including Star Ratings (as detailed in § 423.186), previous intermediate sanctions (as detailed in § 423.750), and consistent with past performance in § 423.503(b); and

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

(c) *Term of appointment.* The term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per § 423.2524(b)) to determine payment rates for the upcoming year.

§ 423.2518 Intermediate sanctions for the LI NET sponsor.

In the event it is determined that the LI NET sponsor violated its contract, CMS may impose intermediate sanctions as outlined in subpart O of this part.

§ 423.2520 Non-renewal or termination of appointment.

(a) *Notice of non-renewal.* If the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS notifies the LI NET sponsor by January 1 of the year before the next contract year.

(b) *Selection of successor and transition period.* After a notice of non-renewal or termination, CMS selects a successor for the LI NET contract from among potentially eligible entities (as detailed in § 423.2516). The outgoing LI NET sponsor must coordinate with the successor for a period of no less than 3 months to ensure seamless transition of the LI NET program, including timely transfer of any data or files.

(c) *Immediate termination for cause.* (1) Notwithstanding paragraph (a) of this section, CMS may immediately terminate the existing LI NET contract for any of the reasons specified at § 423.509(a)(4)(i) and (xii) or § (b)(2)(i)(A) and (B).

(2) CMS sends notice of an immediate termination as specified at § 423.509(b)(2)(ii).

(d) *Appeal rights.* Subpart N of this part applies to a termination under paragraph (c) of this section.

§ 423.2524 Bidding and payments to LI NET sponsor.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Submission of bids and related information.* (1) The submission of LI NET bids and related information must follow the requirements and limitations in § 423.265(b), (c), (d)(1), (d)(2)(i), (ii), (iv), and (v), (d)(4) and (6), and (e).

(2) The review, negotiation, and approval of the LI NET bid would follow the provisions in § 423.272(a) and (b)(1) and (4).

(3) Basic rule for bid. The bid must reflect the LI NET sponsor's estimate of its revenue needs for Payment Rates A and B per paragraph (c) of this section.

(c) *Monthly payments.* CMS provides advance monthly LI NET payments equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid, as outlined in paragraph (b) of this section. LI NET payments are made on a prospective per-member, per-month basis.

(1) Payment Rate A is an annual rate of payment for projected administrative costs. An annual percentage-based cap on Payment Rate A limiting the year over year increase to Payment Rate A is set as part of the bid review and negotiation under § 423.272(a).

(i) For the 2024 plan year, the LI NET sponsor includes in its bid the assumption that Payment Rate A cannot exceed a 2% increase from the prior year's Payment A, which is a figure CMS will provide to the LI NET sponsor.

(ii) For the 2025 plan year and subsequent plan years, the LI NET sponsor will specify its assumption for any increase needed to the prior year's Payment Rate A, submitting justification to CMS in their bid if the cap exceeds 2%.

(2) Payment Rate B reflects the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit.

(d) *Payment reconciliation and risk corridors*—(1) *Reconciliation*. CMS conducts LI NET payment reconciliation each year for Payment Rates A and B after the annual PDE data submission deadline has passed and makes the resulting payment adjustment consistent with § 423.343(a).

(2) *Risk corridors*. As part of LI NET payment reconciliation, CMS will apply risk corridors to Payment Rate B as follows:

(i) There will be no risk sharing in the symmetrical 1% risk corridor around the target amount as defined in § 423.308.

(ii) There will be symmetrical risk sharing of 0.1% beyond the 1% risk corridor.

(iii) To carry out this section, § 423.336(c) applies to LI NET.

(e) *Reopening*. The LI NET contract will be subject to payment reopenings per § 423.346 as applicable.

(f) *Payment appeals*. The LI NET sponsor can appeal under § 423.350.

(g) *Overpayments*. The overpayment provisions at §§ 423.352 and 423.360 apply to LI NET.

§ 423.2536 Waiver of Part D program requirements.

CMS waives the following Part D program requirements for the LI NET program:

(a) *General information*. Paragraphs (1) and (3)(B) of section 1860D-4(a) of the Act (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(b) *Formularies*. Subparagraphs (A) and (B) of section 1860D-4(b)(3) of the Act (relating to requirements on development and application of formularies; formulary development) and formulary requirements in §§ 423.120(b) and 423.128(e)(5) and (6).

(c) *Cost control and quality improvement requirements*. Provisions under subpart D of this part, including requirements about medication therapy management, are waived except for the provisions in § 423.2508(d)(1) through (5).

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Out-of-network access*. Section 423.124 Special rules for out-of-network access to Part D drugs at out-of-network pharmacies, except for § 423.124(a)(2), which applies to LI NET.

(e) *Medicare contract determinations and appeals*. Subpart N, except for the provisions that apply to LI NET in § 423.2520(d).

(f) *Risk-sharing arrangements*. Section 423.336(a), (b), and (d).

(g) *Certification of accuracy of data for price comparison*. Section 423.505(k)(6).

(h) *Part D communication requirements*. Portions of subpart V of this part related to Part D communication requirements that are inapplicable to LI NET, including:

(1) Section 423.2265(b)(4), (5), (11), and (13);

(2) Section 423.2265(c);

(3) Section 423.2266(a);

(4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), and (33); and

(5) Section 423.2274.

(i) *Medicare Coverage Gap Discount Program*. Subpart W of this part.

(j) *Requirements for a minimum medical loss ratio*. Subpart X of this part.

(k) *Recovery audit contractor Part C appeals process*. Subpart Z of this part.

54. The heading for subpart Z is revised to read as follows:

Subpart Z - Recovery Audit Contractor Part D Appeals Process

PART 460--PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

55. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f).

56. Section 460.6 is amended by revising the definition of “contract year” to read as follows:

§ 460.6 Definitions.

* * * * *

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PACE organization’s initial contract year may be from 19 to 30 months, as determined by CMS, but in any event will end on December 31.

* * * * *

57. Section 460.40 is amended by revising paragraph (b) to read as follow:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(b) If CMS or the State administering agency makes a determination under § 460.50 that could lead to termination of a PACE program agreement, CMS may impose any of the sanctions specified at §§ 460.42 and 460.46. If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administering agency has to determine that the circumstances in § 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension.

58. Section 460.70 is amended by revising paragraph (a) to read as follows:

§ 460.70 Contracted services.

(a) *General rule.* The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, including, at a minimum, the medical specialties identified in paragraph (a)(1) of this section. The PACE organization does not need to have a written contract with entities that provide emergency services as described in § 460.100.

(1) At a minimum, except as noted in paragraph (a)(4) of this section, PACE organizations must have contracts in place for the following medical specialties:

- (i) Anesthesiology.
- (ii) Audiology.
- (iii) Cardiology.
- (iv) Dentistry.
- (v) Dermatology.
- (vi) Gastroenterology.
- (vii) Gynecology.
- (viii) Internal Medicine.
- (ix) Nephrology.
- (x) Neurosurgery.
- (xi) Oncology.
- (xii) Ophthalmology.
- (xiii) Oral surgery.
- (xiv) Orthopedic surgery.
- (xv) Otorhinolaryngology.
- (xvi) Palliative Medicine.
- (xvii) Plastic surgery.

(xviii) Pharmacy consulting services.

(xviii) Podiatry.

(xx) Psychiatry.

(xxi) Pulmonology.

(xxii) Radiology.

(xxiii) Rheumatology.

(xxiv) General Surgery.

(xxv) Thoracic and vascular surgery.

(xxvi) Urology.

(2) Contracts with medical specialists must be executed prior to enrollment of participants and must be maintained on an ongoing basis to ensure participants receive appropriate and timely access to all medically necessary care and services.

(3) A PACE organization is responsible for making all reasonable and timely attempts to contract with medical specialists. If at any time a PACE organization is unable to directly contract or maintain a contract with a specific specialty, the PACE organization must--

(i) Ensure care and services that would otherwise be provided to participants by a contracted specialist are provided and that the participant's needs are met through a different mechanism to include hospitalization; and

(ii) Promptly report the contracting issue to CMS and the SAA, including the attempts made to contract, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary services.

(4) A PACE organization is not required to have a contract with a particular medical specialty if the PACE organization directly employs one or more individuals prior to contracting who are legally authorized, and if applicable, board certified in the participant medical specialty.

* * * * *

§ 460.121 [Amended]

59. Section 460.121 is amended in paragraph (i)(2) by adding the phrase “either orally or” after the phrase “their designated representative”.

60. Section 460.200 is amended by revising paragraph (d)(2) to read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(d) * * *

(2) Maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant’s care, health, or safety including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant’s, care, health, or safety.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

* * * * *

61. Section 460.210 is amended by revising paragraph (b)(6) to read as follows:

§ 460.210 Medical records.

* * * * *

(b) * * *

(6) Original documentation, or an unaltered electronic copy, of any written communication as described in § 460.200(d)(2) must be maintained in the participant’s medical record unless the following requirements are met:

(i) The medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication,

(ii) Original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and

(iii) Original documentation of the communication is available to CMS and the SAA upon request.

* * * * *

Dated: March 31, 2023

Xavier Becerra,
Secretary,
Department of Health and Human
[FR Doc. 2023-07115 Filed: 4/5/2023 4:15 pm; Publication Date: 4/12/2023]