

Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2021 and 2022 (CMS-4190-P)

Proposed Rule Summary

On February 6, 2020, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule providing for policy and technical changes to Medicare Advantage (MA), Part D prescription drug program, PACE and Medicaid for 2021 and 2022.¹ The rule, set to be published in the *Federal Register* on February 18, 2020, implements certain provisions of the Bipartisan Budget Act of 2018 (BBA) 2018, The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act and the 21st Century Cures Act. In addition it includes proposals to permit Part D plans to offer a second “preferred” specialty tier, require MA and Part D plans to offer beneficiaries a real time benefit tool to view formulary information, require plans to disclose pharmacy performance measures, make changes to medical loss ratio calculations, codify and make policy changes to network adequacy requirements, and make a number of changes to the Program of All-Inclusive Care for the Elderly (PACE).

Comments are due on April 6, 2020.

At the same time, CMS also released the annual Medicare Parts C and D Calendar for the 2021 contract year (CY). The calendar provides key dates and timelines for MA plans, MA-PD plans, Prescription Drug Plans (PDPs), Medicare-Medicaid Plans (MMPs), and cost-based plans. It can also be found on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Overview> and the Contract Year (CY) 2021 bidding instructions.²

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¹ Available at <https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the>.

² Memorandum from Amy Larrick Chavez-Valdez, Director Drug Benefit and C & D Data Group dated February 6, 2020.

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I. Summary

CMS says the purpose of the proposed rule is to implement provisions of three recent federal laws: the BBA of 2018, the SUPPORT Act, and the Cures Act. In addition, it would make a number of changes to strengthen and improve the Part C and Part D programs and codify existing policies that previously were adopted through the annual Call Letter and other sub-regulatory guidance. Major provisions include:

Drug Management Provisions of the SUPPORT Act. CMS proposes to codify drug management-related provisions of the SUPPORT Act including requiring plans to have in place a Drug Management Program (DMP), to include beneficiaries who have a history of opioid-related overdose in those DMPs, to increase program integrity reporting around credible allegations of fraud including with respect to opioid prescribing, and provisions related to external review of certain appeals related to drug management reviews.

MA Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries. CMS proposes to codify provisions of the CURES Act that permit individuals with ESRD to enroll in a MA plan beginning for plan years beginning on or after January 1, 2021. Additionally, CMS would codify related provisions of the CURES Act that exclude organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Social Security Act (Act), from the Medicare FFS benefits an MA plan must cover; those costs would be covered under the FFS program. Because these costs would be covered under the FFS program, CMS would codify the requirement to exclude the estimate of standardized costs for payments for organ acquisitions for kidney transplants from MA benchmarks and capitation rates.

Pharmacy Performance Measure Reporting and Star Ratings. Part D plans would, under the proposed rule, be required to disclose to CMS the measures they use to evaluate pharmacy performance. CMS would report the information publicly to increase transparency. CMS also proposes a number of refinements to existing Star Ratings for MA and Part D plans.

Permitting a Second, “Preferred” Specialty Tier in Part D. CMS describes a proposal to permit Part D and MA-PD plans to offer a second specialty tier (although the regulatory text for the proposal is missing). Drugs on the second specialty tier would be subject to the same cost threshold as those on a single specialty tier. If two specialty tiers are offered, copayments for drugs on the second specialty tier would be required to be below those on the first specialty tier. Exceptions requests must be permitted but only between the two tiers.

Beneficiary Real Time Benefit Tool (RTBT). Beginning January 1, 2022, CMS would require Part D plan sponsors to offer beneficiaries with a RTBT that would include information about the formulary, cost, formulary alternatives, and utilization management requirements.

Medical Loss Ratio (MLR). The definition of “incurred claims” for the purpose of calculating the MLR would be modified to permit plans to include new supplemental benefits that are primarily health related and that are offered under the new special supplemental benefits for chronically ill (SSBCI). Other existing provisions, parameters, and methodologies would be codified. In addition, a new factor reflecting high deductibles for MA medical savings accounts plans would be proposed.

MA and Cost Plan Network Adequacy. Existing guidance on network adequacy would be codified. In addition, CMS proposes to modify the application of network adequacy requirements to give credit for plans offering telehealth benefits in certain specialties and for plans offered in states with certificate of need restrictions. In addition, standards for the percentage of beneficiaries meeting time and distance requirements would be reduced for plans operating in certain rural county designations.

Special Election Periods (SEPs) for Exceptional Conditions. CMS codifies the dozens of specific special election periods (SEPs) for exceptional conditions it established for the Part C and D programs through subregulatory guidance. It also proposes two new SEPs: one for plans placed in receivership and the other for consistently poor performing plans.

Service Delivery Request Processes under PACE. CMS proposes to provide specificity to its regulations on service delivery requests, including what does and does not constitute such a request. The agency would provide what it describes as more transparent requirements for how PACE organizations (POs) process those requests. It would specify who may make a request and how a request may be made; specific timeframes for processing these requests would be added. CMS would allow the PACE interdisciplinary team (IDT) to use a streamlined version of the process when a request may be approved in full by an IDT member at the time it is made. For other service delivery requests brought to the IDT, an in-person reassessment must be conducted before a request is denied (which is consistent with current requirements); however, where the full IDT would approve the request, it is not required but may elect to conduct reassessment, either in-person or through remote technology.

Beneficiaries with Sickle Cell Disease. Due to concerns about misapplication of opioid restrictions in the sickle cell disease (SCD) patient population, CMS proposes, beginning with plan year 2021, to classify beneficiaries with SCD as exempt individuals with respect to Drug Management Programs (DMPs) requirements.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Special Supplemental Benefits for the Chronically Ill (SSBCI) (§422.102)

The Bipartisan Budget Act (BBA) of 2018 authorized MA plans to provide chronically ill enrollees additional supplemental benefits that have a reasonable expectation of improving or maintaining the health or overall function of those enrollees. These additional supplemental benefits do not have to be primarily health related.

The BBA of 2018 defined a chronically ill enrollee to mean an individual who (i) has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee; (ii) has a high risk of hospitalization or other adverse health outcomes; and (iii) requires intensive care coordination.

CMS may waive otherwise applicable uniformity requirements for these special supplemental benefits for the chronically ill (SSBCI).

CMS proposes to codify its existing guidance (the April 2019 Health Plan Management System (HPMS) Memo³ and the 2020 Call Letter⁴) and parameters for the SSBCI authority.

CMS proposes to permit an MA plan to offer SSBCI to a chronically ill enrollee only as a mandatory supplemental benefit. Further, CMS proposes that upon approval by the agency of a plan's SSBCI benefit, an MA plan may offer SSBCI that are not uniform for all chronically ill enrollees in the plan.

CMS uses a panel of clinical advisors to develop a list of conditions that meet the definition of a severe or disabling chronic condition; MA plans may consider any enrollee with a condition on that list to meet the first criterion of the definition of chronically ill enrollee (i.e., of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee). CMS notes that, for purposes of SSBCI, this list is "non-exhaustive" and that an MA plan may also consider a chronic condition not on the list if that condition is life threatening or significantly limits the overall health or function of the enrollee. While MA plans do not have to submit to CMS the processes they use to identify chronically ill enrollees that meet all three criteria, CMS emphasizes that all those criteria must be met. CMS expects MA plans to document enrollee eligibility for SSBCI and to make information and documentation available to the agency upon request.

CMS notes that SSBCI must comply with criteria for supplemental benefits which CMS proposes to codify at §422.100(c)(2)(ii) (discussed later in this summary in section VI.F). Because SSBCI do not have to be primarily health related, CMS proposes to modify its longstanding guidance on supplemental benefits to accommodate this difference. Specifically, it proposes to clarify that the MAO must incur a "non-zero direct non-administrative cost" for SSBCI that are not primarily health related. The expectation is that the MAO's incurred cost

³ https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf
⁴ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>

should be a non-administrative cost for providing the benefit even if it is not necessarily a cost paid to a medical provider or facility. Where SSBCI are primarily health related, the supplemental benefits must meet the otherwise generally applicable requirements, including that the MAO incur a “non-zero direct medical cost” for all primarily health related supplemental benefits. The April 2019 HPMS memo referenced above provides examples of non-primarily health related benefits for purposes of SSBCI.

CMS states that MA plans may consider social determinants of health as a factor when determining eligibility for an SSBCI, but they may not use it as the sole basis for determining SSBCI eligibility.

CMS proposes to codify requirements under the April 2019 HPMS memo that MA plans that offer SSBCI must have written policies for determining enrollee eligibility for SSBCI based on objective criteria (e.g., health risk assessments, claims data review); must document those criteria; must document each determination of enrollee eligibility for an SSBCI; and must make this information available to CMS upon request.

CMS clarifies that a determination on the benefits an enrollee is entitled to receive under an MA plan’s SSBCI is an organization determination that is subject to grievance and appeals under procedures specified under subpart M of part 422 of the regulations.

CMS does not expect its proposed codification of policies or its new definitions will have any impact on current operating expenses or impose any collection of information requirements.

B. Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§422.101)

The BBA of 2018 substantially modified requirements for Chronic Condition Special Needs Plans (C-SNPs) as follows:

- The C-SNP’s interdisciplinary team must include a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the C-SNP.
- The C-SNP must comply with CMS requirements to provide face-to-face encounters with enrollees at least once annually.
- As part of the mandatory model of care (MOC), the results of the initial assessment and annual reassessment required for each enrollee must be addressed in the individual’s individualized care plan.
- As part of the annual evaluation and approval of the MOC, CMS will take into account whether the plan fulfilled the previous year’s goals (as required under the MOC).
- CMS will establish a minimum benchmark for each element of the MOC and only approve a C-SNP’s MOC if each element of the model of care meets such minimum benchmark.

CMS proposes to codify these requirements; further, CMS proposes to extend new requirements for SNP enrollee management and SNP MOC submissions to all MA special needs plans (SNPs). The agency’s rationale for extending the new requirements to all SNPs is that they are consistent with current regulations and sub-regulatory guidance and that the requirements are important

safeguards to preserve quality of care for special needs individuals enrolled in any type of SNP. **CMS welcomes comment on extending these requirements to all SNPs.**

1. The Interdisciplinary Team in the Management of Care

CMS proposes to amend its regulations to require MAOs offering a SNP to provide “each enrollee with an interdisciplinary team in the management of care that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.” CMS believes that plans are best suited to identify an interdisciplinary team with the appropriate expertise and training to meet the clinical needs of each enrollee. **It seeks comment on its proposed implementation of the law and welcomes feedback on how plans can meet requirements for both demonstrated expertise and training in an applicable specialty.**

2. Face-to-Face Annual Encounters

CMS proposes to require every MA SNP plan to provide for at least annual face-to-face encounters between each enrollee and a member of the enrollee’s interdisciplinary team or the plan’s case management and coordination staff. CMS states that a visit to or by a member of an individual’s interdisciplinary team or the plan’s case management and coordination staff that perform clinical functions, such as direct beneficiary care, would satisfy this requirement. Examples include an annual wellness visit, health risk assessment (HRA) completion, care plan review, health related education, care coordination activities, and encounters addressing concerns related to physical or mental/behavioral health or overall health status.

The face-to-face encounter could be done either in person or through a visual, real-time, interactive telehealth encounter.

The first encounter would have to occur during the first 12 months of enrollment, as feasible and with the individual’s consent.

CMS seeks comment on its proposal and the suggested criteria for what constitutes a face-to-face encounter.

3. Health Risk Assessments (HRAs) and the SNP Enrollee’s Individualized Care Plan

Currently, MA SNPs must conduct a comprehensive initial health risk assessment of an individual’s physical, psychosocial, and functional needs as well as annual HRAs, using a comprehensive risk assessment tool that CMS may review during oversight activities. CMS proposes to require that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual’s individualized care plan. **CMS welcomes comment on its proposed addition.**

4. SNP Fulfillment of the Previous Year’s Model of Care (MOC) Goals

CMS proposes to codify the BBA of 2018 requirement that the evaluation and approval of the model of care for a SNP enrollee must take into account whether the plan fulfilled the previous

MOC's goals. CMS proposes that all SNPs must submit their model of care to CMS for evaluation and approval by the National Committee for Quality Assurance (NCQA) in accordance with CMS guidance. CMS would further require the NCQA, as part of the evaluation and approval of the SNP model of care, to evaluate whether goals were fulfilled from the previous model of care.

SNPs would have to provide relevant information relating to the MOC's goals as well as appropriate data related to the fulfillment of the previous MOC's goals. A SNP that submits an initial MOC must provide relevant information pertaining to the MOC's goals for review and approval by the NCQA. If the SNP MOC did not fulfill the previous MOC's goals, the plan must indicate in its MOC submission how it will achieve or revise the goals for the plan's next MOC.

NCQA would determine whether each SNP provided adequate information and whether the SNP met goals from the previous MOC submission. CMS believes its proposal aligns with current guidance on the MOC submission and review process on SNP fulfillment of goals; **it seeks comment on the proposal.**

5. Establishing a Minimum Benchmark for Each Element of the SNP Model of Care

Under the current methodology for scoring models of care, each subfactor of a MOC element is valued at 0-4 points with the score of each element based on the number of factors met for that specific element; the aggregate total of all possible points across all elements equals 60. The total points awarded to an MOC are divided by 60 and converted to a percentage score.

CMS proposes new regulation text to codify the requirement that benchmarks must be met for an MOC to be approved. For all SNPs submitting a model of care, CMS proposes that each element of the MOC must meet a minimum benchmark score of 50 percent. A SNP's model of care would only be approved if each element of the MOC meets the minimum benchmark. **CMS seeks comment on its proposed benchmark and scoring criteria.**

C. Coverage Gap Discount Program Updates (§§423.100 and 423.2305)

CMS proposes conforming changes to its regulations to implement changes to the Part D coverage gap discount program under the BBA of 2018. Specifically, CMS would amend its definition of applicable discount under the coverage gap discount program to provide that, for plan years after 2018, the applicable discount is 70 percent of the portion of the negotiated price of a manufacturer's applicable drug that falls within the coverage gap and that remains after the negotiated price is reduced by any available supplemental benefits.

CMS also proposes to revise the definition of applicable drug to include biosimilar products in the coverage gap discount program for plan years after 2018.

D. Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts (§423.286)

The Affordable Care Act (ACA) imposed an income-related monthly adjustment amount (i.e., a payment in addition to the Part D premium) under the Medicare Part D program (the Part D-IRMAA). This applies to beneficiaries whose modified adjusted gross income (MAGI) exceeds the same income threshold amount tiers established under section 1839(i) of the Act for the Medicare Part B income-related monthly adjustment amount (Part B-IRMAA).

The Part D-IRMAA is calculated using the Part D national base beneficiary premium (BBP) and the applicable premium percentage (P) as follows: $BBP \times [(P - 25.5 \text{ percent})/25.5 \text{ percent}]$. The premium percentage (30, 50, 65, or 85) depends on the beneficiary's MAGI. The BBA of 2018 increased the highest premium percentage from 80 to 85 percent. CMS proposes to revise the regulations to conform them with the statutory change as well as to make what it describes as technical changes to correctly describe the calculations used in the methodology for updating the Part D-IRMAA. The proposed revision reads as follows:

(ii) The income-related monthly adjustment is equal to the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, $\text{premium percentage} - 25.5 \text{ percent} / 25.5 \text{ percent}$).

20 CFR 418.2120⁵ contains the regulatory explanation of the methodology used to determine the monthly income-related adjustment amount.

CMS notes it does not score this provision in the Regulatory Impact Analysis or in the Collection of Information sections of the proposed rule because it codifies existing guidance and all information impacts have already been accounted for under OMB control number 0938-0964 (CMS-10141). **The agency seeks comments on these assumptions.**

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

CMS expresses concerns with D-SNP look-alike plans. These plans are not SNPs, but they have levels of dual eligible enrollment that are “virtually indistinguishable” from D-SNPs, and far above those of a typical MA plan. D-SNP look-alike plans are regulated as non-SNP MA plans and do not have to meet the federal regulatory and state contracting requirements that apply to D-SNPs. Thus unlike a D-SNP, a D-SNP look-alike plan is not obliged to perform health risk assessments; develop individualized care plans for enrollees; prepare or seek approval of models of care for each enrollee; prepare comprehensive written statements for prospective enrollees; enter into a contract with the state Medicaid agency; meet minimum Medicare/Medicaid

⁵ https://ecfr.io/Title-20/se20.2.418_12120.

integration standards; meet Medicaid coordination requirements; or have a unified grievance and appeals system for Medicare and Medicaid benefits.

To address these (and other) concerns, CMS proposes to establish regulatory requirements for dual eligible enrollment and for transitioning enrollees from certain D-SNP look-alike plans to other MA plans. CMS believes new contracting standards will ensure that all MA plans that predominantly serve dual eligibles will integrate Medicare and Medicaid services and coordinate care in the same manner as D-SNPs are required to do.

1. Rule on Dual Eligible Enrollment

CMS proposes to limit the availability of D-SNP look-alike plans in any state where there is a D-SNP or any other plan authorized by CMS to exclusively enroll Medicaid beneficiaries (such as Medicare-Medicaid Plans). CMS believes it has the statutory authority to impose this policy and proposes to do so to maintain the integrity of the D-SNP statutory framework.

Starting with plan year 2022, CMS would not enter into or renew a contract for an MA plan that is not a MA SNP plan based on its actual or projected enrollment of dual eligibles. An MA plan could not contract with CMS for plan year 2022 or any subsequent plan year if it:

- Projects enrollment in its bid that 80 percent or more of the plan's total enrollment are dual eligibles; or
- Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of dual eligibles, 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.

To reiterate, these requirements would not apply to any type of MA SNP. CMS considered alternative percentage thresholds (such as 50 percent) but concluded that 80 percent would demonstrate a clear intent by a non-SNP plan to target dual eligibles. **CMS seeks comments on alternative thresholds.**

As of July 2019, there were only 8 states that do not have any D-SNPs. CMS is concerned about the impact of D-SNP look-alike plans on dual eligibles in those states in part because of the lack of data sharing and care coordination; **it seeks comment on whether this would disadvantage dual eligibles in those states.**

2. Transition Process and Procedures

To ensure a smooth transition for enrollees from a plan that is discontinued for failure to meet the 80 percent thresholds described above, CMS proposes several rules for transitioning enrollees from a discontinued D-SNP look-alike plan to another MA plan, which would be effective for coverage effective January 1 of the next year.

An MAO could transition enrollees in a plan that is being discontinued because it does not meet the proposed 80 percent thresholds into another MA-PD plan or plans (including a D-SNP for enrollees eligible for a D-SNP) offered by the MAO, or by another MAO that shares the same

parent organization as the MAO. The individual would have to be eligible to enroll in the MA-PD plan, meaning they would have to reside in the plan service area and meet other requirements.

The MA-PD plan receiving enrollment from the discontinued D-SNP look-alike plan would have to satisfy certain requirements. First, in the case of a plan that is not a SNP plan, the resulting total enrollment of the receiving plan could not exceed the 80 percent threshold for dual eligibles. CMS notes it would have to make this determination prospectively; it would add the cohort of enrollees the MAO proposes to enroll into a different non-SNP plan to the April enrollment and calculate the resulting percentage of dual eligibles. Second, a MA-PD plan receiving transitioned enrollment from a D-SNP look-alike must have a combined Part C and D beneficiary premium of \$0 after application of the premium subsidy for full subsidy eligible individuals (as described at §423.780(a)).

CMS proposes that the MAO may transition individuals without requiring the individual to file an election form if the individual is eligible to enroll in the MA plan and the MAO describes changes to MA-PD benefits and information about the MA-PD plan into which the individual is enrolled in the Annual Notice of Change. The notice describing the change in plan enrollment and any differences would have to be provided at least 15 days before the annual election period.

If the MAO does not transition current enrollees, it must send a written notice to enrollees who are not transitioned following the rules for notice of non-renewal of plans.

3. Marketing

CMS also is concerned about beneficiary confusion due to misleading marketing practices by brokers and agents of D-SNP look-alike plans. CMS proposes to codify sub-regulatory guidance that prohibits MAOs from marketing their non-D-SNP plans as though they were D-SNPs, such as implying the plan is designed for dual eligibles, targeting marketing efforts exclusively to dual eligibles, or claiming a relationship with the state Medicaid agency unless there is a contract in place to coordinate Medicaid services.

4. Effective Dates

CMS proposes that the transition process take effect in time for D-SNP look-alikes operating in 2020 to use the transition process for enrollments effective January 1, 2021; thus, the transition authority would be effective after publication of the final rule. However, contract terminations for plans that fail to meet the proposed dual eligible enrollment thresholds would take effect no earlier than December 31, 2021.

III. Implementation of Opioid Provisions under the SUPPORT Act

A. Mandatory Drug Management Programs (DMPs) (§423.153)

All Part D plans are required to have a Drug Utilization Management Program, a program for quality assurance, and a medication therapy management program described in existing 42 CFR sections 423.153(b), (c) and (d). In addition, through the 2019 plan year, Part D plans could

choose to voluntarily provide a DMP to address overutilization of frequently abused drugs for at-risk beneficiaries. The features of those programs are described in existing section 423.153(f).

The SUPPORT Act made several changes to the requirements for Part D DMPs that CMS proposes be codified. Section 2004 of the SUPPORT Act requires Part D sponsors to adopt DMPs beginning with plan years starting on or after January 1, 2022. CMS states in the preamble that it proposes to codify this requirement at section 423.153(f) although it does not appear in the proposed regulation text. CMS notes that even though DMPs have been optional for plans, 99% of Medicare Part D enrollees were in plans that offered a DMP in 2019.

B. Beneficiaries with History of Opioid-related Overdose in DMPs (§423.100)

Section 2006 of the SUPPORT Act requires CMS, beginning January 1, 2021, to identify Part D beneficiaries with a history of opioid-related overdose and include them as potential at-risk beneficiaries. In response, CMS proposes to modify the definition at §423.100 of a “potential at-risk beneficiary” to include those individuals with a history of opioid-related overdose. Those individuals would be described as people who have at least one recent Medicare fee-for-service (FFS) claim containing a principal diagnosis of opioid overdose and at least one recent prescription drug event (PDE)⁶ for an opioid medication has been submitted. (The regulatory text does not make clear that both of those conditions must be met. The interpretation that both must be met in this summary is based on the preamble description.)

CMS notes that this proposed change to the definition of potential at-risk beneficiary, if finalized, will be operationalized by including both overdoses due to prescription as well as illicit opioid use, will use a 12-month lookback period for identifying those overdoses, and will use a 6-month lookback for identifying a PDE for an opioid medication. It expects an additional 18,268 individuals to be identified as at risk under this proposal.

CMS considered alternatives for incorporating section 2006 into the definition of a potential at-risk beneficiary. It considered only including those experiencing an overdose of a legally prescribed opioid. It rejected this approach due to both the difficulty of knowing whether the overdose was attributable to a validly prescribed opioid. It also considered alternative look-back periods for identifying overdoses but believes that 12 months best identifies those individuals most at risk of having another opioid-related overdose. Additional approaches considered and rejected are identified in the Regulatory Impact Analysis. In addition, CMS describes its methodology for estimating the number of individuals that would be added to those potentially at risk as a result of the proposed changes.

CMS encourages providers to consult with state-based prescription drug monitoring programs before prescribing opioids to reduce the number of beneficiaries meeting the current Overutilization Management System (OMS)⁷ criteria and to consider prescribing opioid-reversal

⁶ A PDE is different from a claim because a PDE record includes some additional information that is not on a claim including any post-transaction adjustments between a plan and a pharmacy, adjustments for enrollment mistakes, and adjustments related to certain demonstrations.

⁷ CMS' Overutilization Management System (OMS) is the tool designed and implemented by CMS to oversee sponsors' compliance with CMS' opioid overutilization policy. Through the OMS, Part D sponsors are provided

agents if they become aware of a beneficiary's history of opioid-related overdose. CMS also notes that the goal is to ensure the best possible care for each unique patient – not to stigmatize patients, nor abruptly taper or discontinue their medications. **It requests feedback on additional ways to facilitate case management for potentially at-risk beneficiaries.**

Information Collection and Regulatory Impact Analysis. CMS provides estimates for the costs of designing a DMP, conducting case management including sending written information about being identified as a beneficiary at risk or potentially at risk, and disclosing data to CMS about case management via OMS for those plan sponsors who do not already operate a DMP. CMS estimates that there are only 111 contracts run by 79 parent organizations that would be affected. Altogether the costs for these activities would total about \$13 million in the first year and \$10 million for each subsequent year. The greatest costs would be for creating the DMPs and for conducting case management for individuals identified as potentially at risk.

Creating the DMPs is estimated to require 79 entities to devote 80 hours each with a total cost in year one of about \$3.0 million. Taking into account the proposed new definition of potentially at-risk beneficiaries, CMS estimates that 288 entities would need to provide case management to an additional 18,268 individuals at a total cost of \$9.9 million per year.

In the Regulatory Impact Analysis, CMS discusses the impact on various stakeholders of the DMP provisions, including on pharmacy-related businesses. It expects the DMP provisions to reduce prescription drug use for the targeted population and to reduce Medicare Trust Fund spending. Network pharmacies that participate in drug utilization review may also be impacted by the additional case management for potentially at-risk beneficiaries. Overall, CMS estimates that the DMP provisions will cost \$29 million over the 2021 to 2030 period. This is net of \$75 million in savings to the Medicare Trust Fund (about \$7.7 million per year) and an additional cost of \$105 million mostly for plans and mostly resulting from the additional required case management.

C. Information on the Safe Disposal of Prescription Drugs (§422.111)

Section 6103 of the SUPPORT Act requires MA plans to provide beneficiaries with information on the safe disposal of prescription drugs when doing an in-home health risk assessment. CMS proposes to require in new paragraph (j) in §422.111 (a section establishing disclosure requirements), that such information be provided beginning with in-home health risk assessments provided on or after January 1, 2021. Such written materials must include the following information:

- Unused medications should be disposed of as soon as possible.
- The US Drug Enforcement Administration (DEA) allows unused prescription medications to be mailed back to pharmacies and other authorized sites.
- Community take back sites are preferred for disposing unused controlled substances.
- The locations of take back sites available in the MA plan service area.

quarterly reports on high risk beneficiaries and are required to provide CMS with the outcome of their review of each case.

- Instructions on how to safely dispose of medications in the trash or when they can be safely flushed.
- A web link to the information available on the HHS website identifying methods for the safe disposal of drugs (www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html).

D. Beneficiaries’ Education on Opioid Risks and Alternative Treatments (§423.128)

Section 6102 of the SUPPORT Act requires Part D plans, including MA-PDs and standalone PDPs to provide, beginning with plan year 2021, enrollees with information about the treatment of pain, including the risks of prolonged opioid use and the coverage of non-pharmacological therapies, devices, and non-opioid alternative under the plan. Plan sponsors can choose to provide the opioid risk and alternative treatment coverage information to subsets of enrollees or to every plan enrollee.

CMS codifies this requirement in §143.128 (a section addressing required dissemination of Part D plan information) in new (b)(11). In addition, CMS provides its own estimates of the number of people who would be provided with such information if a plan chose to limit the disclosures to certain subsets of individuals. Those estimates are provided in Table 2 (duplicated below). In addition, CMS provides considerably more estimates of options for providing such information in Table 17 in discussing Information Collection Requirements.

Table 2: Suggested Subset Options to Receive Education on Opioid Risks and Alternate Treatments*

Subset	Suggested Subset	Number of Enrollees in this Subset	Percent of Total Opioid Users
1	All Part D Enrollees	46,759,911	N/A
2	Any opioid use in last 2 years	16,134,063	100%
3	Any opioid use in past year	11,027,271	100%
4	7 days continuous opioid use	7,163,615	65%
5	Greater than 30 days continuous opioid use, 7 day or less gap	3,816,731	35%
6	Greater than 90 days continuous opioid use, 7 day or less gap	2,698,064	24%

*All figures based on 2018 PDE data as of 7/6/2019, except subset 2 which is based on 2017 and 2018 PDE data. Beneficiaries were excluded from the opioid use subsets if they were in hospice, in a resident facility, or had a palliative care diagnosis (07/01/2018 - 12/31/2018). Beneficiaries were also excluded if they had a cancer diagnosis (01/01/2018 - 12/31/2018). No exclusions were applied to the all Part D enrollees figure (subset 1).

E. Eligibility for Medication Therapy Management Programs (MTMPs) (§423.153)

1. At-Risk Beneficiaries and MTMPs

Section 6064 of the SUPPORT Act added a provision requiring that, beginning January 1, 2021, “at-risk beneficiaries” as defined in §423.100 be targeted for enrollment into Part D plans’ MTMPs. MTMPs, described in §423.153(d), are designed to improve outcomes for targeted beneficiaries and reduce the risk of adverse events. Under existing rules, plans can identify their own criteria for whom to target for the MTM program as long as they include beneficiaries who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur Part D costs in excess of a specified cost threshold.

CMS proposes to codify this requirement into §143.153(d)(2), which, under existing rules describes targeted individuals for MTMPs.

CMS describes existing requirements under the MTMP standards that will apply to at risk beneficiaries under Section 6064 including that the enrollees must be automatically enrolled with an opt-out (existing 423.153(d)(1)(v)); that plan sponsors must offer an annual comprehensive medication review (existing §423.153(d)(1)(vii)(B) and targeted medication reviews no less than quarterly. If an enrollee declines the annual comprehensive medication review, CMS notes that the sponsor is still required to offer interventions to the prescriber and conduct the targeted medication reviews.

CMS solicits input into how sponsors can coordinate DMPs and MTM programs and effectively perform outreach; how to leverage MTM services to improve medication use and reduce adverse events; how to measure the quality of MTM services, how to increase meaningful engagement of the new target population, and the type of information that CMS should use to monitor the impact of MTM services on at-risk beneficiaries.

CMS provided a Standardized Format for the comprehensive medication review⁸ which is approved through August 31, 2020. Because of some of the SUPPORT Act provisions, CMS notes that the Standardized Format must be revised. CMS is also considering further modifications to allow the form to be completed in a machine readable format and notes that the Interoperability rule⁹ encourages the use of Health Level Seven (HL7®) Fast Healthcare Interoperability Resources–based API. **It seeks feedback on the value of doing so for the comprehensive medication review Standardized Format.**

2. Information on Safe Disposal

Section 6103 of the SUPPORT Act requires Part D plans to provide beneficiaries in MTM programs with information about the safe disposal of prescription drugs that are controlled substances. CMS proposes to incorporate this requirement in proposed new §423.153(d)(1)(E). Under the proposal, plan sponsors must provide information on safe disposal at least annually. The information could be provided as part of a comprehensive medication review, a targeted medication review, or another follow-up service. The components of information to be provided would need to conform to the components of such disclosures proposed in §422.111(j) (described above).

F. Automatic Escalation to External Review under a DMP for At-risk Beneficiaries (§§ 423.153, 423.590, 423.600)

Under existing rules, an individual who is determined to be at-risk for overuse or abuse of frequently-abused drugs has the right to appeal that at-risk determination as well as any point-of-

⁸ CMS-10396, OMB Control Number 0938-1154)

⁹ Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers Proposed Rule (84 FR 7610).

sale edits or lock-in provisions that are applied to the enrollee. The Secretary has the discretion to identify any appeals that should be automatically escalated to external review but has not so far exercised that discretion.

Section 2007 of the SUPPORT Act requires that, if upon reconsideration, a Part D sponsor affirms its denial of a DMP appeal, the case will be automatically forwarded to the independent review (IRE) entity contracted with CMS for review and resolution.

CMS proposes to codify that provision by:

- Modifying content requirements for initial and second notices at §423.153(f)(5)(ii)(c)(3) and §423.153(f)(6)(ii)(c)(4)(iii) to explain that if a plan sponsor affirms its at-risk decision on redetermination, the enrollee’s case will be automatically forwarded to the IRE for review and resolution.
- Revising adjudication timeframes for redeterminations at §423.590 to state that the plan sponsor must forward the case to the IRE by the expiration of the applicable timeframe.
- Revising §423.600(b) to clarify that the requirement that the IRE solicit the views of the prescribing physician or other prescriber applies to determinations that are auto-forwarded to the IRE.

G. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures

Sections 2008(a) and (b) and 6063(a) of the SUPPORT Act added new requirements for Part D and MA-PD plans intended to improve identification of credible allegations of fraud and program integrity. CMS proposes to codify those provisions in sections of existing rules governing Part D plans and MA-PD plans as described below:

1. Substantiated or Suspicious Activities of Fraud, Waste, or Abuse

The SUPPORT Act required CMS to establish a regulatory definition of “substantiated or suspicious activities of fraud, waste, or abuse.” CMS proposes to do so in §422.500 (applicable to MA plans) and §423.4 (applicable to Part D plans). The term would be defined to include (but not be limited to) allegations that a provider (including a prescriber) or supplier engaged in a pattern of improper billing; submitted improper claims with suspected knowledge of their falsity; submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or is the subject of a fraud hotline tip verified by further evidence.

2. Inappropriate Prescribing

CMS proposes a definition of “inappropriate prescribing” in those same sections of existing regulations. It would mean an established pattern of potential fraud, waste, and abuse related to prescribing of opioids that is identified after consideration of all the facts and circumstances through investigation or other information or actions, as reported by the plan sponsors. Plan sponsors can consider factors including documentation of a patient’s medical condition; patient harm or death; medical records and claims; concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of patient harm; dosages prescribed; lack of clinical

indication or documentation in the care management plan; state-level prescription drug monitoring program (PDMP) data; geography, time, and distance between a prescriber and the patient; and refill frequency and factors associated with increased risk of opioid overdose.

CMS indicates that it may consider certain statistical deviations to be an indication of inappropriate prescribing of opioids. It solicits evidence from clinical experts that could be used to develop outlier methodologies for this purpose as well as any other reasonable measures of inappropriate prescribing.

3. Credible Allegation of Fraud

Section 2008(d) of the SUPPORT Act states that a fraud hotline tip without additional evidence is not sufficient evidence for a credible allegation of fraud. In response, CMS is proposing to amend the existing definitions of “credible allegation of fraud” in §§405.370 and 455.2. (existing program integrity provisions applicable to Medicare and Medicaid) to include fraud hotline tips as credible allegations of fraud only when they are verified by further evidence.

In addition, CMS proposes to add a new definition to §423.4 that would be parallel to those definitions in §§405.370 and 455.2 to define a credible allegation of fraud to include (but not be limited to) a fraud hotline tip verified by further evidence, claims data mining, patterns identified through audits, civil false claims cases and law enforcement investigation. Allegations would be considered to be credible when they have indicia of reliability.

4. Fraud Hotline Tip

CMS proposes to add a definition of a fraud hotline tip to §§405.370, 422.500, 423.4, and 455.2 (existing program integrity regulations applicable to Medicare, MA, Part D, and Medicaid). A fraud hotline tip would be defined as a complaint or communications submitted through a fraud reporting number or website such as the HHS OIG Hotline or a health plan’s fraud hotline.

5. Reporting

Section 6063(a) of the SUPPORT Act requires, by October 24, 2020, CMS to establish a secure web-based program integrity portal through which it will provide for secure communications among HHS, MA plans, PDPs and other program integrity contractors. By January 1, 2021, the SUPPORT Act requires all plans to submit through the portal information on investigations, credible evidence of suspicious activities and other actions taken by plans related to the inappropriate prescribing of opioids.

CMS proposes to use, as its portal, a module already available within the HPMS system for the collection and dissemination of such information. It proposes to modify existing sections of the regulations which currently describe the ability of MAOs and Part D plan sponsors to voluntarily report potential fraud or misconduct to be consistent with SUPPORT Act requirements. Sections §§422.503(b)(4)(vi)(G)(4) and 423.504(b)(4)(vi)(G)(4) would be amended to require the MAO or Part D plan sponsor to have procedures in place to identify and report to CMS (or its designee):

- Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy; and
- Any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

In addition, the proposed amendment would provide a list of 68 data elements that would be required to be submitted via the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud. The data elements would be listed in §§422.503(b)(4)(vi)(G)(5) (applicable to MA-PD plans) and 423.504(b)(4)(vi)(G)(5) (applicable to Part D plans.)

CMS notes that such reporting only applies, in the context of Medicare Part C, to MA-PD plans.

With respect to reporting payment suspensions, reports would need to be submitted 14 days prior to the implementation of the payment suspension. With respect to reporting related to inappropriate prescribing (second bullet point above), reporting would begin in 2021 and reports would need to be submitted not later than January 15, April 15, July 15, and October 15 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

In addition to plan sponsor reporting, Section 6063(a) of the SUPPORT Act requires the Secretary to make quarterly reports available to plans on fraud, waste and abuse schemes and trends in identifying suspicious activity. Consistent with that requirement, CMS proposes in new §§422.503(b)(4)(vi)(G)(7)(i) through (iv) and 423.504(b)(4)(vi)(G)(7)(i) through (iv) that CMS will provide MAOs and Part D plan sponsors with quarterly reports or links to data beginning in 2021. Reporting to plans would include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. Any information submitted by plans would be de-identified in the reports. The first quarterly report (April 15, 2021) would reflect data gathered and analyzed for the previous quarter (submitted by plan sponsors on January 15, 2021.) **CMS requests comment on the proposed timing of the CMS reports to plans.**

Information Collection Requirements and Regulatory Impact Analysis. CMS estimates the costs of the proposed reporting requirements based on a recent pilot that tested the reporting of all types of health care fraud, waste and abuse. Based on those costs, CMS expects that the reporting of payment suspensions and information on inappropriate prescribing of opioids will result in all 605 MA plans and 63 Part D plans a total of about \$15 million in the first year of reporting and an additional cost of \$9.5 million for each subsequent year.

IV. Implementation of Certain Provisions of the 21st Century Cures Act

A. MA Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§422.50, 422.52, and 422.110)

CMS provides an overview of the prohibition on enrollment of individuals with ESRD in MA plans, including limited exemptions provided for in subsequent law and regulations for certain

circumstances. Section 17006(a) of the Cures Act removed the prohibition for beneficiaries with ESRD from enrolling in an MA plan. This change is effective for plan years beginning on or after January 1, 2021.

CMS proposes several technical changes to its regulations to implement the statutory mandate; CMS would revise:

- Section 422.50(a)(2) to specify that the prohibition of beneficiaries with ESRD from enrolling in MA plans (and associated exemptions) is only applicable for coverage prior to January 1, 2021.
- Section 422.52(c) to specify that CMS authority to waive the enrollment prohibition in §422.50(a)(2) to permit ESRD beneficiaries to enroll in a special needs plan would also only be applicable for plan years prior to 2021. The waiver authority is no longer required as there are no limitations on enrollment of ESRD beneficiaries.
- Section 422.110(b) to specify that the exception to the anti-discrimination requirement, which was adopted to account for the prohibition on MA enrollment by beneficiaries who have ESRD, is only applicable for plan years prior to 2021.

The limitations on enrollment, and provisions for special exemptions, continue to apply for plan year 2020.

B. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for MA Beneficiaries (§422.322)

Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Act, from the items and services an MA plan is required to cover for an MA enrollee. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program.

CMS proposes to revise §422.322 to add a new paragraph (d) to reflect that expenses for organ acquisitions for kidney transplants are an exception to the general rule that payment to MAOs for Medicare-covered benefits is in lieu of the amounts that would otherwise be payable under Part A or B of the program; payment for these costs will be made under the Medicare FFS program.

CMS notes that the Cures Act did not provide for the same policy (i.e., Medicare FFS coverage of organ acquisition costs for kidney transplants) for costs incurred by PACE participants. Thus, PACE organizations will continue to cover organ acquisition costs for kidney transplants; CMS notes that those costs are accounted for in the PACE payment rates.

C. Exclusion of Kidney Acquisition Costs from MA Benchmarks (§§422.258 and 422.306)

CMS must change its regulations to carry out the Cures Act requirement that, effective January 1, 2021, CMS' estimate of standardized costs for payments for organ acquisitions for kidney transplants be excluded from MA benchmarks and capitation rates.

CMS proposes to revise §422.258 (calculation of MA benchmarks for a payment area) to specify that for 2021 and subsequent years, the base payment amount used to calculate the specified

amount is adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. The proposed change would also specify that the average FFS expenditure amount used to determine the applicable percentage is adjusted to take into account that exclusion.

CMS proposes a similar change to §422.306 (relating to the base payment amount of average FFS expenditures) to describe the required adjustment, beginning for 2021, to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under Medicare FFS (including expenses covered under section 1881(d) of the Act) in the area for the year. **CMS seeks comment whether its proposed revisions adequately implement the statutory changes.**

CMS will address the methodology for excluding kidney acquisition costs from MA benchmarks (including the MA ESRD state rates) in the 2021 Advance Notice and Rate Announcement.

As noted above, because PACE organizations are required to cover all Medicare-covered items and services, including organ acquisition costs for kidney transplants, CMS will include kidney acquisition costs in PACE payment rates, including PACE ESRD rates.

V. Enhancements to Part C and D Programs

A. Reinsurance Exceptions (§422.3)

Under existing Medicare statute (Section 1854(b) of the Act), an MAO must assume full financial risk for the provision of basic benefits except the MAO may obtain reinsurance for the aggregate value of costs which exceed a level as established by the Secretary. CMS has heretofore not established such a specified level and has become aware that not having a clear policy on the permissible uses of reinsurance has raised problems for MAOs as reinsurance is a common and longstanding market practice for insurers.

As a result, CMS is proposing in new §422.3 to permit an MAO to obtain stop-loss insurance for the costs of providing basic benefits to an individual that are greater than or equal to an aggregate level of \$10,000. Alternately, the MAO could purchase reinsurance for sharing costs proportionately on a first dollar basis, the value of which does not exceed the actuarial equivalent of the aggregate level of \$10,000 per individual.

CMS explains how it has chosen to specify the threshold for reinsurance at \$10,000. It looked back to the deliberations among the House of Representatives and the Senate for the Balanced Budget Act of 1997 in which the provision was originally included. The House-passed version of the provision which was not ultimately adopted included a threshold of \$5,000. CMS derived the \$10,000 threshold by increasing the House's proposed \$5,000 amount to reflect inflation between 1998 and the present which was then rounded to \$10,000.

CMS acknowledges concerns with permitting excessive reinsurance resulting in a large share of a plans' risk being passed along to another insurer including providing a reduced incentive for the MAO to hold costs down. But CMS also notes that reinsurance improves stability for MAOs

especially in rural and underserved areas and states its belief that the proposed level of risk transfer is reasonable.

CMS solicits comments on the threshold proposed and welcomes information about arrangements for addressing the risk of costs for high cost individuals.

CMS also indicates that it would consider an MAO to include parent organizations which would mean that evaluating compliance with this provision would not be done at the level of wholly-owned subsidiaries. **CMS seeks comment on that proposal and specifically whether a parent organization should be considered part of an MAO or a separate entity from an MAO.**

B. Out-of-Network Telehealth at Plan Option (§422.135(d))

Under existing rules, MA plans may offer additional telehealth benefits but must only do so through contracted providers. If using non-contracted providers, the telehealth benefit must be covered as a supplemental benefit. The limitation was imposed to ensure that plans have more control over how and when services were furnished.

CMS is now considering removing this limitation. It raises the possibility that it is unnecessarily limiting the ability of plans to offer additional telehealth benefits. Specifically, CMS is considering whether to revise §422.135 to permit additional telehealth benefits to be provided by non-contracted providers where those providers satisfy the existing requirements for providing those benefits. **It seeks comments on this potential change in the future.**

C. Supplemental Benefits, Including Reductions in Cost Sharing (§422.102)

Under existing §422.102(a)(4), an MA plan can offer reduced cost-sharing below the actuarial value specified in Section 1854(e)(4)(B) of the Social Security Act (“the Act”) only as a mandatory supplemental benefit. That actuarial value is tied to the value of Part A and Part B benefits so the existing rule addresses the ability of a plan to offer reduced cost sharing for basic benefits. The preamble indicates that this paragraph would be modified to make clear that it is applicable to Parts A and B benefits, but the regulatory text does not reflect that change.

CMS proposes to add a new §422.102(a)(5) to establish that an MA plan may also provide reduced cost sharing for items and services that are not basic benefits. As with basic benefits, the reduced cost sharing may only be offered as a mandatory supplemental benefit.

In addition, CMS proposes a new §422.102(a)(6) to describe some of the alternative forms that reduced cost sharing for supplemental benefits could take. Under the proposal, cost sharing could be reduced: 1) By providing a beneficiary with a debit card, by reimbursing the beneficiary, or through other means. If via reimbursements, those amounts must be limited to a specific plan year; and 2) by providing a uniform dollar amount as a plan allowance for a package of supplemental benefits. The allowance must be limited to a specific plan year and be offered on a uniform basis. The provision would also permit the reduction to be applied to a set of specific items or services so long as it is offered to all enrollees on a uniform basis. CMS notes that these flexibilities do not apply to Part D drugs as they only relate to Part C supplemental benefits.

D. Referral/Finder's Fees (§§422.2274 and 423.2274)

Under existing rules regarding agent and broker compensation (in §§422.2274 and 423.2274), paragraph (h) limits payments for finders or referral fees to an amount as determined by the Secretary. CMS indicates that those limitations are not necessary since total compensation, of which those referral fees are a component, are also subject to limits. Under existing rules, compensation for initial enrollments is limited to fair market value, and compensation for renewal enrollments is limited to 50% of fair market value. Since the limits on referral fees are not necessary, CMS proposes to remove those paragraphs. **CMS seeks comment on eliminating the limits and particularly on whether commenters are concerned about plans paying excessive fees for enrollments.**

E. MA and Part D Prescription Drug Plan Quality Rating System

1. Introduction

In the April 2018 final rule¹⁰, the Star Ratings methodology was codified for MA and Part D. Under these regulations, CMS must use notice and comment rulemaking to make changes to the Star Ratings methodology for calculating the ratings, adding new measures, and making substantive changes to existing measures. The regulations appear at §§422.160, 422.162, and 422.166 for MA and §§423.180, 423.182 and 423.186 for Part D.

In this rule, CMS proposes to amend the definition of “new MA plan;” modify the cut point methodology used to define the Star Ratings categories for measures other than the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures; add a new rule to the process for calculating measure scores when there is a contract consolidation; remove one measure, update two measures and add two others; increase the weight for patient experience and access measures; clarify the treatment of data integrity issues in the context of the extreme and uncontrollable circumstances policy; and clarify and codify certain Quality Bonus Payment (QBP) calculations.

Separately, the Call Letter process will be used to make updates to the Star Ratings measures and to seek comments on possible future measures and measure concepts. For example, the Advance Notice Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II, issued by CMS on February 5, 2020 (<https://www.cms.gov/files/document/2021-advance-notice-part-ii.pdf>) includes reminders to plan sponsors regarding the 2021 Star Ratings datasets, deadlines and processes; announces which measures meet the regulatory requirements for improvement measures; lists the Categorical Adjustment Index candidate measures and adjustment values; identifies areas affected by major disasters for purposes of the extreme and uncontrollable circumstances policy; discusses changes to existing Star Ratings and display measures; and identifies a series of potential new measures concepts.

¹⁰ 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.

2. Definition of New MA Plan (§422.252)

Currently, a “new MA plan” is defined to be a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. The proposed rule would modify this definition to be instead a *plan* that is (1) offered under a new MA contract and (2) offered under a MA contract that is held by a parent organization that has not had an MA contract in the prior 3 years.

CMS notes that it identifies the parent organization as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies.

3. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

Refinements are proposed to the methodology used for calculating the Star Ratings performance scores for non-CAHPS measures. Specifically, the proposal would add a new step to remove outliers prior to applying the hierarchical clustering algorithm used to identify the cut points for the Star Ratings categories for these measures. The April 2019 final rule added “mean resampling,”¹¹ and measure specific caps that provide guardrails to restrict the upward and downward movement in a measure-specific cut point for a year when compared to the previous year.¹² At that time CMS discussed options for removal of outliers after considering comments, but no approach for removing outliers was finalized.

In this rule, CMS proposes to use the “Tukey outer fence outlier deletion” statistical method to remove outliers before determining the measure cut points.¹³ It believes that this method has the advantage over the alternative of trimming all contracts with scores below the 1st percentile or above the 99th percentile because the latter could delete scores that are not true outliers and retain scores that are.

¹¹ Mean resampling is a technique under which the measure-specific scores for the current year’s Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The cut points for each threshold for a measure are then set as the mean of the resulting 10 sets of measure-specific cut points.

¹² The guardrails are set at an absolute five percentage point cap for all measures scored on a 0 to 100 scale, and a restricted range cap that excludes outliers is used for measures not scored on a 0 to 100 scale. The restricted range cap is set at 5 percent of the difference between the minimum and maximum measure score values using the prior year measure scores when excluding outer fence outliers. An outer fence outlier is a measure score that exceeds certain upper or lower boundary values. Specifically, the upper outer fence is set to equal the third quartile plus 3 times the interquartile range, and the lower outer fence is set to equal the first quartile minus 3 times the interquartile range. The first quartile is the median of the lower half of the performance scores while the third quartile is the median of the upper half of the performance scores. The difference between the first and third quartiles is the interquartile range.

¹³ Under the Tukey outer fence outlier deletion method, outliers would be defined as measure scores below the lower fence or above the upper fence (see note above).

Under the proposal, for the first year of implementation CMS would rerun the prior year's thresholds to include mean resampling and the Tukey outer fence outlier deletion step so that the guardrails would be applied consistently between the years.

Use of the Tukey outlier deletion method would result in an estimated \$809 million in savings in 2024, and savings would increase to more than \$1.4 billion by 2030. (These savings would be substantially offset by proposed increases in the weights of some Star Ratings measures as described below.) CMS further estimates that using this method with a 5 percent guardrail would have resulted in 2018 Star Ratings that are half a star higher for 2 percent of MA-PD contracts and 2 percent of PDP contracts, and ratings that are half a star lower for 16 percent of MA-PD contracts and 18 percent of PDP contracts.

4. Contract Consolidations (§§ 422.162(b)(3) and 423.182(b)(3))

CMS proposes changes to the regulations addressing how contract consolidations are treated in calculation of Star Ratings. First, existing regulatory text would be rewritten with the intention of improving clarity. Second, effective for contract consolidations approved on or after January 1, 2021, two new policies are proposed.

- If a measure score for a consumed or surviving contract is missing due to certain data integrity issues, CMS would assign a score of zero for the missing measure score when calculating the enrollment-weighted measure score.¹⁴
 - The specified data integrity issues for MA involve (1) audited data for Healthcare Effectiveness Data and Information Set (HEDIS) measures submitted to the National Committee for Quality Assurance (NCQA) that are designated as missing or biased, and (2) data needed for a measure submitted to CMS by a contract that fails data validation or is not compliant with CMS data validation for those data. They are described in existing regulations at §422.164(g)(1)(i) and (ii).
 - For Part D the data integrity issues are described in existing regulations at §423.184(g)(1)(i) and (ii) which involve (1) data submitted to CMS and needed for a measure by a contract that fails data validation or is not compliant with data validation for those data and (2) incomplete appeals data.
- For appeals measures, the Timeliness Monitoring Project (TMP) or audit data for the consumed and surviving contracts would be combined before applying the existing rules for reducing a contract's measure rating for incomplete independent review entity (IRE) data. This proposal is made for both MA and Part D.

Note that as presented, the proposal to assign a score of zero applies to data integrity issues related to incomplete appeals data for Part D contracts but not for MA contracts. For MA contracts the proposal to assign a zero score would apply with respect to missing to HEDIS data and failure of CMS data validation. The preamble does not discuss this clearly enough to be certain of CMS' intention.

¹⁴ Under existing regulations, for the first year of consolidation the enrollment-weighted scores are used for all measures except survey-based and call center measures. In the second year, for MA, enrollment-weighted scores are used for all measures except for Healthcare Effectiveness Data and Information Set (HEDIS), CAHPS, and Medicare Health Outcomes Survey (HOS) measures. HEDIS and HOS measures scores are used as reported; and CMS ensures that the CAHPS sample includes enrollees from both the surviving and consumed contracts. For Part D in the second year enrollment weighting is used for all measures except CAHPS.

5. Adding, Updating, and Removing Measures (§§422.164 and 423.184)

Measure changes are proposed for Star Ratings performance periods beginning on or after January 1, 2021. These include removal of one measure, substantive updates to two measures and the addition of two new measures.

Measure Removal. The Rheumatoid Arthritis Management measure would be removed from the MA Star Ratings. The NCQA (the measure steward) is retiring the measure from HEDIS due to concerns that the measure does not take into account the effect of Patient Assistance Programs; it does not assess measure adherence; and it is unclear based on evidence whether patients in remission should remain on these medications.

Measure Updates. Two Part C measures from the Medicare Health Outcomes Survey (HOS) would be updated: Improving or Maintaining Physical Health and Improving or Maintaining Mental Health. The case-mix adjustment for these measures would be changed with respect to certain missing variables. Currently, if any of the case-mix variables in a group is missing for a beneficiary, none of the variables in the group are used for that beneficiary. CMS proposed to replace this all or nothing approach with one that would replace a missing variable with the mean value for that adjustor for other beneficiaries in the same contract who supply data for these measures. The proposed approach has been used for the CAHPS surveys. CMS says that in simulations this approach matched or outperformed the current approach for predicting outcomes, and would be easier to implement. In addition, the minimum required denominator for these two measures would be increased from 30 to 100, which CMS says would increase reliability of the measures and would align with the denominator requirements for HEDIS measures.

Another proposed update would classify the Part D measure Statin Use in Persons with Diabetes as a process measure instead of an intermediate outcome measure beginning with the 2023 Star Ratings. The measure was added to the 2019 Star Ratings with a first year weight of 1, and in last year's Call Letter process CMS responded to objections to the intermediate outcome classification by continuing the measure's first year weight of 1 into 2020. CMS reviews the concerns of previous commenters about the classification and notes that the Pharmacy Quality Alliance considers it a process measure.

New Measures. Two new HEDIS measures are proposed for addition to the Part C Star Ratings program for measurement in 2021 (2023 Star Ratings). CMS has now transitioned to using rulemaking (instead of the Call Letter process) for adding new measures to the Star Ratings. As a result, it submitted both the proposed new measures through the Measures Under Consideration process for review by the Measure Applications Partnership, a multi-stakeholder group that makes recommendations on the selection of quality and efficiency measures for CMS programs. Table 3 of the proposed rule provides high-level descriptions of the two proposed new measures.

The Transitions of Care measure assesses the percentage of discharges for members age 18 or older (excluding those in hospice) who have each of four indicators during the measurement year: 1) notification of inpatient admission and discharge, 2) receipt of discharge information, 3) patient engagement after inpatient discharge, and 4) post-discharge medication reconciliation.

CMS notes that NCQA is considering updates to the measure specifications that would broaden the applicable forms of communication, change the timeframe for notifications and receipts, and modify the receipt of discharge information indicator to refer to instructions for patient care generally and not specifically to primary care and ongoing care providers. CMS believes these changes would not change the population covered by the measure and would meet its criteria as non-substantive changes.

The second proposed new HEDIS measure is Follow-up After Emergency Department Visit for Patients with Multiple Chronic Conditions. This measure is the percentage of ED visits for members age 18 or older who have high-risk multiple chronic conditions from a specified list who had a follow-up service within 7 days of an ED visit. Follow-up services include an outpatient visit (including a telehealth modifier); behavioral health visit; telephone visit; transitional care management services; case management visits; and complex care management.

6. Measure Weights (§422.166(e) and 423.186(e))

CMS proposes to increase the weight of the patient experience/complaints and access measures from 2 to 4. The preamble does not specify an effective date, although in the executive summary of the proposed rule CMS says that unless otherwise stated, the proposed changes would begin with the 2021 measurement period and 2023 Star Ratings.

In discussing this proposal CMS notes that the weight increases would not impact the assignment of stars at the measure level, and would only affect the calculation of overall and summary ratings. The high statistical reliability of the CAHPS measures is discussed and statistics provided.

The proposed new weights are estimated to increase payments to MA plans by \$391.4 million in 2024 and a total of \$1.8 billion over the years 2024-2030. These increases would offset the estimated larger savings from the proposed use of the Tukey outlier deletion method. CMS estimates combined net savings to the Medicare program if both proposals were finalized would be \$368 million in 2024, growing to \$994.4 million by 2030 and totaling \$4.9 billion over those seven years, taking ordinary inflation into account. Table 30 in the Regulatory Impact Analysis section of the proposed rule shows the estimated year-by-year savings from these proposals.

7. Extreme and Uncontrollable Circumstances (§§ 422.166(i) and 423.186(i))

CMS is seeking additional feedback on the disaster policy for contracts impacted across multiple years. Under the policy adopted in the April 2019 final rule, contracts that were affected by a disaster in multiple years will receive the higher of the current year's Star Rating or what the previous year's rating would have been in the absence of disaster adjustments. When data are missing for the current or previous year, the final measure rating comes from the current year except where the contract meets the requirements for an exemption from administering the CAHPS survey.

In this rule, CMS proposes to make changes in the regulations to clarify that when there is a data integrity issue in the current or previous year for which the measure rating is reduced (i.e., a data

integrity issue as defined in §422.164(g)(1) or §423.184(g)(1)), the final measure rating comes from the current year. That is, this situation is treated in the same way as missing data.

8. Quality Bonus Payment Rules

Current policies around assigning the QBP ratings for MA contracts would be clarified and codified. These rules have historically been announced through the Advance Notice and Rate Announcement process. Proposed new language in the regulatory text (§422.162(b)(4)) would clarify that for contracts receiving a numerical Star Rating, the final QBP rating for the contract is released in April of each year for the following contract year. The QBP rating would be described as the contract's highest rating from the Star Ratings published by CMS in October of the calendar year 2 years prior to the year to which the rating applies. (For MA-PD contracts the QBP rating is the overall Star Rating; for contracts that do not include Part D, the QBP rating is the Part C summary rating.) Additional language would clarify that the contract QBP rating is applied to each plan benefit package under the contract. As discussed above, the definition of new MA plan at §422.162(a) is amended.

New regulatory text is proposed to codify policies for contracts that do not meet the definition of low enrollment or new MA plans and do not have sufficient data to calculate and assign Star ratings. Under the current policy to be codified, any new contract under an existing parent organization that has had MA contracts with CMS in the previous 3 years receives an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts. The regulatory text (§422.166(d)(2)(vi)) would specify that if the parent organization had contracts with preliminary Star Ratings in November (for the contract year that begins 14 months later), the new contract would be assigned the enrollment-weighted average of the highest Star Ratings of all the parent organization's contracts that will be active in the following year. The rounded stars that are publicly displayed on the Medicare.gov website would be used for this calculation.

For example, the rule could be applied to identify the parent organization of the new contract and the preliminary 2021 QBP ratings for that organization's existing MA contracts in November 2019. Only contracts that anticipated to still exist and be held by the parent organization in April 2020 are included. The November 2019 enrollment-weighted average of the highest published October 2019 Star Ratings of those contracts would be calculated and updated in April 2020 to reflect any changes to the parent organization's contracts, including contracts acquired since November 2019. The final QBP rating would be provided to the MA organization for the new contract in April 2020 and used as the QBP rating for the 2021 payment year. No parent organization changes made after the QBP ratings are finalized in April affect the calculation.

If the parent organization of a new contract does not have any other MA contracts with numeric Star Ratings in November, CMS would look at the MA Star Ratings for the previous 3 years and use as the QBP rating the enrollment-weighted average of the highest ratings for the parent organization's MA contracts from the most recent year. The November enrollment from that year would be used for the enrollment-weighted calculations.

For example, if in November 2019 the parent organization of the new contract had no contracts with numeric 2020 Star Ratings, CMS would look back to the 2019 and 2018 Star Ratings and

select the most recent year for which ratings are available. If the November 2018 ratings (for 2019) were the most recent these would be used, and an enrollment-weighted average calculated using November 2018 enrollment. This average would be used as the final 2021 QBP rating for the new MA contract and provided to the parent organization in April 2020.

In a case where the parent organization has no existing contracts with numeric Star Ratings in the previous 3 years, the contract is rated as a new MA plan and existing rules at §422.258 and §422.166(d)(2)(v) apply.

CMS notes that enrollment data are publicly posted at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDEnrolData>.

F. Permitting a Second “Preferred” Specialty Tier in Part D

CMS describes a set of changes intended to permit Part D plans to offer a second specialty tier. Some of those changes are incorporated in the proposed regulatory text, but others, in particular those intended to be included in §423.104, do not appear. The changes that were to be proposed in §423.104 are described in the preamble as follows. CMS intended to propose a new paragraph at §423.104(d)(2)(iv)(D) to specify that a Part D plan can maintain up to two specialty tiers and to establish a maximum allowable cost sharing of 25 percent for plans with a full deductible and 33 percent for plans with no deductible for a single specialty tier. For a plan with two specialty tiers, those maximums would apply to the higher cost-sharing specialty tier.

CMS indicates that this change would follow the suggestion of the Medicare Payment Advisory Commission (MedPAC) to permit two specialty tiers with differential cost sharing that could potentially encourage the use of lower-cost biosimilars and encourage competition among specialty drugs. CMS expects that the ability to offer a second specialty tier could potentially improve the ability of Part D sponsors to negotiate for better prices with manufacturers and lower costs for beneficiaries.

Under existing regulations, Part D plans offering a specialty tier may exempt the drugs on that tier from the exceptions process. CMS notes that nearly all plans choose to do so. (The exceptions process is when a plan sponsor permits an enrollee to obtain a drug on a specialty tier at a lower cost sharing amount applicable to a lower cost alternative if the lower-cost alternative would not be as effective in treating his or her condition or if it would cause adverse effects.)

CMS proposes to retain, with a significant modification, the ability to exempt drugs on both specialty tiers from the exceptions process. Under the proposal, if a Part D plan offers one or two specialty tiers, it would be permitted to exempt drugs on those tiers from a tiering exception requesting copayments that are applicable to a *non-specialty tier drug*. The provision would effectively require plans with two specialty tiers to permit tiering exceptions between the two specialty tiers – permitting requests for copayments for a drug on one specialty tier to be reduced to those applicable to a drug on the second specialty tier. The changes would be made in §423.578 – a section describing the Exceptions process for Part D plans.

CMS proposes a technical change to remove from §423.578 the term “and biological products” wherever it appears because CMS believes it to be redundant since biological products are already incorporated into the definition of a Part D drug at §423.100.

CMS describes at length the derivation of the existing cost sharing limits of 25 percent for plans with a full deductible and 33 percent for plans with no deductible. Those are the maximums that apply under existing rules to a specialty tier and that CMS would propose as the basis for the cost-sharing limits for the higher of the two specialty tiers for plan offering two. While some commenters who have requested a second specialty tier indicate that they would need to charge more than 25/33 percent, CMS believes that doing so would result in increased costs for beneficiaries and so rejects this position. CMS is also concerned about the potential for discriminatory plan design if a second specialty tier could charge beneficiaries higher amounts.

The preamble describes these limitations as proposed in §423.104(d)(2)(iv)(D), however that regulatory text is missing. The preamble describes new paragraph §423.104(d)(2)(iv)(D) as setting the maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier. Further, it would require that the cost sharing for the preferred specialty tier be below that of the higher cost-sharing, specialty tier. The maximum amounts would be (1) 25 percent coinsurance for plans with the full deductible provided under the Defined Standard benefit; (2) 33 percent coinsurance for plans with no deductible; and (3) for plans with a deductible that is greater than \$0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is between 25 and 33 percent, determined by subtracting the plan’s deductible from 33 percent of the initial coverage limit (ICL), dividing this difference by the difference between the ICL and the plan’s deductible, then rounding to the nearest one percent.

CMS solicits comment on plan design for two specialty tiers including the impact of permitting higher cost sharing than proposed; whether higher cost sharing than 25/33 percent would cause discriminatory plan design; the potential impact of a maximum allowable cost sharing of 25 percent without regard to deductible; and whether CMS should set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.

Under existing rules, drugs that exceed a specific cost threshold may be included on the specialty tier. The cost threshold is intended to reflect the cost of outlier claims for the highest cost drugs which CMS identifies as those in the top one percent of claims with the highest negotiated prices. Since contract year 2017, that threshold has been equal to \$670 per month.

CMS indicates that among the missing regulatory text, there is a proposal to codify the methodology for calculating the specialty tier threshold. The preamble describes the proposal to calculate that amount in largely the same manner as under existing practice except to identify the top one percent of claims based on ingredient costs rather than negotiated prices. CMS states that the other components of negotiated prices, administration and dispensing fees and sales taxes, are highly variable and so using only ingredient costs will be more predictable and transparent. CMS does not expect the change to significantly affect the number of Part D drugs meeting the specialty tier threshold since the ingredient cost is the major component of the negotiated price.

Applying this methodology to the calculation for 2021 would result in a threshold of \$780. CMS proposes to apply the methodology for contract year 2020 as well as to 2021 and to announce the changed amount in the final rule. The threshold would be re-determined annually and the result of the calculation would be rounded to the nearest \$10 as under existing practice. **CMS requests feedback on a potential alternative to its practice of always rounding up to the nearest \$10 increment.**

Information Collection Requirements and Regulatory Impact Analysis. CMS qualitatively describes the potential impact on plan sponsors of its proposal to permit the offering of a second specialty tier. On the plus side, there may be savings due to a plan's improved ability to negotiate formulary position and to encourage the use of biosimilar biological products. On the other hand, the proposed requirement to permit tiering exceptions between the two specialty tiers could exceed the benefit of offering the second specialty tier. CMS concludes that the proposal is unlikely to have a material impact on Part D costs.

G. Beneficiary Real Time Benefit Tool (RTBT) (§423.128)

CMS proposes new requirements for Part D plan sponsors to implement a *beneficiary* RTBT that would allow enrollees access to timely, clinically appropriate, patient-specific formulary and benefit information in a beneficiary-specific portal or computer application (in proposed §423.128(d)(vi)(4)). This proposal, which would become effective January 1, 2022, is an extension of the existing requirement for plans to provide *prescribers* with a similar electronic real-time benefit tool, a requirement which becomes effective January 1, 2021.

The information that would be required to be available through the “beneficiary RTBT” would include enrollee cost sharing amounts, clinically appropriate alternative medications for the beneficiary, and formulary status and utilization management requirements for each alternative. The alternatives that would be provided via the RTBT could not exclude those based on cost.

CMS believes that once a plan has established the prescriber RTBT, it will already have developed the information needed for the proposed beneficiary RTBT. CMS is also aware that some Part D plans have beneficiary portals already in place and encourages Part D sponsors to explore adding the beneficiary RTBT functions to those existing portals.

CMS believes the availability of this information will permit enrollees to take a more active role in health care decision-making and improve medication adherence. It reviews evidence to that effect as included in the May 2019 final rule (84 FR 23832) implementing the prescriber RTBT. In addition, it cautions plan sponsors to ensure they remain in compliance with non-discrimination requirements – ensuring that individuals who are deaf, hard of hearing, blind or have other impairments as well as beneficiaries without computers or smart phone access can obtain the information. The information must also be provided in a manner that is understandable to the average patient.

CMS discusses the types of decisions plans may make in determining which alternative treatments to provide through RTBT and which may be excluded. It notes that a sponsor's Pharmacy & Therapeutics (P&T) Committee could evaluate which medications should be excluded. While not proposing to codify this guidance, CMS states that P&T committees should

exclude medications if: 1) the alternatives would have significant negative side effects for most enrollees and the drug would not typically be a practitioner's first choice for treating a given condition due to those side effects, 2) where medications are considered to be "drugs of last resort," 3) where interactions with other drugs already used by the beneficiary would contraindicate prescribing a given drug, or 4) other clinically-appropriate instances. Otherwise, the medication options that could be provided through RTBTs is left to the discretion of the plan sponsor. CMS indicates that it will monitor for improper use of this discretion and propose future changes if necessary. It states that alternatives may only be excluded based on clinical appropriateness and not based on cost.

Also in preamble but not in regulatory text, CMS indicates that a beneficiary must be provided with a prominent notice that they have received a curated list of options. Information provided through the RTBT must also not advance improper commercial purposes, for example by promoting the commercial interests of the sponsor or promoting certain products based on rebates that the sponsor has negotiated.

CMS does not require, but encourages plans to include each drug's negotiated price in the beneficiary RTBT in addition to the beneficiary's out-of-pocket costs or alternative information that allows the beneficiary to view the comparative plan costs.

CMS seeks input on the proposed timeline for the beneficiary RTBT (January 1, 2022) and whether an information standard should be applied.

Plans would be permitted to offer rewards and incentives (RI) to beneficiaries who use the tool. CMS would define use of the tool as logging into the RTBT via portal or computer application or calling the customer service call center to obtain the information. RI would be required to be:

- Of nominal value. Current guidance specifies a nominal amount as no more than \$15 per log in;
- Be offered for no more than one log-in per month;
- Be available for all enrollees in a manner that is not discriminatory;
- Not be cash or cash equivalents – gift cards would be permitted;
- Not target potential enrollees;
- Be earned solely for logging in; and
- Comply with all relevant fraud and abuse and anti-kickback laws.

CMS requests feedback on the kinds of RI programs Part D sponsors would propose, the level of incentives that could be expected to achieve positive outcomes, and how to mitigate concerns about sponsors potentially selecting healthier beneficiaries for rewards.

Information Collection Requirements and Regulatory Impact Analysis. CMS estimates the costs of implementing an RTBT would be equal to a total of \$3.9 billion. This estimate assumes that most Part D plans already have beneficiary portals that could be used for this purpose so the cost estimate assumes 288 remaining plans would spend on average 56 hours to do the computer programming to set up the beneficiary RTBT. In addition to those costs, CMS estimates that 10% (29) of those plan sponsors would utilize Rewards and Incentives at a cost of about \$.7 million per year. **CMS seeks feedback on its cost estimates and assumptions used.**

H. Establishing Pharmacy Performance Measure Reporting Requirements (§423.514)

CMS proposes to require Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. This would be added to the general reporting requirements for Part D sponsors at §423.514(a). CMS believes that collecting information on these measures would enable it to better understand the extent to which performance measures are used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS). CMS notes that there may be a pharmacy performance problem, as pharmacy price concessions (which may include financial penalties) after the POS have continued to grow annually. Further, CMS believes that information on pharmacy performance measures would provide transparency to the process and confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies. CMS also states that the growing use of pharmacy performance measures and the impact on the amount a beneficiary pays for a Part D drug at the POS makes this information essential if to be predictable reimbursement for pharmacies and cost sharing for beneficiaries.

Once it had the information CMS would make the list of pharmacy performance measures available to the public. It believes the information can document a pharmacy's contribution to value-based care and incentivize high quality care.

Collected data elements would be limited to those necessary to identify and understand each measure and how it is applied by pharmacy type, if applicable and may include:

- Name of the performance measure
- Performance calculation methodology
- Success/failure threshold(s)
- Financial implications of success/failure to achieve threshold(s)
- Pharmacy appeal requirements; and
- Method of payment of collection

CMS is also considering collecting retrospective information on the number and type of pharmacies that achieved established success/failure thresholds and average scores or other statistics for each measure.

However, at this time CMS is not proposing specific pharmacy performance measure data elements for reporting by Part D sponsors. These would be proposed through the Office of Management and Budget Paperwork Reduction Act process if the proposed new requirement is finalized. CMS believes that the industry should first begin to develop, test and achieve a consensus on the measures themselves, via a measure developer. Then, CMS would provide an opportunity for industry comment on more specific data collection instruments through *Federal Register* notices. It believes that this approach would encourage collaboration and consensus within the industry and promote measure alignment across the pharmacies and plans. In the Collection of Information Requirements section of the proposed rule, CMS estimates that fewer than 15 data elements will be required.

The industry is encouraged to continue to work toward developing a set of consensus pharmacy performance measures for adoption by Part D sponsors to ensure standardization, transparency

and fairness. Part D sponsors are encouraged to use an independent third party organization to assess pharmacy performance on such measures (including data aggregation, development of measure thresholds and cut points, and definition of applicable pharmacy types for each measure).

Specifically, CMS reports on a consensus-building workshop hosted by the Pharmacy Quality Alliance (PQA) in early 2019 and an all-member webinar in late August 2019 to build consensus across pharmacy, plan, PBM, and other stakeholders to create a standard set of feasible, valid, and reliable measures that could be used in Part D plan-pharmacy agreements. It says that the participants reached consensus on an approach to prioritize the development of measures, and that the PQA plans to re-specify certain plan-level measures for pharmacy-level measurement and create new pharmacy-level measures. It finds these efforts encouraging progress and seeks to be kept informed by the industry on further developments.

CMS recommends that pharmacy performance measures established for use in Part D adhere to the following principles. The measures should--

- Improve medication use and outcomes for the beneficiaries served;
- Be specified at the right level of attribution and appropriate level of comparison considering pharmacy type;
- Factor in both pharmacy accountability and drug plan performance goals;
- Have clear specifications and be established prior to the measurement period;
- Be reliable, transparent and fair; and
- Use threshold minimums if appropriate.

In the future, CMS may develop measures to consider for use in the Part D Star Ratings that would assess Part D plan sponsors' uptake of a standard set of pharmacy performance measures or that evaluate the percent of high-performing pharmacies in the sponsors' pharmacy network.

Comments are solicited on the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent, and/or rural pharmacies, and recommendations for potential Part D Star Ratings metrics related to these measures. Further, CMS seeks comment on the data elements, timeline, and method of submission for the reporting of pharmacy performance measures.

In the Regulatory Impact Analysis section of the proposed rule, CMS estimates that these proposed reporting requirements would impose a total annual cost of \$235,582 across Part D plans. This estimate assumes the 5,234 Part D plans would each spend about \$45 annually (assuming 30 minutes by an analyst paid \$90 an hour) to comply with the proposed pharmacy performance reporting requirement. **CMS seeks input on the accuracy of this estimate and any steps it could take to decrease the burden.**

I. Medical Loss Ratio (MLR) (§§422.2420, 422.2440, 423.2440)

The medical loss ratio is a percentage that generally represents the percentage of a managed care organization's revenue used for patient care rather than for other administrative expenses or profit. MA plans and Part D plans are required to report their MLRs to CMS and are subject to

sanctions for failure to meet a minimum MLR of 85 percent. The numerator of the ratio includes incurred claims.

CMS proposes a change to the definition of the incurred claims portion of the numerator described in §422.2420 for the purpose of calculating the MLR. The proposed change is intended to better reflect the recent flexibilities that MA plans have to provide supplemental benefits that are primarily health related and to provide special supplemental benefits for people who are chronically ill (SSBCI). In the existing regulations, incurred claims are those paid to a provider. Because the recent supplemental benefits flexibilities may include payment of benefits that may not go to traditional health care providers, CMS proposes to eliminate the use of the phrase “Direct claims that the MA organization pays to providers” from the definition of incurred claims and replace it with a more general “amount that the MAO pays” in §422.2420(b)(2)(i). In addition, under the existing rules, such incurred claims include amounts paid under capitation contracts with physicians. CMS proposes to remove the reference to physicians so that incurred claims include amounts paid under capitation contracts more generally.

CMS points out that some of those new supplemental benefits could, under existing rules, qualify as quality improvement activities (QIA) if they meet a set of criteria and could therefore be included in the numerator of the MLR. But determining whether a particular benefit met all of those criteria would need to be made on a case-by-case basis. The change to incurred claims as proposed would be a preferred way of including those claims in the numerator of the MLR without need for a case-by-case determination.

In addition, CMS codifies definitions for partial, full, and non-credibility and credibility factors in §§422.2440 and 423.2440. A credibility adjustment is an adjustment to a plan’s minimum MLR intended to address the effect of random variation by increasing the MLR of smaller contracts. It therefore reduces the probability that such contracts will fail to meet their minimum MLR requirement because of random claims variability.

CMS explains that since 2015, these adjustments and factors have been updated, announced and finalized through the Annual Advance Notice and Rate Announcement Processes. However, in order to be consistent with the principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (issued October 9, 2019), CMS is proposing to codify the definitions in the Code of Federal Regulations.

In each of §§422.2440 and 423.2440, CMS proposes to remove existing text which states that such factors will be defined and published in the Advance Notice and Rate Announcement Process and add new paragraphs (d)(1) through (3) to specify the number of member months for contracts qualifying partially credible, fully credible or non-credible. CMS would retain the same number of member months as have been in place since 2013:

- A contract’s experience is partially credible if it is based on the experience of 2,400 to 180,000 member months.
- A contract’s experience is fully credible if it is based on the experience of more than 180,000 member months.
- A contract’s experience is non-credible if it is based on fewer than 2,400 member months.

Conforming changes would be made to paragraphs (a), (b), and (c) to refer to the proposed definitions in (d).

Proposed new paragraphs (e) in §422.2440 and §423.2440 would address the credibility adjustment applicable to MA plans and Part D plans, respectively. Paragraph §422.2440(e)(1) would state that, for partially credible MA contracts other than MSA contracts, the credibility adjustment is the base credibility factor determined under proposed paragraph (f).

Proposed paragraph (f) would specify that the base credibility factor for a partially credible MA contract is determined based on the number of member months and the factors listed in proposed Table 1 to §422.2440 (duplicated below). When the number of member months for a partially credible MA contract exactly matches the amount in the “Member months” column, the value associated with that number of member months is the base credibility factor. When the number of member months falls between the values shown in Table 1 to § 422.2440, the base credibility factor would be determined by linear interpolation.

Table 1 to § 422.2440--Base Credibility Factors for MA Contracts

Member months	Base credibility factor (additional percentage points)
< 2,400	N/A (Non-credible)
2,400	8.4%
6,000	5.3%
12,000	3.7%
24,000	2.6%
60,000	1.7%
120,000	1.2%
180,000	1.0%
> 180,000	0.0% (Fully credible)

Proposed paragraph (g) would provide for the inclusion of an adjustment for the deductible in the MLR formula for MA medical savings account (MSA) plans. The factor would increase the applicable MLR based on increasing levels of deductibles. CMS is proposing to use the same deductible factors applicable to commercial plans under 45 CFR Part 158. The proposed deductible factors are displayed in Table 2 to §422.2440. CMS believes the addition of the deductible factor will encourage more MA MSA plans to be offered if their MLRs are easier to achieve. As with the credibility factors in Table 1, if the number of member months for a plan falls between the values identified in Table 2, linear interpolation would be used to calculate the applicable deductible factor.

CMS notes that it would prefer to develop deductible factors using Medicare data and will assess the feasibility for doing so. **It seeks comment on whether and how Medicare data could be**

used to evaluate the need for and to develop Medicare-specific deductible factors, whether and how proposed deductible factors should be adjusted to account for unique features of the Medicare MLR rules (for example, the inclusion of the MA MSA deposit amount in the Medicare MLR numerator and denominator), or to reflect differences between the commercial and Medicare MLR rules (for e.g., the lower minimum MLR requirement for small group and individual health insurance plans compared to Medicare’s MLR). CMS is also interested in feedback on any potential consequences of applying a deductible factor to the MLR calculations for MA MSA contracts, including impacts on MSA plan benefits.

In parallel provisions applicable to Part D plans, at §423.2440, proposed new paragraph (e) would provide that for partially credible Part D contracts, the applicable credibility adjustment is determined based on the number of member months and the factors in proposed Table 1 of §423.2440 (duplicated below).

Proposed paragraph (e) would establish the rules for using the factors in Table 1 of §423.2440 to calculate the base credibility factor: (i) when the number of member months used to determine credibility exactly matches a member month value listed in the table, the value associated with that number of member months is the credibility adjustment; and (ii) the credibility adjustment for a number of member months between the values shown in Table 1 is determined by linear interpolation.

Table 1 to § 423.2440--Credibility Adjustments for Part D Contracts

Member months	Credibility adjustment (additional percentage points)
< 4,800	N/A (Non-credible)
4,800	8.4%
12,000	5.3%
24,000	3.7%
48,000	2.6%
120,000	1.7%
240,000	1.2%
360,000	1.0%
> 360,000	0.0% (Fully credible)

CMS provides an example of a linear interpolation for calculating credibility adjustments when member months fall between the listed values in the applicable Table 1 for MA plans and Part D plans and when deductibles fall between the listed amounts in Table 2 for MA MSA plans. The adjustment would be based on the percentage of the difference between the two listed values. That percentage would be multiplied by the difference between the two credibility (or deductible) adjustment amounts associated with the two values.

Information Collection Requirements and Regulatory Impact Analysis. CMS expects that the proposed changes to the MLR numerator would result in some MA contracts that were unable to meet the minimum 85% threshold to begin to meet or exceed it. For contracts that continue to be unable to meet the threshold, CMS expects that their remittances would be reduced. These changes would result in a transfer of funds from the Treasury to the MA organizations via the Medicare Trust Fund.

CMS estimates that amount by assuming a 53% increase in projected spending for “primarily health related” supplemental benefits which would be included in the MLR numerator, resulting in a reduction in remittance payments of \$25.8 million (in 2017 dollars). CMS increases that amount for inflation but notes that over time it expects considerably greater plan spending for primarily related supplemental benefits – it does not incorporate that increase in the estimates, however. Overall, the transfer from the Treasury to MA organizations as a result of the proposed change is estimated to total \$455 million over the 2020 to 2030 period.

J. Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests

CMS proposes a large number of amendments intended to codify and clarify the conditions for withdrawing or dismissing certain determination and redetermination requests. The proposed amendments address both withdrawals of requests – when an enrollee voluntarily determines that the determination or redetermination is no longer necessary – and dismissals – when a plan decides to stop consideration before issuing a decision.

CMS notes that while there are some procedures for withdrawals or dismissals in current rules (in §405.952 and §405.972) those rules are not applicable in all situations. For example, §405.952 only applies to the withdrawal or dismissal of a redetermination and not an initial determination. CMS also notes that even though §405.952 is applicable only to redeterminations, plan sponsors have looked to those provisions as a guide for handling withdrawal or dismissals of initial requests for coverage.

CMS states that the proposed amendments largely codify current practice. CMS proposes to:

- Permit a plan to dismiss a request for the *initial plan level decision* (an organization determination, integrated organization determination or coverage determination) when: i) the individual or entity making the request is not permitted to request an organization determination or coverage determination; ii) the plan determines that the request for an organization determination or coverage determination is not valid; iii) the enrollee dies while the request is pending and the enrollee’s spouse or estate has no remaining financial interest in the case; or iv) the individual or entity who requested the review submits a timely written request for withdrawal. These conditions would apply to an expedited organization determination or coverage determination as well.
- Permit a plan to dismiss a request for the second plan level decision (a reconsideration, integrated reconsideration or redetermination) under the same conditions as described above including for expedited reconsiderations.
- Permit the Part C and Part D Independent Review Entity (IRE) to dismiss a request under the same conditions as described above.

- Require that written notice of the dismissal be delivered to the individual or entity who made the request. The notice must include certain information, as appropriate, including applicable appeal rights.
- Permit a dismissal to be vacated by the entity that issued the dismissal (that is, MAOs, applicable integrated plans, Part D plan sponsors, and the IRE) if good cause for doing so is established within 6 months of the date of the dismissal. The dismissal of the organization determination or coverage determination is binding unless vacated by the MAO, applicable integrated plan, or Part D plan sponsor. The dismissal of the reconsideration or redetermination is binding unless the enrollee or other valid party requests review by the IRE or the dismissal is vacated under the applicable regulation. A dismissal by the IRE is binding and not subject to further review unless a party meets the amount in controversy threshold requirements necessary for the right to a review by an administrative law judge or attorney adjudicator and the party files a proper request for review with the Office of Medicare Hearings.
- Permit a party that makes a request to withdraw its request at any time before the decision is issued. The request for withdrawal would need to be in writing.

CMS also proposes the following new policies:

- To permit an enrollee (or other party) to request an IRE review of an MAO's reconsideration. CMS states that this amendment is necessary because there is no current process for an enrollee to request an IRE review of an MAO's reconsideration. Such request would need to be filed within 60 calendar days from the date of the MAO's dismissal notice. Conforming provisions would be incorporated in provisions describing the IRE process.
- To establish a process for enrollees to request IRE review of a Part D plan sponsor's dismissal of redetermination requests. CMS notes that unlike for MAOs there is already an existing provision permitting enrollees to request IRE review of reconsiderations but not for dismissals. A conforming paragraph would be added at §423.590(j) to permit an enrollee to request review of a PDP sponsor's dismissal of a redetermination request. Finally, new §423.600(k) would establish that if the IRE determines that the PDP's dismissal was in error, the IRE could reverse the dismissal and remand the case to the plan for redetermination.

CMS states that it expects that many of these provisions reflect existing practice including for current D-SNP operations. **It seeks comment, however, on whether the rule would create any inconsistencies with Medicaid procedures regarding dismissals or withdrawals and whether the inconsistencies could be addressed through contractual language. CMS also requests comment on whether additional clarification or regulatory changes would be needed to ensure smoother operations, ease implementation, or necessitate additional beneficiary protections.**

K. Methodology for Increasing Civil Money Penalties (CMPs) (§§422.760 and 423.760)

Existing statute and regulations permit CMS to impose CMPs on MAOs and Part D plan sponsors for certain regulatory offenses. Existing rules provide that CMS should determine the appropriate amount of the penalty, but do not describe how the penalty amounts must be updated. CMS notes that the Federal Civil Penalties Inflation Adjustment Act Improvement Act

of 2015 requires agencies to make adjustments for annual inflation but CMS has the discretion to set the CMP amount below the maximum required by law.

CMS proposes to codify in new paragraphs §§422.760(b)(3)(ii) and §423.760(b)(3)(ii) that it will update the minimum penalty and aggravating factor amounts not more often than every 3 years to be consistent with its 3-year audit cycle for Part C and D organizations.

VI. Codifying Existing Policies

A. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§422.100 and 422.101)

CMS proposes amendments to the regulations at §§422.100(f)(4) and (5) and 422.101(d)(2) and (3) to specify how maximum out-of-pocket (MOOP) limits will be set for 2022 and subsequent years. CMS also proposes to modify these regulations to establish a methodology for setting the MOOP limits that accounts for Medicare beneficiaries with diagnoses of end-stage renal disease (ESRD).

As discussed below, beginning with coverage for the 2022 contract year, CMS proposes the following:

- Establish up to three MOOP limits, including the current mandatory and voluntary limits and a third, intermediate MOOP limit;
- Codify the methodology for setting MOOP limits; and
- Adjust the methodology to take into account changes in the MA eligibility for Medicare beneficiaries with the removal of the current limits on MA enrollment for Medicare eligible beneficiaries with diagnoses of ESRD.

CMS uses the term “basic benefits” as defined in §422.100(c) instead of referring to Medicare Part A and Part B benefits. CMS proposes to codify the rules for setting the MOOP limits at §422.100(f)(4). Since the current MOOP limits apply to MA local plans and to in-network limits for MA local and regional PPO plans, CMS proposes that §422.101(d)(2) which imposes the MOOP limits for in-network MA regional plans, be revised to cross-reference the MOOP limits for MA local plans at §422.100(f)(4). Similarly, CMS proposes to use a cross-reference providing the same MOOP limits apply under both §422.100(f)(5) (for MA local PPOs) and §422.101(d)(3) (for MA regional plans) for combined in-network and out-of-network cost sharing. CMS states these cross-references clarify how certain MOOP limits are the same and avoids repetitive regulations text.

CMS proposes to amend §422.100(f)(4) to state the general rule that, except as provided in paragraph (f)(5), MA local plans must establish MOOP limits for basic benefits. Consistent with current regulation, proposed paragraph (f)(5) would address how the MOOP limits apply to the out-of-network coverage provided by local PPO plans. CMS also proposes to include in §§422.100(f)(5) and 422.101(d)(2) the rules for PPOs in establishing in-network and combined (or catastrophic) MOOP limits. Finally, CMS proposes to codify in §§422.100(f)(4) and (5) and 422.101(d)(2) and (3) MA organizations responsibilities to track enrolled beneficiaries’ out-of-pocket spending and to alert enrollees and contracted providers when the MOOP limit is reached.

CMS believes that codifying these responsibilities emphasizes that these requirements are integral to MA organizations administration of basic benefits.

CMS proposes that §422.100 (f)(4) would authorize CMS, for 2022 and subsequent years, to set up to three MOOP limits using projections of beneficiary spending that are based on the most recent, complete Medicare FFS data. CMS proposes three MOOP limits: the lower MOOP limit, the intermediate MOOP limit, and the mandatory MOOP limit. CMS notes these lower, intermediate and mandatory would be used instead of only “voluntary” and “mandatory” MOOP limits. CMS would also codify the current practice of setting the MOOP limits based on a percentile of projected beneficiary out-of-pocket spending.

CMS also proposes to codify the current rule for using ranges to identify the type of MOOP limit an MA plan has established and applying that rule to the three types of MOOP limits.

- A mandatory MOOP limit is any dollar limit that is above the intermediate MOOP limit and at or below the mandatory MOOP limit threshold established each year.
- The intermediate MOOP limit is any dollar limit that is above the lower MOOP limit and at or below the intermediate MOOP limit threshold established each year.
- The lower MOOP limit is any dollar limit that is between \$0.00 and up to and including the lower MOOP limit threshold established each year.

CMS proposes each MOOP limit would be rounded to the nearest whole \$50 increment. When the MOOP limit is projected to be exactly in between two \$50 increments, CMS would round to the lower \$50 (e.g., \$7,125 would be rounded to \$7,100).

CMS also proposes to codify the rules for establishing the MOOP limits for contract year 2022. For contract year 2022, the MOOP limits would be a recalibration of the MA MOOP limits to using a methodology that is adjusted from the current practice. CMS proposes:

- The mandatory MOOP limit is set at the 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending.
- The intermediate MOOP is set at the numeric midpoint of mandatory and lower MOOP limits.
- The lower MOOP limit is set at the 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

CMS proposes it would use projections for the applicable contract year of out-of-pocket (OOP) expenditures for Medicare beneficiaries that are based on the most recent, complete Medicare FFS data that incorporates a percentage of costs incurred by beneficiaries with ESRD (the proposed ESRD cost transition schedule is discussed below).

To set the mandatory and lower MOOP limits for contract years 2023 and 2024, or, if later, until the end of the ESRD cost transition, CMS proposes:

- Review of OACT projections of out-of-pocket spending for the applicable year that is based on updated Medicare FFS data, including all spending regardless of ESRD diagnoses;
- Compare the applicable year’s projection for the 95th and 85th percentile to the prior year’s projections;
- Determine if the prior year’s projections for the 95th and 85th percentile are within a range, above or below, two percentiles of the applicable percentile in the updated projection.

- As an example, for the contract year 2023 mandatory MOOP limit, CMS would determine if the 95th percentile projection for contract year 2022 is between or equal to the 93rd and 97th percentiles of the projections for 2023 out-of-pocket expenditures.
- If the prior year's projections for the 95th and 85th percentile are between or equal to the two percentile range (above or below), CMS would continue the ESRD cost transition schedule for one or both of the MOOP limits.
- If one or both of the prior year's 95th and 85th percentile projections are not within the two percentile range (above or below), CMS would increase or decrease one or both of the MOOP limits up to 10 percent of the prior year's MOOP limit annually until the MOOP limit reaches the projected 95th percentile for the applicable year, subject to the rounding rules.
 - As an example, if the dollar amount needed to be transitioned is 15 percent, 10 percent would be addressed during the first year, and any remaining amount would be addressed during the second year, if applicable, based on updated data projections from the OACT.
 - During this transition, CMS would delay implementation of the next step in the ESRD cost transition schedule. The ESRD cost transition schedule would resume when the prior year's projected 95th and 85th percentiles remains within the range of two percentiles (above or below) the projected 95th percentile for the upcoming contract year.
- The intermediate MOOP limit would be set by either maintaining the prior year's intermediate MOOP limit (if the mandatory and lower MOOP limits are not changed) or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, rounding as proposed.

For contract year 2025, or following the proposed ESRD cost transition schedule, and for subsequent years, CMS proposes to include in the methodology a means to account for trends that are consistent for three years. CMS notes that the ESRD cost transition schedule may end in 2025 or extend longer. To set the mandatory and lower MOOP limits for contract years 2025 or following the ESRD cost transition, CMS proposes:

- The prior year's corresponding MOOP limit is maintained for the upcoming contract year if:
 - (1) the prior year's MOOP limit amount is within the range of two percentiles, above or below, the projected 95th or 85th percentile of Medicare FFS beneficiary out-of-pocket spending by beneficiaries with and without ESRD and
 - (2) the projected 95th or 85th percentile did not increase or decrease for three consecutive years.
- If the prior year's corresponding MOOP limit is not maintained, CMS will increase or decrease the MOOP limit by up to 10 percent of the prior year's MOOP amount annually until the MOOP limit reaches the projected applicable percentile for the applicable year, based on the most recent projections from OACT.

The intermediate MOOP limit would be set by either maintaining the prior year's intermediate MOOP limit (if the mandatory and lower MOOPs are not changed) or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounded as proposed.

CMS believes these proposals will allow plans to provide stable benefit packages and minimize MOOP limit fluctuations unless there is a consistent pattern of increasing or decreasing costs. CMS intends to issue annual guidance applying these rules in advance of the bid deadline.

CMS will continue its current policy of setting the combined MOOP limits (MOOP limits that cover in-network and out-of-network benefits) for PPOs by multiplying the respective in-network MOOP limits by 1.5 for the relevant year and rounding as proposed. CMS proposes to codify this rule for MA regional plans in §422.101(d)(3) and to cross-reference that rule for MA local PPOs in §422.100(f)(5)(i).

CMS **seeks comments** on these proposals including whether or not these proposals would avoid enrollee confusion and maintain stable benefit packages. CMS is also interested in comments on whether or not the proposed regulation text adequately and clearly specifies the methodology that will be used to set the MOOP limits.

MOOP Limits Revisions to Include Beneficiaries With ESRD

Beginning in contract year 2021, Medicare beneficiaries with ESRD can enroll in MA plans.¹⁵ CMS proposes a multi-year transition from its current practice of excluding all costs incurred by beneficiaries with ESRD to including all related costs into the Medicare FFS data used to set the MOOP limits. CMS and OACT do not expect 100 percent of Medicare beneficiaries with ESRD will enroll in the MA program during the first available contract year and it is not proposing to integrate 100 percent of the costs within one contract year

CMS proposes to use the term “ESRD cost differential” to refer to the difference between:

- (1) projected OOP costs for beneficiaries using Medicare FFS data excluding the cost incurred by beneficiaries with ESRD for contract year 2021 and
- (2) the projected OOP costs for all beneficiaries using Medicare FFS data (including the costs incurred by beneficiaries with ESRD) for each year of the ESRD cost transition.

CMS proposes a specific schedule for factoring in a percentage of the ESRD cost differential annually until 2024 or, if later, the final year of the transition and beyond.

- For MOOP limits after contract year 2022, CMS proposes to incorporate an additional 20 percent of the ESRD cost differential, as it is calculated each year using the most recent data projection from OACT.
- In the final year of the transition, 100 percent of the costs incurred by beneficiaries with ESRD would be integrated into the Medicare FFS data that is used to project and determine MOOP limits.

In the proposed rule, CMS states it provides more details on the MOOP limits in Table 11, but Table 11 provides labor rates and there is no table in the proposed rule that provides this information. The proposed text at §422.100(f)(4)(vii) includes the following schedule for the transition:

- For 2022, CMS factors in 60 percent of the ESRD cost differential.

¹⁵ Based on 2018 contract year data, approximately 0.6 percent of the MA enrollee population have a diagnosis of ESRD (see page 14 from the 2020 Rate Notice and Final Call Letter available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>).

- For 2023 or the next year of ESRD cost transition, CMS factors in 80 percent of the ESRD cost differential.
- For 2024 or the final year of the ESRD cost transition and beyond, CMS uses the most recent, complete Medicare FFS data that includes the OOP cost incurred by beneficiaries with and without diagnoses of ESRD.

CMS **seeks comments** on the proposed transition schedule, including comments on alternatives such as 50 percent in 2022, 70 percent in 2023 or, if later, the next year of transition, and 100 percent in the final year of transition.

Using the most recent Medicare FFS data available (2018 data), OACT projected the OOP costs for Medicare FFS beneficiaries. As reproduced below, Table 4¹⁶ illustrates the MOOP limits for in-network basic benefit contracts and Table 5¹⁷ (reproduced twice in the preamble) illustrates the MOOP limits for in-network and out-of-network basis benefits based on CMS’ proposed methodology. These examples of potential MOOP limits integrate the ESRD cost differential over multiple years and include application of the proposed rounding rule. CMS will update these numbers in the final rule. CMS intends to publish the annual MOOP limits and the methodology used through the Health Plan Management System (HPMS) memoranda issued prior to each year’s bid submission.

Table 4: Illustrative Example of In-Network MOOP Limits Based on Most Recent Medicare FFS Data Projections				
MOOP Limit	Approximate Original Medicare Percentile	Contract Year 2022	Contract Year 2023	Contract Year 2024
Mandatory	95th	\$5,601 to \$7,750	\$5,701 to \$7,950	\$5,801 to \$8,150
Intermediate	Approximate numeric midpoint*	\$3,451 to \$5,600	\$3,501 to \$5,700	\$3,501 to \$5,800
Lower	85th	\$0 to \$3,450	\$0 to \$3,550	\$0 to \$3,550

*The intermediate MOOP limit would be based on the mandatory MOOP limit, less approximately 50 percent of the numeric difference between the mandatory and lower MOOP limits.

Table 5: Illustrative Example of Combined MOOP Limits for LPPO and Catastrophic (MOOP) Limits for RPPO Plans Based on Most Recent Medicare FFS Data Projections				
MOOP Limit		Contract Year 2022	Contract Year 2023	Contract Year 2024
Mandatory		\$5,601 to \$7,750	\$5,701 to \$7,950	\$5,801 to \$8,150
Intermediate		\$3,451 to \$5,600	\$3,501 to \$5,700	\$3,501 to \$5,800
Lower		\$0 to \$3,450	\$0 to \$3,550	\$0 to \$3,550

*Combined MOOP limits are calculated by multiplying the respective MOOP limits by 1.5 for the relevant year

CMS **seeks comments** on the following:

- Whether it should publish annual MOOP limits through the HPMS memoranda on through subregulatory guidance.
- Whether additional regulation text is needed to achieve CMS’s goal of providing additional transparency on how it will determine MOOP limits, transition ESRD costs

¹⁶ This Table 4 is the first Table 4; a subsequent Table 4 illustrates examples of cost sharing for inpatient hospital stays.

¹⁷ A subsequent Table 5 illustrates contract year 2022 in-network service category cost sharing limits.

into MOOP limit calculations, and calculate MOOP limits during and after completion of the ESRD cost transition.

B. Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§422.100 and 422.113)

Section 1852 of the Act imposes several requirements that apply to the cost sharing and benefit design of MA plans. CMS annually analyzes Medicare program data to interpret and apply the various cost sharing limits and to publish guidance on MA cost sharing limits in the annual Call Letter. CMS reviews cost sharing established by MA organizations to determine compliance with the cost sharing limits and requirements established in the statute and regulations, as interpreted and implemented in sub-regulatory guidance, including Chapter 4 of the MMCM. CMS proposes to codify, with some modifications, its current practice and methodology for interpreting and applying limits on MA cost sharing.

CMS reminds organizations that they must also comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, national origin, gender, disability, chronic disease, health status, or other prohibited bases. CMS states that none of the proposed regulations under this rule limit application of such anti-discrimination requirements.

1. General Non-Discriminatory Cost Sharing Limits (§422.100(f)(6))

CMS proposes to codify a set of general rules for cost sharing for basic benefits. “Basic benefits” is defined in §422.100(c) to mean items and services (other than hospice care and, beginning 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at §422.135. CMS proposes that the rules in §422.100(f)(6) must be followed by MA plans in addition to other regulatory and statutory requirements for cost sharing. MA organizations have the option to charge either coinsurance or a copayment for most benefit category benefits. MA plans cannot exceed the coinsurance or copayment limit for benefit category standards established by CMS.

CMS proposes to codify its longstanding interpretation of the anti-discrimination provisions that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who have high health care needs and discourages beneficiaries from enrolling in the plan. CMS defines the term “total MA plan financial liability” as the total payment paid and includes both the enrollee cost sharing and the MA organization’s payment. CMS states it is difficult to set a cost sharing limit for every possible benefit and this longstanding policy is an important beneficiary protection. This rule would apply regardless of the established MOOP limit and regardless of whether the benefit is furnished in-network or out-of-network. Under this proposal, if the MA plan uses copayments, the copayment for an out-of-network benefit cannot exceed 50 percent of the average Medicare FFS allowable cost for that service area and the copayment for in-network benefits cannot exceed 50 percent of the average contracted rate of that benefit (item or service). If the MA plan uses coinsurance, then the coinsurance cannot exceed 50 percent.

CMS also proposes general rules for how it would set copayment limits: CMS would round to the nearest whole \$5 increment for professional services and nearest whole \$1 for inpatient acute and psychiatric and skilled nursing facility cost sharing limits. In addition, for cases when the projected copayment limit is exactly between two increments, CMS will round to the lowest dollar amount.

CMS proposes modifications in how MA plans set cost sharing for professional services to account for its proposal to establish three MOOP limits each year and to account for OACT projections of OOP costs for beneficiaries with and without ESRD. The cost sharing limits would vary based on the type of MOOP limit used by the MA plan:

- (1) Mandatory MOOP limit: 30 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 70 percent of the total MA plan financial liability.
- (2) Intermediate MOOP limit: 40 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 60 percent of the total MA plan financial liability.
- (3) Lower MOOP limit: 50 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 50 percent of the total MA plan financial liability.

CMS notes that it assigned the highest coinsurance amount that was not discriminatory (50%) to the lowest MIIP limit; and 30% coinsurance to the mandatory MOOP limit. To establish actuarially equivalent values for each year, CMS will work with OACT to establish copayment limits that are approximately equal to the identified coinsurance percentage limit based on projections of the most recent Medicare FFS data that includes 100 percent of the OOP costs representing all beneficiaries with and without ESRD.

For primary care, physician specialties, mental health specialty services, and physical and speech therapy, CMS proposes to base the approximate actuarially equivalent copayment limits on the most recent Medicare average cost data weighted by utilization by the applicable provider specialty type for each service. The applicable provider specialty types include:

- Primary Care: Family Practice; General Practice; Internal Medicine
- Physician Specialties: Cardiology; Geriatrics; Gastroenterology; Nephrology; Otolaryngology
- Mental Health Specialty Services: Clinical Psychologist; Licensed Clinical Social Work; Psychiatry
- Physical and Speech Therapy; Physical Medicine and Rehabilitation; Speech-language Pathologists

For psychiatric services, occupational therapy, and chiropractic care, CMS proposes to base the approximate actuarially equivalent copayment limits on the most recent Medicare average cost data from a single, most applicable provider specialty which would include Psychiatry, Occupational Therapist, and Chiropractor. CMS **seeks comments** on the whether other provider specialty types should inform its proposed actuarially equivalent copayment limits.

CMS discusses the guidance in Chapter 4, section 50.1 of the MMCM that requires MA plans to identify (and charge) the enrollee's entire cost sharing responsibility as a single copayment (if using copayment rather than coinsurance) even if the MA plan has differential cost sharing that varies by facility setting or contracted arrangements that involve separate payments to facilities (or settings) and providers. CMS states it is aware of situations where a facility charges a

separate amount from the health care provider, such as an emergency department fee and a fee for the emergency room physician) and in these situations these fees should be combined (bundled) into the cost sharing amount for that particular service and be clearly reflected as a total copayment to beneficiaries. CMS **seeks comments** on whether this is clear in existing regulations (§ 422.111) or if clarification in regulation text would be helpful.

2. Cost Sharing Limits for Inpatient Hospital Acute and Psychiatric Services (§422.100(f)(6)(iv))

Annually, CMS announces the maximum cost sharing permitted for inpatient length of stay scenarios for both acute and psychiatric care determined as a percentage of estimated Medicare FFS cost sharing projected to the applicable contract year.

CMS proposes cost sharing limits for each of the seven inpatient stay scenarios for which cost sharing would apply under original Medicare: the inpatient hospital acute stay scenarios are for 3, 6, 10 and 60 days; and the psychiatric inpatient hospital stay scenarios are for 8, 15 and 60 days. CMS notes these scenarios are similar to those used in the contract year 2020 Call Letter. Plans may vary cost sharing for different admitting health conditions, providers, or services provided, but overall benefit costs sharing must satisfy the limits established by CMS. CMS proposes it would use projected OOP costs and utilization data based on the most recent Medicare FFS data that factors in OOP costs incurred by beneficiaries with ESRD (based on the proposed transition) and may also use patient utilization information from MA encounter data. CMS would not include the ESRD cost transition exceptions for the MOOP limit calculations because it believes this exception is not relevant for setting inpatient cost sharing limits.

CMS discusses the impact of including all costs incurred by beneficiaries with ESRD in cost sharing limits. OACT's analysis found that adding related ESRD costs affects inpatient hospital acute cost sharing limits due to increased Part B professional fees but did not impact inpatient hospital psychiatric cost sharing limits. Based on this analysis, CMS proposes to update its methodology and use the same proposed transition schedule of ESRD costs for the MOOP limit calculations for all inpatient hospital acute and psychiatric standards. Specifically, for contract year 2022, CMS proposes to integrate approximately 60 percent of the difference between Medicare FFS costs incurred by all beneficiaries and the costs excluding beneficiaries with ESRD into the data used to set the inpatient hospital acute and psychiatric cost sharing limits. After contract year 2022, CMS will incorporate an additional 20 percent of costs incurred by beneficiaries with ESRD each year until contract year 2024, when CMS will integrate 100 percent of costs incurred by beneficiaries with ESRD.

CMS proposes it will apply the transition of ESRD costs across all inpatient hospital length of stay scenarios and also proposes to add a 3-day length of stay scenario for acute hospital stays and an 8-day length of stay scenario for psychiatric care to the existing scenarios. The proposed 3-day and 8-day scenarios are based on 2015-2017 claims data and MA encounter data.

CMS proposes specific cost sharing limits (stated as percentages of the FFS costs for each length of stay scenario) tied to the type of MOOP limit used by the MA plan:

- (1) Mandatory MOOP limit: cost sharing must not exceed 100 percent of estimated FFS cost sharing, including the Part A deductible and related Part B costs.

- (2) Intermediate MOOP limit: cost sharing must not exceed the numeric mid-point between the cost sharing limits for the mandatory and lower MOOP limits.
- (3) Lower MOOP limit: cost sharing must not exceed 125 percent of estimated FFS cost sharing, including Part A and related Part B costs. Consistent with existing policy, for inpatient acute 60 days length of stays, MA plans that establish a lower MOOP have the flexibility to set cost sharing above 125 percent of estimated FFS cost sharing as long as the total cost sharing for the inpatient benefit does not exceed the MOOP limit or cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

CMS would continue to publish acceptable inpatient hospital acute and psychiatric cost sharing limits calculated by its methodology through subregulatory means, such as HPMS memoranda, issued each year prior to bid submission.

Table 4 in this section (the second table 4 in the proposed rule), reproduced below, provides an example of how CMS would calculate cost sharing limits. A detailed discussion of these calculations for contract year 2022 are provided to the proposed rule.

MOOP Limit	Percent of Estimated Medicare FFS Cost Sharing	Contract Year 2022	Contract Year 2023	Contract Year 2024
Mandatory	100%	\$2,242	\$2,257	\$2,273
Intermediate	Approximate numeric midpoint*	\$2,522	\$2,540	\$2,557
Lower	125%	\$2,802	\$2,822	\$2,841

*The intermediate MOOP limit would be based on the mandatory MOOP cost sharing limit, less approximately 50 percent of the numeric difference between the mandatory and lower MOOP cost sharing limits.

CMS **seeks comments** on these proposals and whether additional regulatory text §422.100(f)(6)(iv) or restructuring would be helpful.

3. Basic Benefits for Skilled Nursing Facilities (SNFs), Outpatient, and Professional Services Subject to Cost Sharing Limits (§422.100(j))

CMS proposes to codify and adopt specific cost sharing limits for certain benefits (by individual service and by category) that are based on a comparison to the cost sharing in the Medicare FFS program. Table 5 (the third Table 5 in the proposed rule and occasionally referred to as Table 8 in the preamble), reproduced below at the end of this section, illustrates the cost sharing limits based on the methodology proposed for contract year 2022.

Range of Cost Sharing Limits for Certain Outpatient and Professional Services

In the 2020 Final Call Letter, CMS established a policy of allowing MA plans greater flexibility in establishing Parts A and B cost sharing when the MA plan adopts a lower, voluntary MOOP limit and less flexibility to MA plans that adopt the higher, mandatory MOOP limit. CMS is proposing to establish a range of cost sharing limits based upon the MOOP limits established by the MA plan for specific basic benefits offered on an in-network basis.

CMS proposes to specify that for basic benefits that are professional in-network services, MA plans may have greater flexibility in setting cost sharing based on the MOOP limit they establish. As illustrated in Table 5, multiple standards will apply to the cost sharing for professional and outpatient benefits. CMS notes that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care (e.g., several sessions of cardiac rehabilitation) as long as the overall (or total) cost sharing amount satisfies CMS standards.

CMS states that if these proposals are finalized, contract year 2022 bids must reflect enrollee cost sharing for in-network services no greater than the amounts calculated using these proposals. For example, CMS would permit an MA plan that established a lower MOOP limit to establish up to 50 percent coinsurance or actuarial equivalent copayment for cardiac rehabilitation (a professional service for which cost sharing is subject to §422.100(f)(6)(iii)), and other services included in Table 5 where CMS does not propose a specific actuarially equivalent copayment limit.

Emergency and Urgently Needed Services (§422.113(b)(2)(v) and (vi))

CMS discusses how most of its proposals for limiting cost sharing for basic benefits use methodologies that allow CMS to annually update the dollar amount applicable to copayments while the coinsurance limits remain at a specified percentage of the total MA plan financial liability. Based on OACT analysis, CMS believes a different approach is appropriate for emergency services.

CMS proposes that a maximum cost sharing limit permitted per visit for emergency services corresponds to the MOOP limit established by the MA plan. Specifically, effective for contract year 2022 and subsequent years, the MA organization if financially responsible for emergency and urgently needed services, would establish a dollar limit on emergency services including post-stabilization service costs for enrollees that is the lower of:

- A. The cost sharing established by the MA plan if the emergency services were provided through the MA organization; or
- B. A maximum cost sharing limit permitted per visit that corresponds to the MA MOOP limit as follows:
 - i. \$115 for MA plans with a mandatory MOOP limit;
 - ii. \$130 for MA plans with an intermediate MOOP limit; and
 - iii. \$150 for MA plans with a lower MOOP limit.

CMS developed this proposal by finding the projected median total allowed amount for emergency services (including visit and related procedure cost) using the most recent Medicare FFS data that includes 100 percent of the OOP costs incurred by beneficiaries with ESRD. Because the difference between median costs with and without ESRD costs is only \$4, CMS proposes to include 100 percent of ESRD costs instead of using an ESRD cost transition.

CMS believes it can be difficult for enrollees to differentiate emergency services from post-stabilization services and proposes to clarify that cost sharing limits for emergency services include post-stabilization service costs. CMS considers urgently needed services similar to professional services and proposes that the same cost sharing limits for professional services will apply to urgently needed services, regardless of whether they are furnished in-network or out-of-network.

Services No Greater Than Original Medicare

Section 1852(a)(1)(B) of the Act specifies that MA plans may not charge enrollees higher cost sharing than is charged under original Medicare for chemotherapy administration services,¹⁸ skilled nursing care, and dialysis services. This rule is implemented in §§417.454(e) for cost plans and 422.100(j) for MA plans; CMS does not propose any changes to the cost sharing standards for cost plans.

For skilled nursing care, CMS currently allows different cost sharing for the first 20 days of a SNF stay and for days 21 through 60. MA plans that establish a voluntary MOOP limit can establish per-day cost sharing for the first 20 days of a SNF stay, but the total cost sharing for the overall SNF benefit (days 1 through 100) must not be higher than the actuarially equivalent cost sharing in original Medicare and the per-day cost sharing for days 21 through 100 must not be greater than the projected original Medicare SNF amounts. MA plans that establish the higher, mandatory MOOP limit must establish \$0 per-day cost sharing for the first 20-days and the per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount. Beginning in contract year 2022, CMS proposes to permit limited cost sharing for the first 20 days of SNF for MA plans that establish either the lower or intermediate limit.

CMS proposes to add the following services to the requirement that cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare:

- Home health services (as defined in section 1861(m) of the Act for MA plans that establish a mandatory or intermediate MOOP limit, and
- Durable medical equipment (DME).

For home health services, CMS proposes that when the MA plan establishes the lower MOOP limit, the MA plan may have cost sharing up to 20 percent of the total MA plan financial liability. For DME, for plans that establish a mandatory MOOP limit, CMS proposes the per-item or service cost sharing must not be greater than original Medicare cost sharing. For MA plans that establish a lower or intermediate MOOP limit, total cost sharing for all DME service categories combined must not exceed original Medicare on a per member per month actuarially equivalent basis but may establish cost sharing for specific items of DME that exceed the cost sharing under original Medicare.

In-Network Service Category Cost Sharing Requirements

If the above proposals are finalized, CMS plans to update the in-network service category cost sharing limits annually (listed in Table 5). The cost sharing limits for emergency services would remain the same each year. Under its proposals, all standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles.

CMS notes that Table 5 does not include copayment limits for cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, supervised exercise therapy for symptomatic peripheral artery disease, partial hospitalization, home health, therapeutic radiological services,

¹⁸ CMS has implemented chemotherapy administrative services to include Part B chemotherapy/radiation drugs integral to the treatment regimen.

DME, dialysis, Part B Drugs - Chemotherapy/Radiation Drugs, and Part B Drugs – Other. CMS found these categories were subject to a higher variation in cost or unique provider contracting arrangements which makes using Medicare FFS average or median cost data less applicable for developing a standardized actuarially equivalent copayment value. MA plans may be required to provide information demonstrating how contracted rates comply with the regulation standards. CMS notes that MA plans are required to attest when they submit their bid that their benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations.

CMS **seeks comments** on whether an explicit regulatory provision should be added to require MA organizations to demonstrate compliance with these standards upon request by CMS. This would include providing CMS with information substantiating the contracted rates for basic benefits that are professional services without an established copayment limit and illustrate how the MA organization determined its cost sharing amounts.

Service Category	PBP Section B data entry field	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Inpatient Hospital – Acute - 60 days	1a	N/A	\$5,514	\$4,902
Inpatient Hospital – Acute - 10 days	1a	\$2,802	\$2,522	\$2,242
Inpatient Hospital – Acute - 6 days	1a	\$2,536	\$2,282	\$2,029
Inpatient Hospital Acute – 3 days	1a	\$2,339	\$2,105	\$1,872
Inpatient Hospital Psychiatric - 60 days ⁶	1b	\$3,408	\$3,067	\$2,726
Inpatient Hospital Psychiatric - 15 days ⁶	1b	\$2,339	\$2,105	\$1,871
Inpatient Hospital Psychiatric – 8 days ⁶	1b	\$2,173	\$1,955	\$1,738
Skilled Nursing Facility – First 20 Days ^{1,2}	2	\$20	\$10	\$0
Skilled Nursing Facility – Days 21 through 100 ^{1,2,7}	2	\$184/d	\$184/d	\$184/d
Cardiac Rehabilitation ⁵	3	50%	40%	30%
Intensive Cardiac Rehabilitation ⁵	3	50%	40%	30%
Pulmonary Rehabilitation ⁵	3	50%	40%	30%
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD) ⁵	3	50%	40%	30%
Emergency Care/Post Stabilization Care ³	4a	\$150	\$130	\$115
Urgently Needed Services ³	4b	50% / \$55	40% / \$45	30% / \$35
Partial Hospitalization ⁵	5	50%	40%	30%
Home Health	6a	20% ⁵	\$0	\$0
Primary Care Physician	7a	50% / \$55	40% / \$45	30% / \$35

TABLE 5: ILLUSTRATIVE CONTRACT YEAR 2022 IN-NETWORK SERVICE CATEGORY COST SHARING LIMITS

Service Category	PBP Section B data entry field	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Chiropractic Care	7b	50% / \$25	40% / \$20	30% / \$15
Occupational Therapy	7c	50% / \$60	40% / \$45	30% / \$35
Physician Specialist	7d	50% / \$80	40% / \$65	30% / \$50
Mental Health Specialty Services	7e	50% / \$65	40% / \$55	30% / \$40
Psychiatric Services	7h	50% / \$65	40% / \$50	30% / \$40
Physical Therapy and Speech-language Pathology	7i	50% / \$85	40% / \$65	30% / \$50
Therapeutic Radiological Services ⁵	8b	20%	20%	20%
DME-Equipment	11a	N/A	N/A	20% ⁵
DME-Prosthetics	11b	N/A	N/A	20% ⁵
DME-Medical Supplies	11b	N/A	N/A	20% ⁵
DME-Diabetes Monitoring Supplies	11c	N/A	N/A	20% ⁵
DME-Diabetic Shoes or Inserts	11c	N/A	N/A	20% ⁵
Dialysis Services ^{1,5}	12	20%	20%	20%
Part B Drugs Chemotherapy/Radiation Drugs ^{1,4,5}	15	20%	20%	20%
Part B Drugs-Other ⁵	15	50%	40%	30%
Partial Hospitalization ⁵	5	50%	40%	30%
Home Health	6a	20% ⁵	\$0	\$0
Primary Care Physician	7a	50% / \$55	40% / \$45	30% / \$35

¹MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under original Medicare for Part B chemotherapy/radiation drugs integral to the treatment regimen, skilled nursing care, and renal dialysis services (§ 417.454(e) and proposed § 422.100(j)(1)(i), (ii), and (iii)).

²MA plans that establish a lower and intermediate MOOP limit may have cost sharing for the first 20 days of a SNF stay (proposed § 422.100(j)(1)(iii)). The per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount, proposed at § 422.100(j)(1)(iii)(A). Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in original Medicare, pursuant to section 1852(a)(1)(B), and proposed § 422.100(j)(1)(iii)(B).

³ The dollar amount for Emergency Care/Post Stabilization Care and Urgently Needed Services included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance) under proposed §422.113(b)(2)(v) and (vi).

⁴No text is provided for this table note.

⁵MA plans may set cost sharing limits that are actuarially equivalent to the coinsurance limits based on their contracted rates under proposed § 422.100(f)(6)(iii)(A).

⁶ Inpatient hospital psychiatric standards will be updated for contract year 2022 to incorporate differences in Part A deductible and cost impacts for beneficiaries with diagnoses of ESRD.

⁷ This SNF limit is based on the 1/8th of the projected contract year 2021 Part A deductible, which will be updated for 2022.

4. Per Member Per Month Actuarial Equivalent Cost Sharing Limits for Basic Benefits (§422.100(j)(2))

Under the statute and current regulations, total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Medicare FFS on an actuarially equivalent basis and must not be discriminatory. CMS proposes requiring that the total cost sharing for all basic benefits covered by a MA plan, excluding out-of-network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. CMS also proposes to codify its existing policy regarding the specific benefit categories that MA plans must not exceed the cost sharing in original Medicare on a per member per month actuarially equivalent basis. The services subject to this existing policy are:

- Inpatient hospital acute and psychiatric services, defined as services provided during a covered stay in an inpatient facility during the period for which cost sharing would apply under original Medicare;
- DME;
- Drugs and biologics covered under Part B of original Medicare, including both chemotherapy/radiation drugs and other drugs covered under Part B; and
- Skilled nursing care, defined as services provided during a covered stay in a SNF during the period for which cost sharing would apply under original Medicare.

CMS states this proposal would ensure that MA plans with greater cost sharing in these categories are not designing benefits that discriminate against enrollees with health status factors and conditions that require these services. CMS also states limiting cost sharing is important to encourage beneficiaries' enrollment in MA plans.

CMS believes that setting copayments through quantitative formulas may be less appropriate for some categories, like DME and Part B drugs, and cost sharing for these services may be better evaluated for discrimination on an aggregate service basis. CMS states these categories include items or services that significantly vary in costs and/or may be subject to provider contracting arrangements that make it difficult for CMS to establish a specific copayment amount for the entire category as opposed to specific items and benefits. CMS proposes that it may extend flexibility for MA plans when evaluating actuarial equivalent cost sharing limits for these service categories to the extent that the per member per month cost sharing limit is actuarially justifiable based on generally accepted actuarial principles and supporting documentation in the bid, provided that the cost sharing for specific services otherwise satisfies published cost sharing standards. CMS believes this exception will apply in limited situations, such as when the MA plans uses capitated arrangements with provider groups.

C. Plan Crosswalks for MA Plans and Cost Plans (§§417.96 and 422.530)

CMS proposes to codify the current process used by MA organizations and 1876 cost plans to transfer enrollees into the same plan or plan type from year to year when no other election has been (referred to as "plan crosswalk"). CMS also codifies the rules that protect a beneficiary's right to choose a plan and specifies when a MA organization or cost plans can transfer their enrollees to other plans of a different type offered by the same MA organization or cost plan (referred to as a "crosswalk exception). For cost plans, enrollees can be transferred from one cost

plan benefit to another plan benefit package (PBP) under the same contract.¹⁹ CMS notes that these crosswalk policies are a mechanism for operationalizing evergreen elections²⁰; evergreen elections are when an individual who has made an election is considered to have continued to make the same election until the individual makes a change to the election, or the MA plan is discontinued or no longer serves the area where the individual resides.

CMS proposes to define a plan crosswalk as the movement of enrollees from one PBP to another PBP under the same contract between the MA or cost organization and CMS. Crosswalks are part of the annual contract renewal process.

For purposes of a MA plan crosswalk, CMS proposes that health maintenance organizations, provider-sponsored organizations, and regional and local preferred provider organizations coordinated care plans are different plan types, even though they are all coordinated care plans. This proposal is specific to MA plans because cost plans do not include these different plan types.

- CMS notes that segmented plans are not a “type” of plan in MA and that crosswalks are permitted between segmented and non-segmented plans.

For cost contracts, CMS proposes to codify that crosswalks are prohibited between different cost plan IDs under a cost contract unless the crosswalk qualifies for an exception to this requirement.

- CMS proposes an exception for cost contracts terminating PBPs with optional supplemental benefits. Plans may transfer enrollees to another PBP with or without optional benefits under the same contract as long as enrollees who have Part A and B benefits only are not transferred to a PBP that includes Part D.
- CMS proposes that an enrollee in a terminating PBP that includes Part D may only be moved to a PBP that does not include Part D if the enrollee is notified in writing that they are losing Part D coverage, the options for obtaining Part D, and the implications of not getting Part D through some other means.

1. Cost Plans and All MA Plan Types (§§ 417.496 and 422.530)

Renewal Plan

CMS proposes to codify that an MA or cost organization may continue to offer (renew) a current PBP that retains all of the same service area for the following year; the renewing plan must retain the same PBP ID number as in the previous contract year. CMS states that current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP. The MA or cost organization will not submit enrollment transactions to CMS for current enrollees but will transition all enrollees from the current PBP to the new PBP with the same PBP number for the following years and provide an Annual Notice of Change (ANOC) notifying these enrollees of any changes to the renewing plan. New enrollees must complete enrollment requests and the MA or cost organization must submit enrollment transactions for these enrollees to CMS.

¹⁹ CMS notes it generally uses the terms “plan” and “PBP” interchangeably to refer to a specific plan offered under a contract. The term PBP is used to describe the individual benefit packages that may be offered under a singular plan.

²⁰ Section 1851(c)(3)(B) of the Act provides for evergreen elections.

Consolidated Renewal Plan

A plan consolidation occurs when MA and cost organizations combine two or more PBPs offered under the same contract in the current contract year into a single renewal plan. CMS proposes to codify as a permissible crosswalk consolidation that includes two or more complete PBPs combined into one PBP in the next contract year. Under these circumstances, CMS will permit the MA or cost organization to transition all enrollees in the combined plans under one PBP contract, with the same benefits in the following contract year. The resulting combined PBP must have the plan ID of one of the consolidated plans.

Current enrollees will not be required to make an enrollment election to enroll in the consolidated single plan. The MA or cost organization will not submit enrollment transactions to CMS for current enrollees but will provide an Annual Notice of Change (ANOC) to all current enrollees in the consolidated renewal plan. New enrollees must complete enrollment requests and the MA or cost organization must submit enrollment transactions for these enrollees to CMS.

Renewal Plan with a Service Area Expansion (SAE)

To expand the service area of its plan, an MA or cost organization must submit a SAE application to CMS for review and approval. In order for all current enrollees to remain enrolled in the PBP, the PBP with a SAE must retain the renewed PBP's ID number. Consistent with the prior discussions, current enrollees are not required to take enrollment action and the MA or cost organization must submit only enrollment transactions to CMS for those new enrollees. MA and cost plans are required to provide an ANOC to all current enrollees of a renewed PBP with a SAE.

Renewal Plan with a Service Area Reduction (SAR)

An MA or cost organization may reduce the service area of a current contract year PBP; a SAR means that enrollees who were in the part of the service area being reduced will generally not be eligible to remain in the plan because of the residence requirement. CMS proposes that when there is a service area reduction for a plan, the MA organization or cost plan may only crosswalk the enrollees who reside in the remaining service area to the plan in the following contract year that links to a current contract year. CMS notes that MA organizations may have different options available to them in terms of notices and the ability to offer a continuation of enrollment depending on the other MA plans in the area (§422.74(b)(3)(ii)).

CMS proposes that enrollees that are no longer in the service area of the MA or cost plan will be disenrolled at the end of the contract year and will either need to elect another plan or default to original Medicare. The plans must submit disenrollment transactions to CMS. The plans must send a Medigap guaranteed issue rights to the affected enrollees and a nonrenewal notice to enrollees in the reduced portion of the service area, including notification of the special election period (SEP). CMS also proposes to codify its special rules about what information may be provided by MA organizations about other MA plan options (§422.530(b)(1)(iv)(D)).

2. Special Needs Plans (SNPs) (§422.530(b))

Chronic Condition SNPs (C-SNPs)

C-SNPs enroll special needs individuals who have a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan. MA organizations may target one or

more specific severe or disabling chronic conditions; CMS considers a “grouping” when more than one severe or disabling chronic condition is targeted by the C-SNP.

CMS proposes to codify four permissible crosswalks specific to C-SNPs:

- (1) Renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains the same chronic condition.
- (2) Non-renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains the same chronic condition.
- (3) Renewing C-SNP with a grouping that is transitioning eligible enrollees into another C-SNP with one of the chronic conditions from that grouping.
- (4) Non-renewing C-SNP with a grouping that is transitioning eligible enrollees into a different grouping C-SNP if the new grouping contains at least one condition that the prior plan contained.

Institutional-SNPs (I-SNPs)

I-SNPs are limited to enrolling individuals who are institutionalized or institutionalized-equivalent individuals or may enroll both categories of individuals. CMS proposes to codify five permissible crosswalks specific to I-SNPs:

- (1) Renewing I-SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.
- (2) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.
- (3) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.
- (4) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.
- (5) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

Dual Eligible-SNPs (D-SNPs)

CMS does not propose to codify any permissible crosswalks specific to D-SNPs.

Exceptions

Crosswalk exceptions are crosswalk actions that must be manually reviewed by CMS and address certain unusual circumstances involving specific types of plans or contract activities.

CMS proposes the following exceptions to the crosswalk process:

- (1) Non-network or partial network based private fee-for-service (PFFS) plan transitioning to either a partial network or full network PFFS. CMS proposes to permit a crosswalk when it determines it is in the interest of beneficiaries.
- (2) Consolidation of MA plans offered by two different MA organizations that share the same parent organizations into one contract. CMS proposes that enrollees from the consolidating plans may be moved to the consolidated MA plan.
- (3) Renewing D-SNP in a multi-state service area that is reducing its service area to accommodate a state contract in part of the service area. CMS proposes to permit a crosswalk exception to accommodate state contracting efforts in the service area. CMS proposes enrollees who are no longer in the service area would be moved into one or more new or renewing D-SNPs in their service area.

- (4) Renewing D-SNP that transitions eligible enrollees into another D-SNP. CMS proposes an exception when an MA organization renews a D-SNP for the upcoming contract year, but has another available new or renewing D-SNP for the upcoming contract year, and the two D-SNPs are offered to different populations. CMS states an MA organization may change a D-SNP's eligibility criteria for the upcoming contract year and some enrollees may no longer be eligible for their current D-SNP. The MA organization may have a new or renewing D-SNP in the same service area with eligibility requirements that can accommodate these enrollees and CMS may determine it is in the enrollees best interest to allow a crosswalk exception.
- (5) Renewing C-SNP with a grouping that is transitioning eligible enrollees into another C-SNP with one of the chronic conditions from that grouping. CMS proposes to allow this exception, which would allow identification of enrollees that are moving from the renewing plan to the other plan.

D. MA Change of Ownership Limited to Medicare Book of Business

Under existing practice and contracting regulations in §422.550, when an MAO changes ownership, the execution of a novation agreement is required for a transfer of ownership to a new entity. CMS states that it has been its longstanding practice to only permit such MA contract novation for transfers involving the organization's entire line of MA business. CMS will not recognize the sale or transfer of just one MA contract because it states that it could have a negative effect on beneficiary election rights.

CMS proposes to codify this restriction in new §422.550(f). Under the amendment, CMS would only recognize the sale or transfer of an organization's entire MA line of business, with one exception. CMS would recognize the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization. In addition, CMS would not recognize or allow a sale or transfer that consists only of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan, or one contract if the organization holds more than one MA contract.

E. MA and Cost Plan Network Adequacy (§422.116)

CMS proposes to codify MA and cost plan network adequacy requirements in new §422.116. Under Medicare statute, MA plans must ensure that benefits are available and accessible with reasonable promptness to each individual electing the plan within the plan service area. Existing rules provide for that assurance in §422.112(a), which requires plans to maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. Existing §422.112(a)(10) further describes how MA plans must meet access and availability requirements and establishes a benchmark for CMS to evaluate whether plans have done so. CMS has since developed a process for reviewing network adequacy based on such benchmarks and operationalized network adequacy measures and assessment through sub-regulatory guidance.

Proposed new §422.116(a) would codify, largely consistent with current sub-regulatory guidance, the general rules for ensuring that a network-based MA plan has an adequate provider network. By cross reference to §422.114(a)(3)(ii) and a conforming amendment to §417.416(e),

plans subject to these rules would include all coordinated care plans, network-based MA private fee-for-services plans and 1876 cost organizations. MA MSA plans would not be subject to the proposed rules.

In general, the provisions would require:

- A MAO to attest that it has an adequate network even for provider types that CMS does not independently evaluate in any given year.
- A MA plan to meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type. Each contract provider type must be within maximum time and distance of at least one beneficiary in order to count toward the minimum number. The minimum number criteria and the time and distance criteria would vary by the county type.
- That certain provider and facility types do not count toward meeting network adequacy criteria: specialized, long-term care, and pediatric/children's hospitals; providers that are only available in a residential facility; providers and facilities contracted with the organization only for its commercial, Medicaid, or other products.
- CMS proposes to clarify that hospital-based dialysis can count toward network adequacy criteria for the facility type: Outpatient Dialysis.

1. Annual updates.

CMS would make available and provide for annual updates of:

- Health Service Delivery (HSD) Reference file that identifies minimum provider and facility number requirements, provider and facility time and distance standards, and ratios established for determining the minimum number of providers and facilities (described below) in advance of network reviews each year; and
- A Provider Supply file that lists available providers and facilities and their corresponding office locations and specialty types that is updated annually.

2. Maximum Time and Distance Standards.

Proposed new §422.116(b) would include a Table of “base” time and distance standards that would apply to each of 27 provider types and 14 specific facility types and would vary by county type. The providers and facilities would be listed in (b)(1) and (2). CMS proposes that a specialty or facility type could be removed from network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD Reference File. Additions to the list of provider and facility types would need to be made through future rulemaking.

Types of counties would vary based on the population and population density. The types and parameters for those country types would be as follows:

**County Designations & Population Size and Density Parameters
for Application of Time and Distance Standards**

COUNTY DESIGNATION	POPULATION	DENSITY
Large Metro	≥ 1,000,000	≥ 1,000/mi ²
	500,000 – 999,999	≥ 1,500/mi ²
	Any	≥ 5,000/mi ²
Metro	≥ 1,000,000	10 – 999.9/mi ²
	500,000 – 999,999	10 – 1,499.9/mi ²
	200,000 – 499,999	10 – 4,999.9/mi ²
	50,000 – 199,999	100 – 4,999.9/mi ²
	10,000 – 49,999	1,000 – 4,999.9/mi ²
Micro	50,000 – 199,999	10 – 99.9/mi ²
	10,000 – 49,999	50 – 999.9/mi ²
Rural	10,000 – 49,999	10 - 49.9/mi ²
	< 10,000	50 - 999.9/mi ²
CEAC	Any	< 10/mi ²

Notes: CEAC= Counties with Extreme Access Considerations

Source: Table 6 of the Proposed Rule.

Table 1 to Paragraph (d)(2)) (Table 7 in the preamble and duplicated below) would provide standards applicable to each of the provider and facility types by county designation:

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
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100

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
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology - Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology - Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services	20	10	45	30	160	120	145	120	155	140
– Intensive Care Units (ICU)										

Provider/Facility Type	Large Metro		Metro		Micro		Rural		CEAC	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Outpatient Dialysis	20	10	45	30	65	50	55	50	100	90
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100

CMS notes that those time and distance standards are not static and can be changed based on the application of specific population size and density standards. CMS will publish in the annual HSD Reference file the county designation and applicable time and distance standards for each county for the applicable year.

i. Customization.

In the past, CMS notes that it has incorporated flexibility into some of the time and distance standards beyond those base standards in Table 1 above. It refers to this as “customization” and in the past this has happened where a shortage of supply of providers or facilities has made it impossible to meet the base time and distance requirements. Where customization has been necessary, CMS uses data to map the point at which 90% of the population has access to at least one provider or facility of each type. **CMS requests comment on its customization approach and whether factors should be further adjusted to achieve more equitable results. For example, CMS could change the 90% to another percentage or could identify the point at which 90% of the population has access to more than one provider or facility instead of just one.**

CMS proposes that it only be permitted to customize time and distance standards by increasing them but not by reducing them below the base standards. **CMS requests feedback from the industry on sources of information that it should consider in determining network adequacy standards.**

ii. New Proposed Network Adequacy Standards.

While the majority of the provisions proposed in new §422.116 would codify existing guidance and current practice, CMS proposes a few new provisions as follows:

- Percentage of Beneficiaries Residing Within Maximum Time and Distance Standards. CMS has historically required that, in order to meet the time and distance standards, at least 90% of beneficiaries must have access to at least one provider and facility of each specialty type within the county. CMS proposes to reduce this percentage to 85% in Micro, Rural and CEAC counties (proposed in (d)(4)(i)). CMS is proposing to do so

because it states that in rural counties there is a lower supply of physicians and in particular specialists compared to urban areas. CMS cites a similar policy in place in two state Medicaid programs and for Part D's pharmacy network coverage standards. CMS estimates that 14% of contracts in those county types will benefit from the proposal. CMS proposes to codify the 90% threshold for other counties in (d)(4)(ii).

- Bonus for Coverage of Telehealth Services. In addition to reducing the threshold for meeting minimum time and distance standards, CMS proposes to give MA plans a 10-percentage point credit for certain provider specialty types when it contracts with telehealth providers in those specialties. CMS notes that this is in response to stakeholders commenting at earlier opportunities who have favored taking into account telehealth access in evaluating network adequacy. CMS notes that cost plans would not be eligible for the proposed credit. Proposed (d)(5) would permit the 10 percentage point credit toward the percentage of beneficiaries meeting time and distance standards when telehealth benefits are offered in the following areas: dermatology, psychiatry, cardiology, neurology, and otolaryngology.

CMS notes that it chose those provider specialty types for the 10-percentage point credit based on observed access challenges and suggests that since most plans have not met challenges in providing access to primary care, CMS does not propose to include primary care as a type of provider for which the 10-percentage point credit is available. **CMS solicits comments on the provider specialty types that would be eligible for the telehealth credit and whether CMS should expand or limit this list.**

- Credit for Beneficiaries Affected by State Certificate of Need (CON) Laws. Executive Order 13890 on Protecting and Improving Medicare (October 3, 2019) directs CMS to make adjustments to network adequacy requirements to account for the competitiveness of state health care markets taking into account state CON laws or other anticompetitive restrictions. CMS summarizes research literature that finds that CON laws have resulted in increased health care costs (or did not reduce costs), and that their removal leads to better access to higher quality providers.

In order to take into account the adverse effects that CON laws have on access, CMS is proposing MAOs receive a 10-percentage point credit towards the percentage of beneficiaries meeting time and distance standards for any affected provider and facility types in states with CON laws or other state-imposed anticompetitive restrictions that limit the number of providers or facilities in a state.

The 10-percentage point credit would be in addition to the 10-percentage point telehealth bonus. **CMS requests feedback on any additional criteria or factors that it should consider in applying the CON credit; other actions CMS could take in markets with CON laws; whether there are circumstances where a more limited application of network adequacy flexibility might be more appropriate; and whether there are circumstances in which CMS should refrain from applying the 10-percentage point credit or to mitigate the size of this credit, or other flexibilities that should be considered.**

CMS is considering changes in the future to improve standards for access to dialysis services recognizing that home-based dialysis can sometimes offer advantages over in-center dialysis. **At this time it requests comment on: (1) Whether outpatient dialysis should be removed from the list of facility types subject to time and distance standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services) instead of requiring time and distance standards for providers of these services be met; (3) allowing exceptions to time and distance standards if a plan is covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for dialysis facilities.**

CMS notes that even though the SUPPORT Act established a new Medicare Part B benefit for Opioid Use Disorder treatment services furnished by Opioid Treatment Programs (OTPs), it has opted not to include OTPs as a facility type subject to the network adequacy evaluations. CMS may evaluate over time as the program gains experience with this facility type and reconsider in the future.

3. Minimum Numbers of Providers and Facilities

CMS codifies its current practice that each year it determine the minimum number of providers that must be made available. The minimum standards for each provider type would be required to be consistent with the following: 1) In order for a provider to count toward the time and distance requirements for a plan it must be within the time and distance of at least one beneficiary – and it cannot be a telehealth provider; and 2) For most provider and facility types, CMS sets a minimum ratio which reflects the number of providers required per 1,000 beneficiaries (for acute hospitals, the number of beds per 1,000 beneficiaries). Minimum ratios for most provider and facility types would be codified in Table 2 to Paragraph (e)(3)(i)(c). For the following facility types, the minimum number is equal to one: Cardiac Surgery Program, Cardiac Catheterization Services, and Critical Care Services – Intensive Care Units.

The “number of beneficiaries required to cover” is the minimum population that an MA plan’s network should be able to serve. CMS proposes to codify the established methodology for this calculation in §422.111(e)(3)(ii)(A). It would be determined by multiplying the 95th percentile base population ratio by the total number of Medicare beneficiaries in a county. The 95th percentile base population ratio is calculated annually for each county type. It is the proportion of Medicare beneficiaries enrolled in the 95th percentile of MA plans – or the point at which 95 percent of plans have enrollment below that level.

4. Exceptions Process

CMS proposes to codify a process for MA plans to use to request and receive an exception from the network adequacy standards. As under existing practice, exceptions would be available when:

- Certain 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.

- 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.

In evaluating exceptions requests, CMS would consider

- Whether the current access to providers and facilities is different from the HSD Reference and Provider Supply files for the year;
- Other factors that demonstrate that network access is consistent with or better than original Medicare; and
- Whether approval of the exception is in the best interests of beneficiaries.

F. Supplemental Benefit Requirements (§§422.100 and 422.102)

CMS proposes to codify existing guidance related to supplemental benefits, its recent re-interpretation of benefits that are primarily health related, and its recent re-interpretation of uniformity requirements.

CMS proposes to codify its longstanding definition of supplemental benefits as those used to diagnose, compensate for physical impairments or act to ameliorate the functional or psychological impact of injuries or health conditions, or reduce avoidable emergency and health care utilization; for which the plan incurs a non-zero direct medical cost, and the benefits are not covered by Medicare. The proposed codification provides exemptions for SSBCI benefits that do not need to be primarily health -related and may have a non-zero cost that is not a direct medical cost.

CMS states that the proposed definition of supplemental benefits incorporates its recent guidance that provides greater flexibility over what may be consider primarily health-related supplemental benefits. CMS notes that such benefits may include those that enhance beneficiaries' quality of life and improve health outcomes. As long as they are recommended by a licensed medical professional as part of a care plan, they do not need to be provided by a licensed medical professional.

CMS also proposes to codify in §422.100(d)(2)(ii) its re-interpretation of uniformity flexibility that permits MA plans to meet uniformity flexibility requirements by providing supplemental benefits (such as specific reductions in cost sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly. The proposed rule would state that and would require that there be a nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

G. Rewards and Incentives Program Regulations for Part C Enrollees (§422.134 and Subpart V)

In response to many questions the agency has received about reward and incentive programs over the years, CMS proposes to amend §422.134 to codify its guidance, unify principles governing rewards and incentives (R&I) programs, and clarify regulatory requirements and flexibilities. CMS also proposes to reorganize the section for clarity.

1. Definitions (§422.134(a))

CMS proposes the following definitions:

- Reward and incentive program would mean a program offered by an MA plan to qualifying individuals to voluntarily perform specified target activities in exchange for reward items.
- Reward item (or incentive item) would mean the item furnished to a qualifying individual who performs a target activity as specified by the plan in the reward program.
- Target activity would mean the activity for which the reward is provided to the qualifying individual by the MA plan.
- Qualifying individual:
 - In the context of a plan-covered health benefit, qualifying individual would mean any plan enrollee who would qualify for coverage of the benefit and satisfies the plan criteria to participate in the target activity.
 - In the context of a non-plan-covered health benefit, qualifying individual would mean any plan enrollee who satisfies the plan criteria to participate in the target activity.

CMS also proposes to clarify that certain terms used in these R&I program regulations are synonymous: (i) incentive item means the same thing as reward item; (ii) incentive(s), R&I, and rewards and incentives mean the same thing as reward(s); and (iii) incentive(s) program, reward(s) program, and R&I program means the same thing as rewards and incentives program.

2. Authority to Offer an R&I Program (§422.134(b))

CMS proposes to move the current statement of both the ability to offer an R&I program as well as the duty to meet requirements of the regulations to paragraph (b). The substance of current paragraph (b) (nondiscrimination requirements) would be moved to paragraph (c) to be part of the requirements for a target activity.

3. Target Activities (§422.134(c))

In order to offer a reward, an R&I program must comply with the requirements imposed for a target activity. CMS proposes to specify that a target activity must (i) directly involve the qualifying individual and performance by the qualifying individual; (ii) be specified, in detail, as to the level of completion needed in order to qualify for the reward item; and (iii) be health-related by doing at least one of the following: promoting improved health, preventing injuries and illness, or promoting the efficient use of health care resources.

The proposal specifies that the qualifying individual must be directly involved—meaning, for example, that the individual and not the individual’s caregiver must perform the activity. With respect to the level of completion, this is intended to clarify that a plan could require completion of the entire activity or a component of the activity to offer the reward; however, the plan must make the expectations clear and specific.

CMS proposes to list prohibitions connected with target activities. The target activity could not (i) be related to Part D benefits or (ii) discriminate against enrollees.

CMS proposes to specify that, in addition to complying with general anti-discrimination requirements under part 422, the MAO, in providing an R&I program, would have to meet all the following new requirements:

- Uniformly offer any qualifying individual the opportunity to participate in the target activity.
- Provide accommodations to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.
- Not design a program based on the achievement of a health status measurement.

On the first requirement, use of the term qualifying individual (as defined above) is intended to clarify that a target activity that is a covered benefit would be medically necessary for the particular enrollee who is seeking the reward and that other conditions on coverage imposed by the MA plan are met. On the requirement for accommodations, CMS envisions this would include permitting an enrollee to engage in a comparable activity in a manner that meets the goal or providing the enrollee additional access to the target activity. **CMS seeks comment on whether the accommodations requirement is sufficient as formulated or whether restrictions should be included.** The third requirement is intended to address the concern that basing a target activity on health status measurement may be a health-status discrimination. Thus, CMS proposes that the activity must be formulated without reference to achieving a specific outcome and instead focus on rewarding desired behavior; in other words, enrollees should only be required to demonstrate a motivation to reach desirable measurements of health status or outcomes. **CMS seeks comment on whether the additional specifications for target activities are necessary.**

4. Rewards Items (§422.134(d))

CMS proposes to codify and clarify existing guidance on reward items, focusing on requirements, prohibitions, and flexibilities.

A reward item for a target activity would have to meet all of the following requirements:

- Be offered uniformly to any qualifying individual who performs the target activity.
- Be a direct tangible benefit to the qualifying individual who performs the target activity.
- Be provided, such as through transfer of ownership or delivery, to the enrollee in the contract year in which the activity is completed, regardless if the enrollee is likely to use the reward item after the contract year.

With respect to the third requirement, CMS seeks to ensure that a reward item, such as a gift card, provided toward the end of a contract year would still be available for use after the end of the year; it seeks to prevent a plan from invalidating a reward in the next contract year. The transfer of ownership during the current contract year is a safeguard against that possibility.

CMS proposes that reward items may not be offered in the form of cash, cash equivalents, or other monetary rebates (including reduced cost-sharing or premiums). CMS proposes to adopt the OIG's definition of cash equivalent which classifies an item as a cash equivalent if it either

(i) is convertible to cash (such as a check); or (ii) can be used like cash (such as a general purpose debit card). However, a gift card that could only be redeemed at certain retailers or retail chains, or for a specific category of items or services (e.g., a gas card), is not a cash equivalent and thus could be used as a reward item. CMS clarifies that a gift card offered to an enrollee in a state which require gifts cards to be converted to cash by a retailer if it only has minimum value would be a permissible reward item because the card could only be used in certain locations.

Current regulations require CMS to impose a cap on the amount of a reward item. CMS has never done so. The agency proposes to establish a limit on the value of a reward item; the value may not exceed the value of the target activity itself.

Finally, a reward item may not involve elements of chance such as lottery tickets. However, CMS proposes to specifically permit reward items that consist of points or tokens that can be used to acquire tangible items. Because the value of a point or token is known in advance and there is no element of chance, CMS distinguishes this form of reward form a lottery.

5. Other Provisions (§422.134(e), (f), and (g))

MAOs offering R&I programs would have to comply will all communications and marketing requirements under subpart V of part 422.

MAOs would have to make information available to CMS upon request about the form and manner of any R&I programs it offers and any evaluations of the effectiveness of such programs. **CMS seeks comment on whether specific reporting should be required for program oversight and monitoring purposes.**

CMS proposes to codify (i) the application of general anti-discrimination requirements to R&I programs; (ii) the applicability of sanctions for violations of R&I program requirements; (iii) that disputes on rewards and incentives must be treated as a grievance; (iv) a clarification that an R&I program is not a benefit; and (v) a prohibition on mid-year changes.

With respect to the clarification that an R&I program is not a benefit, CMS notes that a MAO must include all costs associated with the program as administrative costs and non-benefit expenses in its bid for the plan year in which the program operates.

Because CMS believes its proposals merely unify and codify existing guidance, it does not believe there is a new cost or savings impact for the MA program.

H. Requirements for Medicare Communications and Marketing (§§422.2260 – 422.2274; 423.2260 – 423.2274)

CMS has promulgated regulations in subpart V of part 422 that specify standards and prohibitions for communications and marketing by MAOs. Additionally, CMS provides sub-regulatory guidance in the Medicare Communications & Marketing Guidelines (MCMG). CMS proposes to codify the guidance in the MCMG in subpart V. This would involve substantial reorganization and renumbering of the regulations because CMS proposes to follow the order of topics in the MCMG. CMS states that the policies it proposes to codify are not new to the

industry and that any reorganization of existing regulations is not intended to change the policies contained therein. The proposed new and revised regulatory sections and their content is as follows:

Sections	Description
422.2260 and 423.2260	Definitions: Revise definitions of “communications” and “marketing;” codify definitions for additional key terms from the MCMG
422.2261 and 423.2261	Submission & review: requirements for plans to submit certain materials for review, the process for review and the standards by which CMS will perform the review, taken from current §§422.2262, 422.2264, 423.2622, and 423.2264 and section 90 of the MCMG
422.2262 and 423.2262	Communications materials and activities: general standards for plan communications materials and activities, including endorsements and testimonials, and expands examples of what plans may and may not do. Also, requirements for standardization of key elements of communications materials (i.e., telephone numbers and material IDs). Include policies currently specified in §§422.2268 and 423.2268 as well as sections 30 and 90.1 of the MCMG
422.2263 and 423.2263	Standards for conducting marketing: incorporate requirements currently in §§422.2268 and 423.2268 and additional guidance from section 40 of the MCMG
422.2264 and 423.2264	Plan contact with beneficiaries: rules for contacting beneficiaries, from guidance currently in §§422.2268 and 423.2268 and sections 40 and 50 of the MCMG
422.2265 and 423.2265	Website: requirements for plans to have a website as well as what must, what can, and what must not be on the website; include material in section 70 of the MCMG
422.2266 and 423.2266	Activities in a healthcare setting: requirements that plans must follow; include material from current §§422.2268 and 423.2268 and from section 60 of the MCMG
422.2267 and 423.2267	Materials and content: instructions on materials and content plans must deliver or make available to beneficiaries, including required disclaimers; includes material from section 100 and Appendices 2, 3, 4, and 5 of the MCMG
422.2274 and 423.2274	Agents, brokers, and compensation to third parties: consolidate requirements from §§ 422.2272, 422.2274, 423.2272, and 423.2274 and section 110 of the MCMG

CMS highlights a number of aspects of its proposals.

- The term marketing would be defined to mean communications materials and activities that meet certain standards for intent and content enumerated in the regulation.
- In evaluating the intent of an activity or material, as it has previously, CMS would consider objective and contextual information (for example, audience, timing, etc.) and would not be limited by the plan’s statements about its intent.

- For the content standard, CMS proposes to state affirmatively what must be included for a communications activity or material to be a marketing activity or material, rather than stating what is excluded.
 - CMS proposes to explicitly list rewards and incentive programs as a type of content that falls within the definition of marketing.
 - CMS proposes to remove the current list of examples of materials (e.g., brochures or posters) because it believes the list is unnecessary.
- CMS proposes to modify the definition of communications to explicitly state that communications activities and use of materials are those created or administered by the MAO or any downstream entity.
- CMS proposes to specify in §§422.2261 and 423.2261 that the Health Plan Management System (HPMS) is the primary system of record and the way CMS collects and stores submitted plan materials for review. It also proposes to specify that third parties or downstream entities may not submit these materials directly to the agency.
- Requirements for the conduct of marketing would be a subset of communications and thus marketing is subject to those requirements as well as standards for conducting marketing under §§422.2263 and 423.2263. CMS would clarify that plans may begin marketing October 1 for the upcoming year. CMS would also codify requirements for marketing star ratings.
- CMS proposes to specify in §§422.2264 and 423.2264 that the term beneficiary contact includes all outreach activities to a beneficiary or his or her caregivers by the plan or its agents and brokers.
 - CMS would provide additional detail about activities that it does and does not consider to be unsolicited contacts.
 - It proposes to clarify that plans may contact their current members (including those enrolled in commercial plans who become Medicare eligible) regarding plan business.
- CMS proposes to codify its methodology for calculating fair market value for agent/broker compensation because current regulations do not define fair market value or specify the methodology for its calculation. CMS also proposes to codify the requirement for the recovery of agent compensation for rapid disenrollment (i.e., when a newly-enrolled individual disenrolls within the first three months of enrollment).

CMS seeks comment on how it should implement prohibitions on plan marketing during the open enrollment period (OEP). CMS notes that the MCMG prohibits plans from sending unsolicited materials that call out the opportunity afforded by the OEP, using mailing lists or other anecdotal information to target individuals who made enrollment requests during the annual coordinated enrollment period, or leveraging agent/broker activities that target the OEP as a way to make further sales.

I. Past Performance (§§422.502 and 423.503)

Under existing rules, CMS can deny an application submitted by an organization seeking an MA or Part D contract if the organization has failed to comply with requirements of a previous MA or Part D contract. Present rules allow CMS to review those actions and activities during a 12-month review period. In the past, CMS has established the criteria for such denials based on these reviews in sub-regulatory guidance.

CMS proposes to codify in §§422.502 and 423.503 the criteria it will use to make a determination to deny an application based on prior contract performance. It states that this is proposed to add clarity and predictability to such reviews.

CMS proposes to adopt three factors that it would consider to indicate significant non-compliance in reviewing previous contract activity: i) An intermediate sanction or civil money penalty was imposed under existing MA or Part D rules (CMS excludes those imposed against D-SNPs); ii) failure to maintain a Star Rating Score of least 3 stars, iii) failure to maintain a fiscally sound operation.

CMS explains that, with respect to the exception proposed for sanctions against D-SNPs, D-SNPs are working to comply with complex CMS integration requirements which may subject them to sanctions despite their good faith efforts. It further notes that while the period of review is 12 months, CMS may include in its review conduct that occurred prior to the 12-month review period but that did not come to light or was not yet documented until during the 12-month review period.

With respect to applications submitted for organizations with no recent MA or Part D contracting history, CMS will consider contracts held by the parent organization or by another organization held by the same parent company.

J. Prescription Drug Plan Limits (§423.265)

CMS proposes to codify its existing requirement that PDP sponsors can offer no more than three stand-alone prescription drug plans in a region – one basic plan and no more than two enhanced plans.

CMS discusses the history of its requirement that plan offerings by a single sponsor are meaningfully different from each other. This requirement, in existing rules at §423.265(b)(2), minimizes the risk of sponsors using multiple offerings to segregate enrollees into different plans based on risk and to ensure beneficiaries are able to choose from among meaningfully different options. CMS states that allowing plan sponsors more flexibility, however, to offer options could promote innovation and encourage tailored options targeted to different beneficiary preferences. In examining this rule, CMS analyzed Part D plan data and found that markets with a greater number of enhanced plans have higher costs. As a result, it proposes to retain the existing 3-plan limit and states that doing so reflects a balance between limiting but not eliminating the potential risk segmentation and ensuring meaningful choice for enrollees.

CMS seeks stakeholder input on the impact of limiting enhanced plan offerings to two and the potential impact of expanding the number of enhanced plan alternatives beyond two.

K. Definition of a Parent Organization (§§422.2 and 423.4)

CMS proposes to establish a definition of “Parent Organization” as the legal entity that exercises a controlling interest, through ownership of shares, the power to appoint board members, or other means, in a Part D sponsor or MAO, directly, or through a subsidiary or subsidiaries, and which

is not itself a subsidiary of any other legal entity. CMS believes that this definition codifies current policy.

CMS identifies the different contexts in which it uses the term parent organization and as a result finds that there is a need for a consistent definition of the term. To conform with the proposed definition, CMS would also eliminate existing language defining a parent organization for the specific purpose of applying a prohibition against a parent organization holding more than one PDP sponsor contract in a region (in §423.503(a)3)).

CMS invites comment on the different ways that an entity could hold a controlling interest in a Part D sponsor or MAO.

L. Call Center Requirements (§§422.111 and 423.128)

Under existing law and regulations, MAOs and Part D sponsors are required to have in place a toll-free customer service call center. CMS proposes changes to existing call center requirements to add specificity. For the most part, CMS states that these additions to §§422.111 and 423.128 codify existing guidance. In addition, CMS reminds stakeholders that MA-PD plans are Part D plans that must comply with all Part 423 requirements.

Under the proposals, call centers would need to:

- Be open at least from 8:00 a.m. to 8:00 p.m. in all service areas served by the MA-PD or Part D plan. For Part D plans, any call center serving network pharmacies or pharmacists must be open any time a pharmacy in the plan service area is open.
- Meet the following criteria:
 - Call hold times could be no longer than 2 minutes. The hold time would begin with the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person. Call center monitoring data indicate that 90 percent of MAOs and Part D plans have hold times of less than 2 minutes.
 - 80 percent of incoming calls would be required to be answered within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction. Call center monitoring also indicates that 87 percent of plans answer 80 percent of calls within 30 seconds.
 - The rate of calls disconnected could be no higher than 5 percent. The disconnect rate would be defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center. Call center monitoring data indicate that 82 percent of plans have drop rates below 5 percent.
- Provide interpreters for non-English speaking and limited English proficient individuals. Interpreters must be available within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.
- Respond to TTY-to-TTY calls in accordance with mandatory minimum standards described in 47 CFR 64.604.
- Provide for the use of auxiliary aids and services for automated-attendant systems, including TTYs and other Federal Communication Commission-approved telecommunications relay systems.

M. Special Election Periods (SEPs) for Exceptional Conditions (§§422.62 and 423.38)

The statute specifies specific circumstances under which an individual may make an election during a special election period (SEP) to enroll into an MA plan or a PDP plan which CMS has codified in its regulations. Section 1851(e)(4)(D) of the Act provides authority to CMS to create additional SEPs as it believes is necessary to address exceptional circumstances not listed in the statute. CMS has traditionally done this through subregulatory guidance; it now proposes to codify dozens of SEPs it has created as well as to propose two new SEPs. CMS intends to codify current policy, except as specifically noted. **CMS seeks comment on whether it has overlooked any aspect of current policy in its proposed codifications and whether there are other exceptional circumstances that require an SEP.**

CMS states up front that in order for any SEP to apply with respect to an MA plan or a PDP plan, the individual must be eligible for enrollment under the statute and regulations. CMS also proposes to amend §422.68 (Effectiveness of elections) in paragraph (d) to state a general rule that unless otherwise noted, elections made using a SEP are effective as of the first day of the first calendar month following the month in which the election is made. Additionally, CMS notes that an organization does not have to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of that eligibility.

In the SEP descriptions below, where an SEP for a Part D PDP parallels the SEP for Part C, no further description is provided for the Part D SEP.

1. New SEPs

CMS proposes the following two new SEPs which would apply to MA and PDP enrollment respectively:

a. Plans Placed in Receivership (§422.62(b)(24))

EXTRAORDINARY CIRCUMSTANCES: The individual would have to be enrolled in a plan offered by an MAO that a state or territorial regulatory authority placed in financial receivership.

ELECTION: May elect another MA plan or Medicare FFS.

SEP: Begins the month the receivership is effective and continues until the enrollee makes an election or the receivership is no longer in effect, whichever occurs first.

ADDITIONAL CONDITIONS: The plan placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for the SEP and how to use it.

PARALLEL PART D SEP: Proposed §423.38(c)(31), permitting election of another PDP plan.

b. Consistently Poor Performing Plan (§422.62(b)(25))

EXTRAORDINARY CIRCUMSTANCES: The individual would have to be enrolled in a plan identified with the low performing icon (LPI). The LPI is assigned to plans with summary ratings of fewer than 3 stars for three or more years.

ELECTION: May elect an MA plan with an overall Star rating of three or more or Medicare FFS, with or without enrollment in a PDP.

SEP: At any time when the individual is enrolled in the LPI plan.

PARALLEL PART D SEP: Proposed §423.38(c)(32), permitting election of another PDP plan.

2. Codification of CMS-Established Part C and D SEPs

CMS proposes to codify all SEPs that it established through subregulatory guidance.

a. Employer/Union Group Health Plan (§422.62(b)(4))

EXTRAORDINARY CIRCUMSTANCES: The individual enrolls in or out of an employer sponsored MA plan; disenrolls from an MA plan to take employer sponsored coverage of any kind; or disenrolls from employer sponsored coverage (including COBRA) to elect a MA plan.

SEP: The duration of enrollment in the employer or union sponsored plan plus two months after the employer or union coverage ends.

EFFECTIVE DATE: The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

PARALLEL PART D SEP: Proposed §423.38(c)(11).

b. Sanctioned Plan (§422.62(b)(5))

EXTRAORDINARY CIRCUMSTANCES: The individual is enrolled in an MA plan offered by an MAO that has been sanctioned by CMS.

ELECTION: May elect another MA plan or Medicare FFS and enroll in a PDP.

SEP: Begins when the sanction is imposed and ends when the sanction ends or the individual makes an election, whichever comes first.

ADDITIONAL CONDITIONS: CMS may require the MAO to notify current enrollees that, if they believe they are affected by the matters that gave rise to the sanction, they may use the SEP.

PARALLEL PART D SEP: Proposed §423.38(c)(12), permitting election of another PDP plan.

c. Cost Plans Not Renewing Their Contracts (§422.62(b)(6))

EXTRAORDINARY CIRCUMSTANCES: The individual is enrolled in a section 1876 cost plan (HMO or CMP) that is not renewing the contract in the area where the enrollee resides.

SEP: Begins December 8 of the current contract year and ends the last day of February in the succeeding year.

EFFECTIVE DATE: Elections are effective the first of the month after they are made (e.g., an election made before December 31 would be effective January 1).

PARALLEL PART D SEP: Proposed §423.38(c)(13), permitting election of another PDP plan.

d. PACE Disenrollment / Enrollment (§422.62(b)(7))

EXTRAORDINARY CIRCUMSTANCES: (i) The individual is disenrolling from an MA plan to enroll in a PACE program.

(ii) The individual is disenrolling from a PACE program to enroll in an MA plan.

SEP: The two-month period after the date of disenrollment.

PARALLEL PART D SEP: Proposed §423.38(c)(14), permitting election of a PDP plan.

e. First Time Enrollee in an MA Plan During Trial Period and Medigap Plan Termination (§422.62(b)(8))

EXTRAORDINARY CIRCUMSTANCES: The individual is eligible for a guaranteed issue Medigap policy and disenrolls from the MA plan while they are in a trial period. Trial periods last for 12 months after enrollment in an MA plan for the first time.

SEP: Begins on enrollment in the MA plan and ends 12 months after enrollment or when the beneficiary disenrolls, whichever occurs first.

PARALLEL PART D SEP: Proposed §423.38(c)(14), permitting one-time election of a PDP plan.

f. Retroactive Medicare Entitlement Determination for ESRD Beneficiaries (§422.62(b)(9))

EXTRAORDINARY CIRCUMSTANCES: The individual's Medicare eligibility determination based on ESRD is made retroactively and he or she was not provided the opportunity to elect an MA plan during his or her Initial Coverage Election Period (ICEP). (Note, this SEP is no longer necessary after the 2020 plan year; see Section IV above.)

ADDITIONAL CONDITIONS: The individual (i) was enrolled in a health plan offered by the same MAO the month before entitlement to parts A and B; (ii) developed ESRD while a member of that health plan; and (iii) is still enrolled in that health plan.

SEP: Begins the month of receipt of the entitlement determination and ends two months later.

PARALLEL PART D SEP: No.

g. Retroactive Medicare Entitlement Determination (§422.62(b)(10))

EXTRAORDINARY CIRCUMSTANCES: The individual became entitled to Medicare for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during their ICEP.

SEP: Begins the month of receipt of the entitlement determination and ends two months later.

EFFECTIVE DATE: The first of the month following the month in which the election is made but no earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual. The beneficiary would receive Medicare FFS benefits until enrollment is effective.

h. SNP Enrollees Who Lose Special Needs Status (§422.62(b)(11))

EXTRAORDINARY CIRCUMSTANCES: The individual is enrolled in an MA SNP and is no longer eligible for the SNP because he or she no longer meets the applicable special needs status.

SEP: Begins the month the individual's special needs status changes and ends on the earlier of (i) the date an enrollment request is made or (ii) the end of the third month after the effective date of the involuntary disenrollment from the SNP.

PARALLEL PART D SEP: Proposed §423.38(c)(27), permitting election of a PDP plan. Also allows for disenrollment from a PDP at any time in order to enroll in an MA SNP.

i. State Pharmaceutical Assistance Programs (SPAPs) (§422.62(b)(12))

EXTRAORDINARY CIRCUMSTANCES: (i) The individual belongs to a qualified SPAP and requests enrollment in an MA-PD plan.

(ii) The individual loses eligibility for SPAP benefits.

SEP: While the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after the later of (i) the month of the loss of eligibility or (ii) notification of such loss.

PARALLEL PART D SEP: Proposed §423.38(c)(17), permitting election of a PDP plan.

j. C-SNP Enrollment and Individuals Found Ineligible for C-SNPs (§422.62(b)(13))

EXTRAORDINARY CIRCUMSTANCES: (i) The individual has severe or disabling chronic conditions and is eligible to enroll into a C-SNP designed to serve individuals with those conditions.

(ii) The individual is enrolled in a C-SNP and has a severe or disabling chronic condition which is not a focus of the current SNP; the individual may request enrollment in a C-SNP that focuses on his or her condition.

(iii) After enrollment in a C-SNP, the individual is found not to have the qualifying condition to be eligible for the C-SNP; the individual may enroll in a different MA plan.

SEP: For circumstances described in (i), while the individual has the qualifying condition and ends upon C-SNP enrollment.

For circumstances described in (ii), begins when the MAO notifies the individual of the lack of eligibility and extends through the end of that month and the following 2 calendar months.

For circumstances described in (iii), the SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

PARALLEL PART D SEP: Proposed §423.38(c)(28), permitting election of a PDP plan.

k. Part D Disenrollment to Enroll in or Maintain Creditable Coverage (§422.62(b)(14))

EXTRAORDINARY CIRCUMSTANCES: The individual is enrolled in an MA-PD plan and requests to disenroll from that plan to enroll in or maintain other creditable prescription drug coverage (e.g., TriCare or VA coverage).

ELECTION: May elect Medicare FFS or an MA-only plan.

SEP: While the individual is enrolled in an MA-PD.

EFFECTIVE DATE: The first day of the month following the month the disenrollment request is received by the MAO.

PARALLEL PART D SEP: Proposed §423.38(c)(18), permitting disenrolling from a PDP plan.

l. Enrollment in a 5 Star Plan (§422.62(b)(15))

EXTRAORDINARY CIRCUMSTANCES: The individual seeks to enroll in an MA plan with an overall performance of 5 stars during the plan contract year for which the plan has that rating.

ELECTION: One-time election for the contract year for which the MA plan was assigned a 5-star overall performance rating. May enroll in a 5-Star plan even if coming from Medicare FFS (with or without concurrent enrollment in a standalone PDP). If enrolled in a 5-star plan, may switch to another 5-star plan.

SEP: Begins the December 8th before that contract year through November 30th of that contract year.

EFFECTIVE DATE: The first day of the month following the month in which the MAO receives the enrollment request.

PARALLEL PART D SEP: Proposed §423.38(c)(18), permitting enrollment in a 5-star PDP plan. See also proposed §423.38(c)(29)) for individuals using the proposed SEP to enroll in a MA Private Fee-for-Service plan without Part D benefits or a section 1876 cost plan.

m. Non-U.S. Citizens who Become Lawfully Present (§422.62(b)(16))

EXTRAORDINARY CIRCUMSTANCES: The individual is a non-U.S. citizen who becomes lawfully present in the United States.

ELECTION: May elect an MA plan for which the individual is eligible.

SEP: Begins the month the individual attains lawful presence status and ends the earlier of (i) the date the individual makes an enrollment election or (ii) 2 calendar months after the month the individual attains lawful presence status.

PARALLEL PART D SEP: Proposed §423.38(c)(21), permitting enrollment in a PDP.

n. Equal Time for Individuals Requesting Materials in Accessible Formats (§422.62(b)(17))

EXTRAORDINARY CIRCUMSTANCES: The individual was adversely affected by having requested, but not received, required notices or information in an accessible format within the same timeframe that the MAO or CMS provided the same information to individuals who did not request an accessible format.

DETERMINATION OF ELIGIBILITY: The MAO may determine eligibility when the criterion is met. It must ensure adequate documentation of the situation, including records indicating (i) the date of the individual's request, (ii) the amount of time taken to provide accessible versions of the requested materials and (iii) the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

SEP: Begins at the end of the election period during which the individual was seeking to make an enrollment election and ends at least as long as the time it takes for the information to be provided to the individual in an accessible format.

PARALLEL PART D SEP: Proposed §423.38(c)(22).

o. FEMA-Declared Weather-Related Emergency or Major Disaster (§422.62(b)(18))

EXTRAORDINARY CIRCUMSTANCES: The individual is affected by a Federal Emergency Management Agency (FEMA)-declared weather-related emergency or major disaster.

ADDITIONAL CONDITIONS: The individual:

- is eligible for an election period at the time of incident period;
- did not make an election during that election period due to the weather-related emergency or major disaster; and
- either—
 - resides (or resided at the start of the incident period) in an area for which FEMA has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance; or
 - does not reside in the affected areas but relies on help making healthcare decisions from one or more individuals who reside in the affected areas.

ELECTION: Applies to both enrollment and disenrollment elections.

SEP: The 4-month period that begins at the start of the incident period.

PARALLEL PART D SEP: Proposed §423.38(c)(23), permitting enrollment and disenrollment.

p. Involuntary Loss of Creditable Prescription Drug Coverage (§422.62(b)(19))

EXTRAORDINARY CIRCUMSTANCES: The individual experiences an involuntary loss of creditable prescription drug coverage; this would include a reduction in the level of coverage so that it is no longer creditable. However, any loss or reduction of creditable coverage due to failure to pay premiums does not qualify the individual for this SEP.

ELECTION: May elect an MA-PD plan.

SEP: Begins when the individual is notified of the loss of creditable coverage and ends 2 calendar months after the later of (i) the loss (or reduction) or (ii) the individual's receipt of the notice.

EFFECTIVE DATE: The first day of the month after the enrollment election is made or, at the individual's request, up to 3 months prospectively.

PARALLEL PART D SEP: §423.38(c)(1) currently in regulations.

q. Inadequate Notice of Loss of Creditable Prescription Drug Coverage (§422.62(b)(20))

EXTRAORDINARY CIRCUMSTANCES: The individual was not adequately informed of (i) a loss of creditable prescription drug coverage or (ii) that they never had creditable coverage.

DETERMINATION OF ELIGIBILITY: CMS would determine eligibility on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable.

ELECTION: One enrollment in, or disenrollment from, an MA-PD plan.

SEP: Begins the month of CMS' determination and continues for 2 additional calendar months after the determination.

PARALLEL PART D SEP: §423.38(c)(2) currently in regulations.

r. Federal Employee Error (§422.62(b)(21))

EXTRAORDINARY CIRCUMSTANCES: The individual's enrollment or non-enrollment in an MA-PD plan is erroneous due to an action, inaction, or error by a Federal employee.

DETERMINATION OF ELIGIBILITY: The CMS account manager would review each case to determine whether enrollment or disenrollment was caused by the action, inaction or error by a federal employee.

ELECTION: May enroll in, or disenroll from, the MA-PD plan, as determined by CMS.

SEP: Begins the month CMS approves the SEP and continues for 2 additional calendar months.

PARALLEL PART D SEP: §423.38(c)(3) currently in regulations.

s. Eligibility for an Additional Part D Initial Election Period (IEP) (§422.62(b)(22))

EXTRAORDINARY CIRCUMSTANCES: The individual is eligible for an additional Part D IEP (e.g., an individual currently entitled to Medicare due to a disability and who attains age 65).

ELECTION: May make an MA election to coordinate with the additional Part D IEP. May disenroll from an MA plan (with or without Part D benefits), may enroll in Medicare FFS, or may enroll in an MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D IEP to enroll in a PDP.

SEP: Begins and ends concurrently with the additional Part D Initial Election.
PARALLEL PART D SEP: Intended to coordinate with additional Part D IEP.

t. Significant Change in Provider Network (§422.62(b)(23))

EXTRAORDINARY CIRCUMSTANCES: The individual was affected by a significant change in the plan's provider network. The individual is affected by a significant network change when he or she is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

ADDITIONAL REQUIREMENTS FOR PLAN: Upon CMS direction, the plan that significantly changed its network must notify enrollees who are eligible for the SEP of their eligibility for the SEP and how to use the SEP.

ELECTION: May disenroll from the MA plan that changed its network to enroll in another MA plan or to Medicare FFS.

SEP: Begins the month the individual is notified of eligibility for the SEP and continues for 2 additional calendar months.

PARALLEL PART D SEP: §423.38(c)(30).

u. Other Exceptional Conditions (§§422.62(b)(26) and 423.38(c)(33))

CMS proposes to retain the authority to create SEPs for Part C and D enrollment for individuals who meet other exceptional conditions.

3. Codification of Additional CMS-Established Part D SEPs

CMS proposes to codify its subregulatory guidance for the following SEPs for exceptional conditions for the Part D program.

a. Institutionalized Individuals (§423.38(c)(15))

EXTRAORDINARY CIRCUMSTANCES: The individual moves into, resides in, or moves out of an institution. Institutionalized means, for purposes of defining a special needs individual, an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care facility which is a skilled nursing facility; a nursing facility; an intermediate care facility for individuals with intellectual disabilities; or an inpatient psychiatric facility. CMS proposes, in section VIII.F. of the proposed rule, to expand this list of settings to include rehabilitation hospitals (or units), LTCHs, and swing bed hospitals.

ELECTION: May enroll in or disenroll from a PDP.

SEP: For individuals moving out of an institution, the 2-month period beginning on the date the individual moves out.

b. Enrollment in Part B during the Part B General Enrollment Period (§423.38(c)(16))

EXTRAORDINARY CIRCUMSTANCES: The individual is not entitled to premium-free Part A and enrolls in Part B during the General Enrollment Period (GEP) for Part B.

ELECTION: May enroll in a PDP.

SEP: April through June.

EFFECTIVE DATE: July 1.

c. Disenrollment from Cost Plan with Cost Plan Optional Supplemental Part D Benefit (§423.38(c)(19))

EXTRAORDINARY CIRCUMSTANCES: The individual is enrolled in a section 1876 cost contract and an optional supplemental Part D benefit under that contract.

ELECTION: May elect a Part D plan upon disenrolling from the cost contract.

SEP: Begins the month the individual requests disenrollment from the cost contract and ends when the individual makes an enrollment election or on the last day of the second month following the month the cost contract enrollment ended, whichever is earlier.

d. MA Open Enrollment Period for Institutionalized Individuals to Disenroll from an MA-PD plan (§423.38(c)(25))

EXTRAORDINARY CIRCUMSTANCES: The individual is institutionalized (as defined by CMS) and uses the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to disenroll from an MA-PD plan.

ELECTION: May elect a Part D plan upon disenrolling from the MA-PD plan.

SEP: Begins the month the individual requests disenrollment from the MA-PD plan and ends on the last day of the second month following the month the MA-PD enrollment ended.

e. MA Open Enrollment Period (§423.38(c)(26))

EXTRAORDINARY CIRCUMSTANCES: The individual is enrolled in MA and elects Medicare FFS.

ELECTION: May enroll in a PDP.

SEP: (i) January through March.

(ii) Also available to an individual during the first 3 months of the individual's Medicare entitlement.

f. 5-Star SEP to Enroll in 5-Star Plan without Part D Coverage (§423.38(c)(29))

EXTRAORDINARY CIRCUMSTANCES: The individual uses the SEP proposed at §422.62(b)(15) (described above) to enroll in a 5-star MA Private Fee-for-Service plan without Part D benefits, or enrolls in a section 1876 cost plan. This Part D SEP may not be used by individuals who use the 5-star SEP to enroll in an MA coordinated care plan.

ELECTION: May elect a Part D plan; the PDP does not have to have a 5-star rating.

SEP: Begins the month the individual uses the 5-star SEP and continues for 2 additional months.

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

CMS makes proposals that address reassessments of PACE participants, service delivery requests, appeals, participant rights, required services, excluded services, interdisciplinary team requirements, medical record documentation, access to data and records, safeguarding communications, and service delivery requirements. CMS believes the proposals will reduce burden on PACE organizations (POs), add details about the agency's expectations, and offer more transparent guidance.

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

A. Service Delivery Request Processes under PACE (§§460.104 and 460.121)

1. Background

CMS proposes changes to the service delivery request process whereby PACE participants request that the interdisciplinary team (IDT) conduct a reassessment to initiate, eliminate, or continue a service. The process is currently specified in §460.104(d)(2). Stakeholders have commented that the language in the regulations is overly broad and even simple requests to initiate a service require a reassessment. CMS seeks to define what constitutes a service delivery request and to create clearer guidance on how POs must identify and process the requests. CMS proposes to move and substantially revise the requirements for these requests. It proposes to create a new section §460.121 entitled Service Delivery Requests; **it seeks comment on the title of the section.** It also seeks to align the process with the appeals regulations for the MA and Part D programs.

2. Written Procedures (§460.121(a))

CMS proposes to formally require each PO to have formal written procedures to identify and process service delivery requests with the requirements of the proposed new section. It feels this is necessary to ensure POs develop the requisite internal processes and procedures to implement the process.

3. What Is a Service Delivery Request (§460.121(b))

CMS proposes to define what constitutes a service delivery request and, to a limited extent, what does not. The process for service delivery requests would apply to three types of requests: (i) a request to initiate a service, (ii) a request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service, and (iii) a request to continue coverage of a service that the PO is recommending be discontinued or reduced.

The proposal would substitute the broader term “modify” for the term “eliminate”. CMS clarifies that term service not only includes items but also drugs.

With respect to the third type of service request (i.e., to continue coverage), CMS notes that some POs have provided the participant with appeal rights instead of conducting a reassessment. In section VII.B. of the proposed rule, CMS proposes to make a service delivery request the first level in the appeals process which must be completed before an appeal may be initiated. Participants could also make this request before the service is discontinued (i.e., when the IDT recommends the reduction or discontinuation and before that recommendation is implemented).

CMS proposes an exception to the definition of a service delivery request. A request to initiate, modify, or continue a service that is made before development of the initial care plan would not constitute a service delivery request. Thus, any request before the initial care plan is finalized would not be eligible for the service delivery request process under this new section. CMS

considered other possible ways to limit the scope of service delivery requests; for example, it considered excluding requests not related to a participant's medical, physical, emotional and social needs (e.g., a request for lemon in their beverage). However, CMS is concerned that addressing this type of issue in the regulations may cause confusion and does not propose to add this as an exclusion. **The agency seeks comment on this issue and also suggested wording for such an exception.**

4. Who Can Make a Service Delivery Request (§460.121(c))

CMS proposes to specify the individuals who can make a service delivery request. This would include the participant, the participant's designated representative, and the participant's caregiver. The proposed addition of caregiver seeks to acknowledge the role of caregivers in those circumstances where the caregiver is not the designated representative. **CMS seeks comment on this proposal as well as whether there are additional individuals (e.g., a provider or prescriber) who should be able to initiate a service delivery request on behalf of the participant.**

5. Method for Making a Service Delivery Request (§460.121(d))

CMS proposes to specify that an individual may make a service delivery request either orally or in writing. It believes this is consistent with current practice.

CMS also proposes that the request may be made to any individual who provides direct care to the participant on behalf of the PO, whether an employee or contractor of the PO. CMS notes that all individuals who provide direct care to participants, whether as contractors or employees, should be trained to recognize service delivery requests and ensure such requests are documented appropriately and brought to the IDT; this should be included as part of the training employees and contractors are required to undergo pursuant to §460.71(a)(1). **CMS seeks comment on whether this requirement should apply to a smaller subset of individuals, such as only those providing direct patient care in the participant's residence, the PACE center, or while transporting patients.**

6. Processing a Service Delivery Request (§460.121(e))

CMS proposes that a service delivery request be brought to the IDT as expeditiously as the patient's condition requires but in no case later than 3 days. There would be a second timeframe (described below) for the IDT to make a decision and notify the participant. **CMS seeks comment on the proposed 3-day deadline to bring the request to the IDT.**

CMS proposes an exception to the processing requirements for a service delivery request in §460.121(e)(2). Where a member of the interdisciplinary team can approve the service delivery request in full at the time the request is made, a substantially streamlined process would be followed. This would apply only where the IDT member can approve the request exactly as made. If so, the PO would only be required to notify the participant of the approval decision; implement the request as expeditiously as the patient's condition requires; and document, track, and maintain records on the request and approval. Other requirements described below would

not apply. CMS reiterates that the exception applies only to requests made to IDT members—not to contractors or employees of the PO.

7. Who Must Review a Service Delivery Request (§460.121(f))

CMS proposes that the full IDT would have to review and discuss each service delivery request and decide to approve, deny, or partially deny the request based on that review. This requirement would not apply to a request made directly to an IDT member that the member approves in full under the proposed exception in §460.121(e)(2) (described immediately above).

8. Interdisciplinary Team Decision Making (460.121(g))

When evaluating a service delivery request, the IDT would have to consider all relevant information, which includes at a minimum the following:

- the findings and results of any reassessments;
- the participant’s current medical, physical, emotional, and social needs; and
- current clinical practice guidelines and professional standards of care applicable to the particular service.

CMS believes the IDT should not make decisions based on one aspect of the participant’s condition (e.g., physical health related to ability to perform activities of daily living).

9. Reassessments in Response to a Service Delivery Request (§460.121(h))

CMS proposes to require the IDT to conduct an in-person reassessment only when it expects to deny or partially deny a service delivery request; the reassessment would have to be completed before the IDT makes a final decision. CMS would consider a request denied or partially denied when the IDT makes a decision that does not fully approve the request; a compromise, alternative service, or decision to grant only a part of the request would constitute a partial denial.

The reassessment would have to be conducted by the appropriate members of the IDT; the IDT would identify those members. The IDT members who perform the reassessment would have to evaluate whether the requested service is necessary to meet the participant’s medical, physical, emotional, and social needs.

While CMS proposes not to require a reassessment where the IDT approves a service delivery request, it clarifies that the IDT may elect to do so either in-person or through the use of remote technology, if the team determines that a reassessment is necessary.

10. Notification Timeframe (§460.121(i))

Similar to the timeframe above for bringing a service delivery request to the IDT, CMS proposes that as a general rule when the IDT receives a service delivery request, it must make its decision and notify the participant or their designated representative as expeditiously as the participant’s condition requires, but no later than 3 calendar days after receipt of the request.

CMS proposes to permit extensions of up to 5 calendar days under limited circumstances as follows:

- When the participant, designated representative or caregiver requests the extension.
- When the extension is in the participant's interest because the IDT requires additional information from an individual not directly employed by the PO that may change the interdisciplinary team's decision to deny a service.

CMS is concerned by routine extensions; it proposes to require the IDT to document the circumstances that led to the extension and to demonstrate how the extension is in the participant's best interest.

CMS also proposes to require the IDT to notify the participant when the IDT extends the timeframe. The notice would have to be in writing and explain the reason(s) for the delay. The notice would have to be provided no later than 24 hours after the IDT decides to extend the timeframe.

11. Notification Requirements (§460.121(j))

CMS proposes requirements for notice to the participant or designated representative (but not the caregiver) of decisions to approve or deny (or partially deny) a service delivery request. While CMS permits caregivers to submit requests, it nonetheless believes that the participant or his or her designated representative should receive the decision.

a. Notice of Approval

Where the IDT decides to approve a service delivery request, it would have to notify the participant. Notice could be communicated orally or in writing. If there are any conditions to the approval decision, the notice would have to explain those conditions in understandable language; that information should include when the participant may expect to receive the approved service. For those requests that can be approved in full by an IDT member at the time the request is made, that IDT member would be responsible for ensuring the notice satisfies these requirements.

b. Notice of Denial or Partial Denial

CMS proposes that if the IDT decides to deny (or partially deny) a service, it must provide the participant or the designated representative both oral and written notice of the determination. This is designed to ensure that the participant understands the denial.

The denial notice would have to state the specific reason(s) for the denial; this would include an explanation of why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s).

The notice would have to be provided in understandable language to ensure the participant comprehends the rationale for the denial.

CMS proposes to retain current requirements that the PO inform the participant of his or her right to appeal the decision. The notice would also have to describe the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services.

In the case of a Medicaid participant, the notice would have to include information on the participant's right to continue receiving disputed services during the appeals process until issuance of the final determination and the conditions for continuing to receive disputed services.

12. Effectuation Requirements (§460.121(k))

CMS states that it proposes to specify a timeframe for when approved services are provided to the participant. However, the agency would not establish a specific deadline; instead, it would require the PO to provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. Nonetheless, CMS expects POs to develop processes to identify how quickly services should be provided based on the participant's condition.

Consistent with the notice of approval provisions of proposed section §460.121(j)(1) (described immediately above), CMS also proposes to require the IDT to explain when the participant may expect to receive the service.

13. Effect of failure to meet the processing timeframes (§460.121(l))

The regulations currently provide that if the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PO as an appeal. CMS proposes to retain this requirement without change.

14. Recordkeeping (§460.121(m))

CMS proposes requirements for record keeping of service delivery requests. POs would have to establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests received both orally and in writing. These requirements would apply to all requests, even those approved in full by an IDT member at the time of the request. The records would have to be available to the IDT so all members remain alert to pertinent participant information.

Documentation would have to be safeguarded against alteration, and written requests for services would have to be maintained in their original form.

B. Appeals Requirements under PACE (§§460.122 and 460.124)

CMS proposes changes to its regulations on appeals to provide more detail on the appeals process, to ensure consistency when the process is administered by POs, and to increase beneficiary awareness of and access to the appeals process.

CMS proposes to modify its current definition of appeal by adding a sentence at the end that requires a PO to process a request to initiate, modify or continue a service under proposed new section §460.121 first as a service delivery request before the PO can process an appeal.

CMS proposes to specify that POs must provide PACE participants with written information about the appeals process at each of the following times: (i) upon enrollment, (ii) at least annually thereafter, and (iii) whenever the IDT denies, in full or in part, a service delivery request or other request for services or payment.

Currently, §460.122(c) establishes requirements for the minimum written procedures POs must establish for their appeals process. CMS proposes a number of changes to this section. CMS would specify that a participant's designated representative may file an appeal on the participant's behalf. Additionally, POs would have to accept both oral and written appeal requests.

CMS also proposes to specify qualifications of appropriate third-party reviewers or members of a review committee who, as a basic requirement, must be both independent and appropriately credentialed. CMS incorporates review committees in its regulations to ensure that committee members satisfy the same requirements as third-party reviewers. These individuals would have to be appropriately credentialed in the field(s) or discipline(s) related to the appeal. To demonstrate impartiality, the individuals may not have been involved in the original action and may not have a stake in the outcome of the appeal.

To address concerns about inconsistent decisions by third-party reviewers, CMS proposes to require POs to distribute written or electronic materials to the third-party reviewer or committee to ensure they understand the PACE benefit package and the coverage requirements under the PACE program. Those materials would have to, at a minimum, explain all of the following:

- Services must be provided in a manner consistent with the requirements in §§460.92 and 460.98.
- Decisions must be made in a manner consistent with how medical necessity determinations are made under section 1862(a)(1)(A) of the Act.
- Certain limitations and conditions applicable to Medicare benefits, Medicaid benefits or both do not apply pursuant to §460.90(a).

CMS proposes to specify that a PO must give all parties involved in the appeal (e.g., participants), a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

With respect to notice requirements, CMS proposes to specify that POs must give all parties involved in the appeal appropriate written notification of all appeal decisions. A notice of a favorable decision would have to explain any conditions of the approval in understandable language.

A notice of a fully or partially adverse decision would have to be provided in writing and state the specific reason(s) for the denial; explain the reason(s) why the service would not improve or maintain the participant's overall health status; inform the participant of the right to appeal the

decision; and describe the external appeal rights under §460.124. For any adverse decision, the PO must notify CMS, the State administering agency, and the participant.

CMS also proposes to modify §460.124 (Additional appeal rights under Medicare or Medicaid) to describe additional appeal rights PACE participants are entitled to under Medicare or Medicaid as well as to add processing requirements for POs.

First, CMS proposes to specify that Medicare participants have the right to a reconsideration by an independent review entity (IRE) and Medicaid participants have the right to a State Fair Hearing (SFH). Dual eligibles may choose either a Medicare IRE or the Medicaid SFH process. CMS proposes to require POs to inform participants in writing of their appeal rights under Medicare or Medicaid managed care, or both, and assist the participant in choosing which to pursue if both are applicable; the PO would also have to forward the appeal to the appropriate external entity. CMS notes the participant may file the request without assistance from the PO.

With respect to appeals to a Medicare IRE, the written request for reconsideration would have to be filed with the IRE within 60 calendar days from the date of the decision by the third-party reviewer. The IRE is required to conduct the review as expeditiously as the participant's health condition requires, but it must not exceed the deadlines specified in the contract. Parties to an IRE reconsideration would also include the PO as well as the participant or his or her designated representative.

C. Access to Data and Safeguarding Records under PACE (§460.200)

Current regulations require POs to afford access to data and records to CMS and State Administering Agencies (SAAs). CMS says that some POs interpret this as meaning they only have to permit the agencies to view the records. CMS proposes to codify what it describes as its longstanding policy that CMS and SAAs must be able to obtain, examine, or retrieve the information. CMS notes this may include reviewing information at the PACE site or remotely, and it may also include CMS requiring a PACE organization to upload or electronically transmit information, or send hard copies of required information by mail.

CMS also states that POs do not always maintain or safeguard important records, such as communications from family members, caretakers, and the participant's community that relate to the participant's care. CMS proposes to require POs to maintain all written communications received from a participant or another party in their original form when the communication relates to the participant's care, health, or safety. CMS expects that this would include most, if not all, communications that an organization receives on these topics. CMS also proposes corresponding changes to require POs to maintain original written communications in the participant's medical record at §460.210(b)(6).

CMS seeks comment on these proposals.

D. PACE Services, Excluded PACE Services, and the Interdisciplinary Team (§§460.92, 460.96, and 460.102)

1. Required Services (§460.92)

CMS proposes to more clearly define required services, and to specify the agency's expectations for making decisions about required services under the PACE benefit package. It proposes to change the language in §460.92(a) to refer to Medicare-covered services to clarify that these services include drugs whether the drugs are covered under Parts A, B or D.

CMS proposes to specify in regulation standards IDTs must consider when evaluating whether to provide or deny services for a participant. IDT decisions to provide or deny services would have to be based on an evaluation of the participant that takes into account both of the following:

- The participant's current medical, physical, emotional, and social needs; and
- Current clinical practice guidelines and professional standards of care applicable to the particular service.

CMS states that it does not intend to restrict a PO's ability to determine what service is appropriate or necessary.

CMS does not believe these proposals will increase costs or burden on POs because they are already required to use current clinical practice guidelines.

2. Excluded Services (§460.96)

The regulations list a number of services that are excluded from coverage under PACE. Section 460.96(a) states that any service not authorized by the IDT, even if it is a required service, is an excluded service unless it is an emergency service. Section 460.96(b) states that in an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental, are excluded from coverage unless the IDT specifically authorizes them as part of the participant's plan of care. CMS proposes to strike these two provisions.

CMS believes that some POs are incorrectly interpreting the exclusion in §460.96(a) to permit an IDT to exclude any service that it does not authorize for the participant, including services clearly covered under the Medicare or Medicaid program. CMS believes this change is necessary to ensure participants receive services to which they are entitled. CMS says it does not intend to waive or eliminate the IDT approach to care management and service delivery; the IDT would retain its ability to determine which services are appropriate for a participant and would remain responsible for coordinating care.

The agency's rationale for striking §460.96(b) appears to be that placing this provision in a regulation section entitled "Excluded Services" may give the impression that an IDT would never have to consider whether an inpatient facility private room and private duty nursing services are medically necessary, or whether nonmedical items for personal convenience, when part of a plan of care, are medically necessary or necessary to improve or maintain the participant's overall health status.

CMS explains its interpretation of the statute that it believes permits these proposed changes.

CMS does not believe these proposals will increase costs for POs because they are already required to cover all PACE required services.

3. The Interdisciplinary Team (§460.102)

CMS says it has determined that some POs may not consider pertinent input about participants from specialists or from other clinical or non-clinical staff, whether employees or contractors. CMS believes that input from these individuals may contribute to the participant's treatment plan. CMS proposes to add employees, contractors, and specialists to the list of individuals from whom the IDT must remain alert to pertinent input.

CMS also proposes to require IDTs to document all recommendations for care and services, and if the service is not approved, to document the rationale for not approving or providing the care or service.

E. Documenting and Tracking the Provision of Services under PACE (§460.98)

CMS states that it has identified instances of noncompliance of POs with respect to providing all necessary care and services through the use of employees or contractors, as expeditiously as the participant's health requires, and to ensure access to those services 24 hours a day every day of the year. CMS proposes several modifications to its service delivery regulations at §460.98.

The agency proposes changes to §460.98(a) to clarify that not only must the PO have a written plan of care for each participant, it must also carry it out. It also proposes to clarify that the PO must ensure access to those services to meet the needs of participants, across all care settings, 24 hours a day every day of the year. The PO would have to ensure that the care is appropriately furnished. CMS emphasizes that these requirements apply across all care settings.

CMS says that it has determined through monitoring that some POs have relied on individuals other than employees or contractors to provide necessary services (e.g., caregivers). The agency proposes several changes to §460.98(b) to address this and other concerns.

First, CMS would reiterate the requirement for POs to provide all services through employees and contractors, regardless of whether the services relate to medical, health, or social services, including both acute and long-term care.

Second, CMS proposes to repeat in this section of the regulations the requirement under §460.104(e)(4) that all services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's overall medical, physical, emotional and social needs. Again, CMS does not impose a specific timeframe for the delivery of services; however, the PO would be expected to demonstrate that services were provided under this standard.

Third, CMS proposes to require POs to document, track, and monitor the provision of necessary services across all care settings, regardless of whether services are formally incorporated into the participant's plan of care. POs should not only document that a service has been ordered; it should also document when and how the approved service was provided.

F. Documentation in Medical Records under PACE (§460.210)

Based on audit findings, CMS proposes several additional requirements for medical record documentation.

First, POs would have to document in the participant's medical record all recommendations for services made by employees and contractors of the PO, including by all specialists (e.g., dentists, neurologists, cardiologists) and others. Even if the IDT determines a recommended service is not necessary to improve or maintain the participant's health, the IDT would nonetheless have to document the recommendation.

Second, POs would have to document both the decision for not approving or providing a service recommended by employees, contractors, specialists, and others as well as the rationale (including the clinical criteria used) for that decision.

Third, POs would have to maintain certain written communications they receive in the participant's medical record. These would be written communications about the care, health or safety of the participant from the participant, the participant's designated representative or caregiver, and from advocacy or governmental agencies, such as Area Agencies on Aging or Adult Protective Services. The information would have to be maintained in the medical record in its original written form as opposed to a summary.

G. PACE Participant Rights: Contact Information and Access Requirements (§460.112)

Section 460.112 specifies certain rights to which PACE participants are entitled (often referred to as the patient bill of rights). CMS proposes to add three new participant rights.

First, CMS proposes to add a right to contact 1-800-MEDICARE for information or to make a complaint. PACE organizations are not currently required to provide the toll-free number for Medicare; some participants or caregivers are unaware that in addition to the internal grievance process, a participant may contact the toll-free number to file a quality of care complaint, including a complaint regarding the delivery of a service. CMS expects this will require POs to post the toll-free number in an accessible location at the PACE center and include it in enrollment agreements.

Second, CMS proposes to add a right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines. This proposal is in reaction to findings that some PACE participants have not received access to specialist care in accordance with current clinical practice guidelines.

Third, CMS proposes to add a right to receive necessary care across all care settings, up to and including placement in a long-term care facility when the PO can no longer maintain the

participant safely in the community through the support of PACE services. This is intended to provide specific detail about services provided under a PACE program.

H. Enforcement Action Appeal Rights under PACE (§460.56)

The current enforcement provisions of Part 460 describe appeal rights of POs for terminations of contracts with CMS and the state Medicaid agency. However, these regulations do not address a process for a PO to appeal a civil money penalty or intermediate sanction imposed by the agency. While CMS has provided similar appeals rights under the MA program for POs to appeal these actions, CMS proposes to add a new section to Part 460 to specifically address the issue.

Proposed new §460.56, through a series of legal cross-references, would permit a PO to request a hearing on an enforcement action consisting of a civil money penalty or an intermediate sanction in the same manner as an MAO may do so under Part 422, specifically §422.756.

For suspension of enrollment or payment under §§460.42 or 460.48(b), the hearing procedure for intermediate sanctions of MAOs would be used, which includes the right to a hearing before a CMS designated hearing officer. Under this process, CMS must notify the PO of the intent to impose a sanction and the PO's right to a hearing before the CMS hearing officer. The PO would have 15 days from the date of the notice to request the hearing.

For civil money penalties under §460.46, the hearing procedure for civil money penalties imposed on MAOs would be used, which includes the right to a hearing before an Administrative Law Judge (ALJ). Under this process, CMS must notify the PO of the intent to impose a civil money penalty, the amount of the penalty, the due date of the penalty, information on the PO's right to a hearing before the ALJ, and where to file the hearing request.

I. PACE Definitions (§460.6)

CMS proposes changes to its definition of service in the definitions section of the PACE regulations. The first is to change "services" to "service" noting that the singular includes the plural. More significantly, it proposes to state that the term service, for purposes of the PACE regulations, means all services that could be required under §460.92; this would include items as well as drugs. This proposal is intended to eliminate any confusion on the requirement to furnish PACE participants with medically necessary medications.

VIII. Technical Changes

In this section, CMS proposes changes to its regulations on a variety of topics; it describes these changes as technical.

A. Exclusion of Services Furnished Under a Private Contract (§422.220)

CMS proposes to update §422.220 (relating to treatment of private contracts under the MA program) to expand the types of physicians that the regulation applies to and to clarify the types of items and services an opt-out provider may and may not receive payment for from an MAO.

Section 422.220 defines physician, with respect to private contracts, using a reference to section 1861(r)(1) of the Act which limits the application to medical doctors and doctors of osteopathy. To be consistent with the statute, CMS proposes to also include references (through the correct cross-reference) to dentists, optometrists and podiatrists.

In addition, CMS proposes to clarify that the restrictions on payments to opt-out providers apply only to payments for basic benefits (i.e., items and services covered under Parts A and B). The agency also proposes to specify that MAOs may make payments to opt-out providers for supplemental benefits. CMS also proposes to restructure this section.

B. Disclosure Requirements (§422.111)

CMS proposes to codify guidance with respect to the written explanation of benefits (EOB) that MAOs furnish to their enrollees under §422.111. In addition to some restructuring of this section, CMS proposes changes to clarify that MAOs are required to provide EOBs when benefits are provided. It also proposes to codify the following policies:

- EOBs must include certain data, such as descriptor, billing code and amount billed; total cost approved for reimbursement; share of the total cost paid by the plan; and the share of the total cost for which the enrollee is liable.
- MAOs must disclose specific claims data to their enrollees on a monthly or quarterly cycle in an EOB, including all claims for Part A and Part B covered items and services, mandatory supplemental benefits, and optional supplemental benefits.
- EOBs must contain cumulative, year-to-date totals for (i) the cumulative amount billed by all providers; (ii) the cumulative total costs approved by the plan; (iii) the cumulative share of total cost paid for by the plan; (iv) the cumulative share of total cost for which the enrollee is liable; (v) the amount an enrollee has incurred toward the MOOP limit; and (vi) the amount an enrollee has incurred toward the deductible.
- EOBs must include contact information for (i) enrollee customer service; (ii) instructions on how to report fraud; and (iii) for denied claims, a clear identification of the claim(s) denied as well as information about the denial and the enrollee's appeal rights.
- MAOs must send EOBs monthly or quarterly. A per-claim notice must be sent on the same cycle as a monthly EOB; MAOs electing to send per-claim notices must also send quarterly summary EOBs.

C. Special Requirements During a Disaster or Emergency (§422.100)

CMS proposes two technical changes to §422.100: (i) to correct a cross-reference in paragraph (m)(5)(iii), and (ii) to change “Web site” to “website” throughout.

D. Effective Date for Exclusion of Coverage for Kidney Acquisitions from Basic Benefits (§422.100)

In implementing the CURES Act exclusion from MA coverage for organ acquisitions for kidney transplants, CMS omitted the 2021 effective date for the change. It proposes to add the effective date to §422.100(c)(1).

E. Add Back Cost Plan Related Sections from Previous Final Regulation (§422.503)

In finalizing regulations relating to requirements for non-renewing cost plans, CMS incorrectly identified the non-renewal section; it proposes to correct the cross-reference to the correct paragraph of §422.503.

CMS also proposes to codify its policy (in new §422.503(b)(5)(i)) that an entity seeking to contract as an MAO must not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. Additionally, it would specify (in new §422.503(b)(5)(ii)) that an entity seeking to offer an MAO must not accept, or be either the parent organization owning a controlling interest of or subsidiary of, an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it offers an MA plan.

F. Definition of “Institutionalized” for Institutional Special Needs Plans (I-SNPs) (§422.2)

CMS proposes to update its regulatory definition of “institutionalized” for the purposes of establishing eligibility criteria for MA special needs plans for individuals who are institutionalized (I-SNPs) and for purposes of eligibility for a continuous open enrollment period to enroll or change enrollment in an MA plan, except for MA MSA plans. It would revise the definition to account for changes in the types of institutions that could potentially be used for I-SNPs that are not covered by the current definition of institutionalized. The revised definition would include all the following: a SNF, NF, intermediate care facility for the intellectually and developmentally disabled, psychiatric hospital, rehabilitation hospital or unit, LTCH, or swing bed hospital. CMS could also add other settings over time if it determines that the facility (i) furnishes similar long-term, healthcare services that are covered under FFS Medicare or Medicaid and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities CMS proposes to list. **CMS seeks comment on its proposal and the potential impact on MAOs offering I-SNPs, enrollees, and providers. It also seeks comment on whether the proposed standards to add other settings should use additional criteria.**

CMS notes its proposed definition does not align with the definition of “institutionalized individual” under the Part D regulations at §423.772. There, the term means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month. CMS notes this definition is an income and resource-based definition to determine Part D premiums and cost sharing subsidies for low-income individuals. The term “institutionalized” in §422.4 is used to determine eligibility for enrollment in an I-SNP or for a special election period.

Additionally, CMS does not propose to amend its definition of “institutionalized-equivalent” in §422.2 because it believes that definition is not impacted by the proposed amendment to the definition of “institutionalized”.

CMS does not score this provision in the Regulatory Impact Analysis section because it codifies and reconciles existing guidance and practice for the uses of the term “institutionalized” in part 422. It believes that there is no impact on stakeholders who follow the current guidance. CMS

does not score this provision in the Collection of Information section because it believes all information impacts have already been accounted for under OMB control number 0938-1296 (CMS-10565); **it seeks comment on this assumption.**

G. Medicare Electronic Complaint Form (§§422.504 and 423.505)

In section VI.H of the proposed rule, CMS would add new §§422.2265 and 423.2265 to codify requirements for websites maintained by MA and Part D plans. It proposes to move to these new sections current regulatory requirements for plans to provide a direct link on their main web page to the Medicare.gov electronic complaint form. Thus, the required content for websites in those sections would include a requirement for a link to the Medicare.gov electronic complaint form.

CMS also proposes what it describes as minor changes to the text of §§422.504(a)(15) and 423.505(b)(22) to clarify that plans must use the CMS complaint tracking system to address and resolve complaints against the plan received by CMS.

H. Advance Notice and Announcement of Part D Risk Adjustment Factors (§423.329)

CMS proposes to revise the regulation text to codify its interpretation of the statute to publish Part D risk adjustment factors through the Advance Notice and Rate Announcement process. Specifically, it would amend §423.329(b)(4) to stipulate that it will publish Part D risk adjustment factors using the process through which CMS proposes, adopts, and announces the capitation rates and risk adjustment methodology for the MA program.

CMS is not scoring this provision in the Regulatory Impact Analysis section since it codifies statutory provisions that are followed in practice by the agency.

I. Advance Notice and Announcement of Part C Annual Capitation Rate, Benchmarks, and Methodology Changes (§422.312)

When enacted by the BBA of 1997, section 1853(b)(2) of the Act called for a 45 day advance notice period for the annual capitation rate and factors used to adjust those rates and did not explicitly address a minimum comment period. However, section 1853(b)(2) was amended so that, beginning in 2017, a 60-day advance notice period and a 30-day comment period are required. CMS proposes to update its regulations to mirror the statutory change.

CMS is not scoring this provision in the Regulatory Impact Analysis section since it codifies statutory provisions that are followed in practice by the agency.

J. General Requirements for Applicable Integrated Plans and Continuation of Benefits (§§422.629 and 422.632)

CMS proposes minor wording changes to correct technical errors from the April 2019 final rule. It also proposes to correct a cross-reference.

K. Representatives in Part D Appeals (§§423.560, 423.566, 423.578, 423.2014, and 423.2036)

The appeals regulations for Medicare FFS and Part C refer to two types of representatives—authorized and appointed. An authorized representative is authorized under state or other applicable law to act on behalf of a beneficiary or other party involved in an appeal; an appointed representative is an individual appointed by a party to represent the party in a Medicare claim or claim appeal. However, for appeals of Medicare Part D coverage determinations, the term “appointed representative” is defined as meaning either an individual appointed by an enrollee or authorized under state or other applicable law to act on behalf of the enrollee. CMS believes that including authorized representatives in the definition of appointed representatives for Part D appeals is confusing. In §423.560, CMS proposes to change the term being defined from “appointed representative” to “representative.” CMS proposes no other changes to the definition.

CMS welcomes comments on these proposed changes.

L. Copayments and Coinsurance in Amount in Controversy Calculations (§§422.600 and 423.2006)

The statute establishes a minimum amount in controversy (AIC) requirement for hearings before an Administrative Law Judge (ALJ) and judicial review under Medicare FFS program. Those amounts also apply for appeals under Part C and Part D. The methodology for calculating the AIC is to compute the amount that the provider or supplier bills for the items and services, reduced by any Medicare payments already made or awarded for the items or services, and further reduced by “any deductible and/or coinsurance amounts that may be collected for the items or services.”

CMS notes that stakeholders have asked whether copayments should also be included along with deductibles and coinsurance in calculating the AIC. CMS proposes to revise §422.600(b) to clarify that copayments should be treated in the same manner as coinsurance when calculating the AIC.

The agency also proposes to revise the regulations for appeals of Part D plan sponsor coverage determinations and at-risk determinations. The AIC for these appeals is addressed in §423.2006, which does not reference cost-sharing amounts. CMS established its policy to exclude applicable deductible or coinsurance amounts in sub-regulatory guidance. CMS would codify its guidance that in calculating the AIC all cost-sharing amounts, including copayments, are excluded.

M. Stipulated Decisions in Part C (§422.562)

The appeals regulations for FFS claims and entitlement appeals permit for stipulated decisions. A stipulated decision may be made by an ALJ or adjudicator if CMS or one of its contractors submits a written statement, or makes an oral statement at a hearing, indicating the item or service should be covered or payment may be made. In this situation, a stipulated decision is issued finding in favor of the appellant or other liable parties on the basis of the written or oral statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

The MA appeals regulations apply the FFS appeals procedures to MAO determinations. CMS is concerned that because MAOs are not generally included within the definition of “contractors” in the FFS regulations, it may be unclear that stipulations may be made by MAOs in Part C cases. However, the parallel Part D regulations for stipulated decisions specifically apply to stipulations made by Part D plan sponsors. CMS proposes to clarify (in new §422.562(d)(3)) that, for the sole purpose of applying the FFS appeals regulations to Part C appeals, an MAO is included in the definition of “contractors” as it relates to stipulated decisions issued by ALJs and attorney adjudicators.

CMS solicits comment on whether the proposed revision raises unintended consequences for how the part 405 appeal rules apply to reviews at the ALJ of Part C appeals.

N. Beneficiaries with Sickle Cell Disease (SCD) (§423.100)

Section 1860D-4(c)(5)(C)(ii) of the Act contains exemptions from drug management programs (DMPs) for certain beneficiaries; they are for individuals receiving hospice care or residents of a long-term care facility for which frequently abused drugs (FADs) are dispensed for residents through a contract with a single pharmacy. CMS codified these exemptions in the definition of “exempted individual” in §423.100. CMS may elect to treat other beneficiaries as exempted individuals.

CMS proposes to add beneficiaries with sickle cell disease (SCD) to the categories of exempted beneficiaries. Based on clinical guidelines and information, CMS believes that beneficiaries with SCD should be exempted from DMPs given the: 1) clinical nature of the disease; 2) unique presentation of SCD crises; 3) limited evidence to guide opioid administration in SCD; 4) limited knowledge of SCD among providers; and 5) lack of other available therapies or modalities for treatment.

O. Drug Management Programs (DMPs): Additional Requirements (§423.153)

CMS proposes a number of wording and cross-references changes to §423.153 to improve clarity of the DMP regulations.

- Technical cross-reference changes to §§423.153(f)(3)(ii) and 423.153(f)(4).
- Specify the beginning of the 30-day period during which the second notice or alternate second notice must be provided under §423.153(f)(8); also proposes wording changes to improve readability.
- Apply the requirements on data disclosure at §423.153(f)(15) to at-risk beneficiaries (ARBs) who change plans.

§423.153(f)(15) mandates Part D sponsors’ reports to the overutilization management system (OMS) and MARx; sponsors must to provide information to CMS about any potential at-risk beneficiary (PARB) that a sponsor identifies within 30 days from the date of the most recent CMS report identifying PARBs. (A PARB meeting this definition refers to a beneficiary about whom a new plan sponsor receives notice upon the beneficiary’s enrollment through the MARx system that the beneficiary was identified as potentially at-risk by the immediately prior plan

sponsor under its DMP, but a coverage limitation on FADs had not yet been implemented by the prior plan before the beneficiary disenrolled.)

CMS also notes mistakes in the Data Disclosure section of the Part D Drug Management Program Policy Guidance (November 20, 2018) on pages 30-31; in referring to “PARB 2s” and “ARB 2s” in subsection I.2 and I.2.b., it meant to refer to “PARBs” and “ARBs” generally.

IX. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, CMS is required to solicit public comment on any proposals that would require individuals or entities to submit information to the federal government before such information collection requirement is submitted to the Office of Management and Budget for approval. CMS provides a summary table of the provisions in the proposed rule for which it estimates potential burden and that would require an information collection review and approval under the Paperwork Reduction Act of 1995. Table 22 identifies the 44 provisions that would contain proposed collection of information requirements in the following areas:

- Provisions impacting Dual SNPs and other SNPs,
- Drug Management Programs and other provisions of the SUPPORT Act,
- Enrollment of individuals with ESRD,
- Requirement to provide RTBTs to beneficiaries,
- Requirement to submit pharmacy performance measures to CMS
- Calculating MLRs,
- Special enrollment periods; and
- PACE provisions.

In total, CMS estimates that all of the information collection requirements would raise costs for plans and enrollees by a total of \$58 million in year one and would cost \$45 million in subsequent years. Individual provisions with significant estimated information collection costs are described above in the relevant sections. For all others see Table 22 in the document made available for public display.

X. Regulatory Impact Analysis

CMS examined the impact of the proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

CMS concludes that the proposed rule would not have an impact on a significant number of small entities nor on small rural hospitals. It also anticipates that many of the provisions of the

proposed rule would have no impact at all because they codify existing guidance or are technical provisions. A number of provisions cannot be estimated including those permitting a MAPD and Part D plan sponsor to offer a second specialty tier.

CMS provides a summary table (duplicated below) of the costs and benefits of the proposed rule. Overall, CMS estimates that the rule would be a net annual savings to the federal government, MAOs, and Part D sponsors of between \$5.8 and \$6.3 million and total savings over 10 years of \$292 million. Transfers of between \$369 and \$407 million would result in reduced federal spending of an estimated \$4.4 billion over 10 years.

In addition, CMS provides a discussion of alternatives considered for the following provisions:

- Including beneficiaries with a history of opioid-related overdose in a DMP;
- Education material regarding the safe disposal of prescription drugs and on opioid risks and alternative treatments;
- Permitting a second specialty tier for high cost drugs; and
- Requiring plans to offer beneficiaries a RTBT.

Summary Table of Costs and Benefits of Proposed Rule

Provision	Description	Impact
a. Mandatory Drug Management Programs (DMPs) (§ 423.153)	This provision would codify the SUPPORT Act requirement making it mandatory that Part D sponsors implement DMPs, starting in plan year 2022.	There are costs of about \$0.1 million a year with a 10-year total cost of \$0.8 million.
b. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)	This provision would require that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse under sponsors' DMPs.	Part D enrollees with a history of opioid-related overdose have higher than average drug costs. CMS estimates that Part D DMPs could save 5 percent in costs per year. After the first year, the reduction in drug utilization would result in an annual savings of \$7.7 million to the Medicare Trust Fund resulting from reduced drug spending by beneficiaries. The costs for case management and related paperwork is estimated at \$10.1 million annually after the first year.
c. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)	CMS is proposing that if a Part D sponsor denies a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution. CMS proposes that a plan sponsor must forward the case to the independent outside entity by the expiration of the adjudication timeframe applicable to the plan level appeal. Finally, CMS proposes conforming revisions to the notices that are sent to beneficiaries.	CMS estimate there will be about 28,600 appeals per year, of which 0.08 percent will be denied and automatically escalated to the independent review entity (IRE). Therefore, there are only about 23 cases (0.08 percent * 28,600) affected by this provision. Since most IRE cases are judged by a physician at a wage of \$202.46, and typically an IRE will take at most 1 hour to review, the total burden is negligible (about \$4,656.58 (23 cases * \$202.46 * 1 hour)).

Provision	Description	Impact
d. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)	CMS is proposing to implement two sections of the SUPPORT Act, which will-- (1) require Part D plan sponsors to notify the Secretary of the imposition of a payment suspension on pharmacies that is based on a credible allegation of fraud, impose such payment suspensions consistent with the manner in which CMS implements payment suspensions in fee-for service Medicare, and report such information using a secure website portal; (2) define inappropriate prescribing with respect to opioids; (3) require plan sponsors to submit to the Secretary information on investigations and other actions related to inappropriate opioid prescribing; (4) define “substantiated or suspicious activities” related to fraud, waste, or abuse; and (5) establish a secure portal which would enable the sharing of data and referrals of “substantiated or suspicious activities” related to fraud, waste, or abuse among plan sponsors, CMS, and CMS’s program integrity contractors.	While CMS believes there may be savings generated through actions taken by plans that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS and plans sponsors, as well as additional law enforcement actions, it cannot estimate the impact at this time. The reporting requirements will cost about \$9.5 million a year after the first year.
e. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan.	Since there are no new provisions regarding enrollment of beneficiaries with ESRD, or kidney acquisition costs, in this regulation that are not in the Act; there are no impacts to report as resulting solely from this provision.
f. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes that MA organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for their beneficiaries. Instead, CMS proposes to require that Medicare FFS cover the kidney acquisition costs for MA beneficiaries, effective 2021.	To estimate the impact, CMS used a pre-statute baseline. This analysis shows that FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from \$212 million in 2021 to \$981 million in 2030.
g. Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes to remove costs for organ acquisitions for kidney transplants from the calculation of MA benchmarks and annual capitation rates.	To estimate the impact, CMS used a pre-statute baseline. This analysis shows that excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from \$594 million in 2021 to \$1,346 million in 2030.
h. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)	CMS is proposing routine measure updates and an increase in the weight of patient experience/complaints and access measures. CMS proposes some technical clarifications of the current rules for the QBP ratings methodology. CMS also propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers,	Updating the patient experience/complaints and access measures weight would create a cost which is offset by using the Tukey outlier deletion. The net savings to the Medicare Trust Fund is \$368.1 million in 2024; this will grow over time reaching \$999.4

Provision	Description	Impact
	to increase the stability and predictability of the star measure cut points.	million by 2030. The net reduction in spending to the Medicare Trust Fund over 10 years is \$4.9 billion.
i. Permitting a Second, “Preferred”, Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)	CMS is proposing to (1) allow Part D sponsors to establish a second, “preferred,” specialty tier at a lower cost-sharing threshold than the current specialty tier; (2) codify the existing maximum cost sharing for the highest specialty tier; (3) codify a methodology to determine annually the specialty tier cost threshold using ingredient cost and increase the threshold when certain conditions are met; (4) require sponsors to permit tiering exceptions between the two specialty tiers; and (5) permit sponsors to determine which drugs go on either tier.	Permitting Part D sponsors to establish a second, “preferred”, specialty tier is unlikely to have a material impact on Part D costs.
j. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)	CMS is proposing to require that each Part D plan implement a beneficiary real time benefit tool. This tool should allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements) by January 1, 2022.	Adoption of a beneficiary RTBT will be an additional cost and burden on Part D sponsors. Based on its estimates, CMS believes this will cost Part D plans about \$3.9 million for all plans in the first year based on the costs for them to reprogram their computer systems. Additionally, the voluntary provision of rewards by Part D sponsors to enrollees using RTBT will have an impact of \$0.7 million in the first year, in order to implement the program, and \$0.4 million in subsequent years in order to maintain the program.
k. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)	CMS is proposing to amend our MA MLR regulations. There are three proposals. (1) CMS proposes to allow MA organizations to include in the MLR numerator as “incurred claims” all amounts paid for covered services, including amounts paid to individuals or entities that do not meet the definition of “provider” as defined at § 422.2. (2) CMS also proposes to codify our definitions of partial, full, and non-credibility and credibility factors that it published in the May 2013 Medicare MLR final rule (78 FR 31296). (3) For MA MSA contracts receiving a credibility adjustment, CMS proposes to apply a deductible factor to the MLR calculation in order to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles.	(1) The proposed amendment to change the type of expenditures that can be included in “incurred claims” will have neutral dollar impact on the Medicare Trust Fund. These provisions will result in a transfer of funds from the Treasury, through the Medicare Trust Fund, to MA organizations. This transfer would take the form of a reduction in the remittance amounts withheld from MA capitated payments. The amount of this transfer is \$35 to \$55 million a year, resulting in plans obtaining \$455 million over 10 years. (2) Codifying the definitions of partial, full, and non-credibility and the credibility factors, as proposed, is unlikely to have any impact on the Medicare Trust Fund. (3) The proposal to add a deductible factor to the MLR calculation for MA MSA contracts

Provision	Description	Impact
		is estimated to result in a gradually increasing cost to the Medicare Trust Fund of \$1 to \$6 million per year, and will result in a \$43.2 million cost over 10 years.
l. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)	CMS is proposing to (1) strengthen network adequacy rules for MA and cost plans and make them more transparent to plans by codifying our existing network adequacy methodology and standards, with some modifications; (2) allow MA plans to receive a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with certain telehealth providers; and (3) reduce the required percentage of beneficiaries residing within maximum time and distance standards in certain county types (Micro, Rural, and CEAC).	Changes to network standards are unlikely to have any impact on the Medicare Trust Fund.
m. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)	CMS is proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. CMS also proposes to establish two new SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.	This provision codifies existing practice since MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. Consequently, the provision will not have added impact.
n. Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)	CMS is proposing to revise the process by which PACE organizations address service delivery requests. Currently the IDT must determine the appropriate member(s) of the IDT to conduct a reassessment, perform a reassessment, and render a decision on each service delivery request. However, CMS's experience shows that approximately 40 percent of all requests could be immediately approved in full by an IDT member. Therefore, CMS is removing the obligation for a request to be brought to the IDT or for a reassessment to be conducted when a member of the IDT receives and can approve a service delivery request in full at the time it is made. CMS proposes to remove the requirement to conduct a reassessment in response to a service delivery request except when a request would be partially or fully denied.	The proposed revisions create efficiencies which are estimated to create cost savings of \$18.7 million in the first year and gradually increase to \$23.9 million in 2030. The net savings over 10 years is \$216.3 million dollars. The savings are true savings to PACE organizations as a result of reduced administrative burden.
o. Beneficiaries with Sickle Cell Disease (SCD) (§ 423.100)	CMS is proposing that beneficiaries with SCD are classified as exempted from DMPs starting in plan year 2021.	CMS estimates this provision will affect under 70 beneficiaries and therefore the impact is negligible.