

Summary: Medicare and Medicaid Programs; 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 2020 and 2021 (CMS-4185-P)

Publication Date: November 1, 2018

Comments Due: December 31, 2018

On Nov 1, The Centers for Medicare and Medicaid Services (CMS) issued a [proposed rule](#) that updates Medicare Advantage (MA or Part C) and the Medicare Prescription Drug Benefit Program (Part D). The purpose of the proposed rule is to implement several provisions in the [Bipartisan Budget Act of 2018](#), improve program quality and accessibility, and propose policies that strengthen program integrity. Proposed provisions are intended to reduce provider burden and promote flexibility and innovation that will provide MA and Part D sponsors with tools to improve quality of care and increase choice for MA and Part D enrollees. CMS estimates that, if finalized, the proposed changes would result in \$4.5 billion dollars in savings to the Medicare Trust Funds over ten years. CMS plans to release another proposed rule to address the Administration's agenda of reducing drug costs. The second rule is currently under review at the Office of Management and Budget (OMB).

AMCP has offered [comments](#) to CMS in the past on how the Medicare Part C and D programs can be transformed through innovation to best meet the individual health needs of Medicare beneficiaries. AMCP plans to comment on the new proposed rule and is seeking feedback from its members to inform the comments that will be submitted to CMS.

Comments on this proposal must be submitted to CMS by December 31, 2018. AMCP will work with stakeholders to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced as changes to MA and Part D policies are considered. You may provide feedback via email to Afton Wagner, Director of Regulatory Affairs, at awagner@amcp.org by December 7 on any of the provisions included in the proposed rule. AMCP's final comments to CMS will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

In addition, AMCP will host a webinar on November 9 to review the proposed policy provisions that are applicable to AMCP members. This webinar is free for members and \$69 for non-members. To register, please visit AMCP's Calendar of Events at <http://www.amcp.org/calendar/>. A recording of the webinar will be available on the AMCP website the week of November 12 at <http://www.amcp.org/webinars/>.

The following is a summary of the proposed rule and sections that CMS is seeking feedback on from stakeholders, which may be of interest to AMCP members:

Section A: Implementation of the Bipartisan Budget Act of 2018 Provisions (pages 54987 – 55017)

The Bipartisan Budget Act of 2018 included provisions that permitted MA plans to offer additional telehealth benefits, increase integration of Medicare and Medicaid benefits and appeals and grievance

processes for MA Dual Eligible Special Needs Plans (D-SNPs) and required the establishment of a process to allow Part D plan sponsors to request extracts of Medicare Part A and B claims data for their enrollees. In the proposed rule, CMS details how it intends to implement these sections and seeks feedback on its approach and current thinking.

1. Requirements for Medicare Advantage Plans Offering Additional Benefits (pages 54987 – 54992)

The proposed rule would allow MA plans to offer “additional telehealth benefits” beyond what is currently allowable in original Medicare to enrollees starting in plan years 2020. Currently, the MA telehealth benefit is limited in how telehealth services may be delivered outside of the original Medicare telehealth benefit. Under this proposal, MA plans will have broader flexibility in how they pay for coverage of telehealth benefits to meet beneficiary needs. MA plans would be allowed to provide additional telehealth benefits that are not payable under Original Medicare and have been identified by the MA plan as “clinically appropriate” to provide electronically.

- CMS hopes that this change will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access their benefits and MA plans more flexibility to offer telehealth to both rural and urban-based enrollees.

CMS is proposing to allow the MA plan to determine what services are considered clinically appropriate and seeks comment on this approach. CMS is also seeking comment on what types of items and services, such as Medication Therapy Management (MTM), should be considered additional telehealth benefits and whether to impose additional requirements for qualifications of providers of additional telehealth benefits.

2. Dual Eligible Special Needs Plans (D-SNPs) (pages 54992 – 55015)

a) Integration Requirements for D-SNPs

D-SNPs are a type of MA plan that focus on coordination of care for special needs populations. Enrollment is specifically meant for dual-eligible beneficiaries who are at risk of fragmentation of care between the Medicare and Medicaid Programs. The proposed rule would establish new minimum criteria for Medicare and Medicaid integration through one of two ways:

- 1) Covering Medicaid long-term services and supports and/or behavioral health services through a capitated payment from a state Medicaid agency; or
- 2) Notifying the state Medicaid agency (or its designee) of hospital and skilled nursing facility admissions for a least one group of high-risk full-benefits dual eligible individual, as determined by the state Medicaid agency.

Proposed requirements would be effective in 2021. CMS solicits comment on its proposal.

b) Unification of Medicare and Medicaid Grievance and Appeals Procedures in D - SNPs

CMS is proposing to unify grievance and appeals procedures for certain D-SNPs and affiliated Medicaid managed care plans that would be effective in 2021. D-SNPs with fully aligned enrollment and the affiliated Medicaid managed care organization would be affected by this proposed rule. The proposed rule is intended to provide a simplified process for enrollees in these D-SNPs for grievances and appeals. With this provision, CMS intends to address a longstanding misalignment

between the Medicare and Medicaid Program on the grievance and appeals procedures and ensure that beneficiaries' concerns and needs are promptly met.

CMS proposes that unification of these processes must be protective of the enrollee, take into account differences in state Medicaid plans, be easily navigable by an enrollee, include a written notification of all applicable grievance and appeal rights, provide a single pathway for resolution of a grievance or appeal, provide clear notices, employ unified timeframes for grievances and appeals, establish requirements for how the plan must process, track, and resolve grievances and appeals, and incorporate existing law that provides continuation of benefits pending appeal for items and services covered under Medicare and Medicaid.

CMS is soliciting input from stakeholders on the implementation of these new statutory provisions, definitions, and operating requirements for D-SNPs.

3. Prescription Drug Plan Sponsors' Access to Medicare Parts D and B Claims Data Extracts (pages 55015 – 55018)

The proposed rule would allow Part D plans to request that the Secretary provide, in an electronic format and on a periodic basis, standardized extracts of Medicare claims data about its plan enrollees. Extracts would include a subset of Medicare Parts A and B claims data. CMS proposes to accept data requests beginning on January 1, 2020 and anticipates that Medicare claims data will be provided on at least a quarterly basis. The Medicare claims data may be used for the following:

- 1) Optimizing therapeutic outcomes through improved medication use;
- 2) Improving care coordination to prevent adverse healthcare outcomes; and
- 3) For any other purpose determined appropriate by the Secretary.

CMS is also proposing that Part D Plan (PDP) Sponsors would be permitted to use Medicare claims data for purposes of health care operations, fraud, waste, and abuse detection or compliance activities and disclosures that are required by law. CMS is seeking input on whether there are additional purposes where Part D sponsors should be permitted to use Medicare claims data in this section.

The proposed rule lists the following purposes for which PDP sponsors may not use Medicare claims data in this section:

- 1) To inform coverage determinations under Part D;
- 2) To conduct retroactive reviews of medically accepted indications determinations;
- 3) To facilitate enrollments changes to a different PDP or a MA-PD plan offered by the same parent organization; and/or
- 4) To inform marketing of benefits.

CMS proposes that the Secretary may place additional limitations on the use of Medicare claims data to protect the security of protected health information and requests comment on what, if any, additional limitations that should be placed on Medicare claims data. It also proposes that PDP Sponsors contractually bind its contractors that would potentially have access to claims data to the terms and conditions imposed on the PDP Sponsor. Additionally, CMS would consider PDP Sponsors business associates receiving Medicare claims data on behalf of a PDP, a health plan and HIPAA covered entity.

The PDP Sponsor must attest that it will adhere to permitted uses and limitations of Medicare Claims data proposed in the rule.

Finally, CMS proposes that data from the following claim types would be permitted: inpatient, outpatient, carrier, durable medical equipment, hospice, home health, and skilled nursing facility data.

- Information on all Parts A and B services provided to the patient to include the dates of services rendered are proposed to be included.
 - CMS believes that this information would help to inform PDP Sponsors on services or procedures that led to the prescribing of a medication and the care setting in which the medication was prescribed.
- Proposed data elements to be collected include: Enrollee identifier; diagnosis and procedure codes (i.e. Initial Encounter Definition (ICD)-10 diagnosis codes); dates of service; place of service; provider numbers (i.e. National Provider Identifier (NPI)); and claim processing and linking identifiers/codes.

CMS strongly encourages comment on their proposed approach as well as any alternatives.

Section B: Improving Program Quality and Accessibility (pages 55018 – 55029)

In the “[Advance Summary of Methodological Changes for Calendar Year \(CY\) 2018 for Medicare Advantage \(MA\) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter](#)”, CMS codified key aspects of the Part C and Part D Star Ratings methodology, including the principles for adding, updating, and retiring measures (aka the Call Letter process), and the methodology for calculating and weighting measures. In this proposed rule, CMS is considering an enhanced methodology for determining cut points for non-Consumer Assessment of Healthcare Providers (CAHPS), several quality measures updates, and a policy to adjust the methodology for Star Ratings for affected MA and Part D plans in the event of extreme and uncontrollable circumstances such as hurricanes.

a) Proposed Enhancements to Measure-Level Star Ratings

CMS is proposing an enhanced cut point methodology for data collected during the 2020 measurement year and associated 2022 Star Ratings that would improve stability and predictability and reduce the influence of outliers by implementing a guardrail so that cut points do not increase or decrease more than the cap from one year to the next. The proposed rule offers two enhancements to the current clustering methodology that is used to set cut-points for non-CAHPS star measures:

- 1) CMS proposes to utilize mean resampling to reduce the sensitivity of the clustering algorithm to outliers and reduce the random variation that contributes to fluctuations in cut points. This proposal is intended to improve the stability of cut points over time.
- 2) CMS proposes a 5 percent bi-directional cap for measures that have been in the Part C and D Star Ratings for more than 3 years. The cap is intended to allow a degree of predictability

by restricting the movement of a cut point through imposing a maximum movement per measure threshold.

CMS welcomes comment on this proposal to include comments on percentage used for the cap.

b) Proposed Quality Measures Updates

CMS is proposing to modify the following existing measures:

- 1) Controlling High Blood Pressure (Part C) to align with [new clinical guidelines](#) and updated Healthcare Effectiveness Data and Information Set (HEDIS) 2019 measures related to hypertension.
 - Measure would be moved to the display page for 2020 and 2021 Star Ratings.
 - CMS proposes to return this measure with substantive updates to the 2022 Star Ratings.
- 2) Medicare Plan Finder (MPF) Price Accuracy (Part D) to better measure the reliability of a contract's advertised prices.
 - CMS proposes to make substantive changes to this measure to better measure the reliability of a contract's MPF advertised prices.
 - Measure would be moved to the display page for 2020 and 2021 Star Ratings.
 - CMS proposes to use it in the 2022 Star Ratings in place of the existing MPF Price Accuracy measure which will remain in the Star Ratings until its replacement.
- 3) Plan All-Cause Readmissions (Part C) to include observation stays and remove individuals with high frequency hospitalizations.
 - Based on observations from the National Committee for Quality Assurance (NCQA), CMS is proposing to combine 18 – 64 and 65+ age groups as opposed to 65+ age group only.
 - Measure would be moved to the display page for 2021- and 2022-Star Ratings.
 - CMS proposes to return this measure with substantive updates by NCQA to the 2023 Star Ratings.
- 4) CMS proposes to exclude Improvement measures (Part C and D) from the improvement calculation if that measure receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year.

c) Extreme and Uncontrollable Circumstances

CMS proposes to adjust the Star Ratings to account for extreme and uncontrollable circumstances that occur during the performance or measurement period. The proposed rule describes policies for identifying affected contracts and adjusting Star Ratings Measures that are largely the same as those described in the 2019 final Call Letter.

- The one exception is the proposed elimination of the difference-in-differences adjustment for survey data which has shown no consistent, negative impact of extreme and uncontrollable circumstances on the 2019 Star Ratings.

CMS proposes to codify a series of special rules for calculation of the Star Ratings of certain contracts in extreme and uncontrollable circumstances. Adjustments would be tailored to the specific geographic areas experiencing the circumstances and their resulting adverse effects. CMS proposes to target adjustment to specific contracts and further specify and limit adjustments. CMS outlines certain criteria for an MA or Part D contract to be considered an “affected contract.”

- For an MA or Part D contract to be considered an affected contract, CMS proposes that it must meet the following criteria:
 - Contract’s service area must be within an “emergency area” during an “emergency period” as defined in section 1135(g);
 - Contract’s service area must be within a county, parish, U.S. territory or tribal area designated in a major disaster declaration and the Secretary exercised authority under section 1135 of the act based on the same triggered event; and
 - A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and Reward Factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the circumstance.

CMS is proposing that affected contracts with a least 25 percent of enrollees residing in Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year’s Star Ratings or current year’s Star Rating for each Health Outcomes Survey (HOS) and HEDIS-HOS measure for the Star Ratings 3 years after the eligible circumstance.

CMS offers provisions for adjustments in the following areas: Consumer Assessment of Healthcare Providers and Systems (CAHPS), HOS, HEDIS, New Measures, Other Star Ratings Measures, Exclusion Form Improvement Measures, Missing Data, and Cut Points for non-CAHPS measures.

- For adjustments, at least 25 percent 60 percent of the enrollees under the contract must reside in Individual Assistance areas identified because of the circumstance.
- Contracts that do not meet the definition of an “affected contract” would not be eligible for any adjustments.
- Meeting the criteria for an affected contract is not sufficient for all proposed adjustments.

Section C: Clarifying Program Integrity Policies (pages 55029 – 55041)

1. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

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 Benefits Program, and the PACE Program”*](#) final rule released in April 2018, CMS eliminated the prescriber and provider enrollment

requirement for Medicare Part C and Part D, and instead compiled a “Preclusion List” of prescribers, individuals, and entities that fall within certain categories.

In this proposed rule, CMS is proposing to make changes to several of the preclusion list policies outlined in the April 2018 final rule to improve the preclusion list and clarify expectations for stakeholders. Proposed changes include several technical updates and clarifications and focus on the following areas:

- 1) Appeals Process for Individuals and Entities on Preclusion List
 - CMS proposes that, if a prescriber or provider is to be placed on the preclusion list in conjunction with a revocation, no more than 5 months would expire before the preclusion list inclusion occurs to ensure that prescribers and providers appeal rights are preserved, but also that problematic parties are placed on the preclusion list as soon as feasible.
- 2) Timing of Addition to Preclusion List
 - CMS proposes that a prescriber or provider would only be included on the preclusion list after (1) the prescriber or provider fails to file a reconsideration request upon the expiration of the 60-day period in which a reconsideration request is available or (2) CMS denies the prescriber or provider’s reconsideration request.
- 3) Effective Date
 - CMS proposes that the preclusion list revisions would be applicable to MA and Part D plans on January 1, 2020 to allow stakeholders time to prepare.
- 4) Claim Denials and Beneficiary Notification
 - CMS proposes that, upon the posting of the updated preclusion list, MA and Part D plans would be required to (1) send notice to the beneficiary that his or her prescriber or provider has been added to the preclusion list within 30 days and (2) deny a prescriber or provider’s claim beginning 60 days after sending the beneficiary’s notice.
- 5) Beneficiary Appeals
 - CMS proposes that payment denials based on a prescriber or provider’s inclusion on the preclusion list are not appealable by beneficiaries.
- 6) Felony Convictions
 - Would add a definition for a third party that could be included in the preclusion list that covers providers and prescribers that have been convicted of a felony under federal or state law within the previous 10 years and establishes a new section that codifies and clarifies the length of a provider or prescriber’s inclusion on the preclusion list.
- 7) Beneficiary Liability
 - Would add a new paragraph stating that the MA organization agrees that the enrollee must not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list

CMS requests comment regarding the appropriateness of effective dates for preclusion list provisions.

2. Medicare Advantage Risk Adjustment Data Validation Provisions

CMS is providing additional notice and welcoming public input on the agency’s methodology for calculating a contract-level payment error in Risk Adjustment Data Validation (RADV) audits, including the sample sizes used in these contract-level audits. CMS also seek comment on a proposal for an

extrapolated audit methodology based on sub-cohorts of enrollees and whether it should revise the contract-level audits that have been conducted, but not finalized, for years 2011, 2012, and 2013.

Section D: Implementing Other Changes (page 55041)

1. Clarification Regarding Accreditation for Quality Improvement Programs

CMS proposes to make technical corrections and clarify erroneous cross referencing of quality improvement programs throughout the Act.