

AMCP Summary: *Advanced Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter*

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On January 30, 2019, the Centers for Medicare and Medicaid Services (CMS) published an [Advanced Notice of Methodological Changes for Calendar Year \(CY\) 2020 for Medicare Advantage \(MA\) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter](#), known as the “draft Call Letter.” The draft Call Letter outlines payment amounts for beneficiary cost sharing, risk corridors for Part C and Part D plans, and beneficiary payments for calendar year 2020. Many of the draft provisions for the 2020 plan year revolve around opioids and CMS’s effort to ensure beneficiaries are receiving appropriate pain management therapy. CMS also proposes numerous updates, changes and potential new measure concepts for the Star Ratings Program. CMS is also considering changing policies and is accepting comments relating to its tier composition policy for generics and specialty medications in Part D. Comments regarding an implementation timeline for this potential new tier composition policy are also being accepted.

AMCP will host a webinar on February 20, 2019 to review the proposed policy provisions in the Call Letter 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 also be available to members on the AMCP website <http://www.amcp.org/webinars/>.

AMCP is seeking feedback from its members on the proposed changes in the Call Letter to help inform us as we submit a formal response to CMS. You may provide feedback via email to Afton Wagner, Director of Regulatory Affairs, at awagner@amcp.org by February 22, 2019 on any of the provisions included in the Call Letter.

The following are proposed provisions in the Call Letter that may be of interest to AMCP members:

CMS Maintains Specialty Cost Threshold for 2020, Considers Tier Composition Policy Change for Generics and Specialty Products in the Future

For 2020, CMS proposes to maintain the specialty tier threshold at \$670 per month to balance plan flexibility and beneficiary access but seeks comment on the methodology to evaluate specialty tier threshold changes in the future. CMS also intends to maintain a maximum threshold of 25% generic composition for the Non-Preferred Brand tier for 2020.

CMS will continue to allow Part D sponsors the flexibility to determine the cost-sharing structure that is most appropriate for their benefit design for 2020, including the ability to mix brand and generic drugs within the Non-Preferred Drug tier, and will continue to conduct outlier tests for sponsors who choose a

copay structure for the Non-Preferred Drug tier. CMS encourages Part D sponsors to prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded products.

CMS suggests it will maintain its current tiering policy for 2020, but also notes it is *considering* a new policy in order to encourage utilization of more affordable generics and lower out-of-pocket costs for seniors and avoid beneficiary confusion. The alternative policy would revert to a prior policy to discourage or prohibit plan sponsors from placing generics on brand formulary tiers and brand drugs on generic formulary tier and eliminate the non-preferred drug tier.

- Under the potential changes, CMS proposes that generics would be part of generic formulary tiers and brands would be part of brand formulary tiers as opposed to drug tiers with a mix of generic and brand products.
 - CMS is interested in comments on the effects of this potential policy and is specifically looking for stakeholder feedback on:
 - Plan ability to meet the actuarial equivalence tests in the bid pricing tool.
 - Anticipated impact on premium and beneficiary cost sharing.
 - Formulary drug coverage and other formulary benefit design impacts, including sponsors' negotiations with manufacturers.
- Due to their favorable out-of-pocket costs, CMS would expect that FDA-approved, therapeutically equivalent generics would be automatically included on a generic formulary tier immediately following launch.
- For the purposes of this potential policy, CMS is seeking input on whether biosimilars should be treated the same as generic medications and if biosimilars and generic medications should be eligible for specialty tier placement if their cost exceeds the specialty tier threshold.
- CMS is interested in hearing from stakeholders on the appropriateness of providing specific exceptions to the potential policy for vaccines, naloxone agents, or other categories or classes of drugs.
- CMS also welcomes comment on whether this potential policy should be adopted by CMS as an exception for formularies for CY2020 in full or in any form or variation.

AMCP will seek clarification from CMS on the intent and timeline for potential changes to the generic and specialty tier composition policy. AMCP seeks feedback in this area for incorporation into CMS comments.

To Increase Access to Vaccinations, CMS Continues to Urge \$0 Co-Pays

CMS notes several studies that show beneficiary difficulty in affording cost-sharing of vaccinations leading to lower vaccinations rates and reiterates that plans are “encouraged” to cover Part D vaccines at \$0 or the lowest co-payment tier for each plan.

CMS Aims to Improve Naloxone Access Through Lower Cost Sharing and Co-Prescribing

CMS notes the lifesaving role of Naloxone in rapidly reversing most opioid overdoses and acknowledges awareness that high costs could be a barrier to access. CMS is “encouraging” Part D plans to either cover naloxone on a \$0 or low-cost sharing tier or, at a minimum, place naloxone on the plan’s generic tier.

CMS is also “encouraging” Part D plans to ensure authorizations are in place for beneficiaries who are at increased risk to opioid-associated harm (e.g. claims history of greater than 50 morphine milligram equivalents per day.) CMS provides several other suggestions for plans to target patients at risk such as patient-specific pharmacy messaging and recommends targeted education of prescribers and enrollees

on co-prescribing. CMS encourages comments on the feasibility of co-prescribing when clinically appropriate.

No Change in Part D PBP MRx Enhancements for Now

References to the coverage gap phase of the benefit will remain the same in the PBP until proposed enhancements can be considered. Feedback that CMS received in a survey to plans in 2018 may be used to guide changes for 2021 or beyond.

Maintaining Access to Medication-Assisted Treatment (MAT) in Part D Plans

CMS continues to evaluate formulary inclusion, utilization management criteria, and cost-sharing of Part D drugs indicated for MAT. It continues to expect that Part D plans include these products in preferred formulary tiers and avoid placing generic drugs for MAT in brand tiers.

CMS is Not Proposing Changes to the Overutilization Monitoring System (OMS) Criteria in 2020

CMS will continue to gain experience with drug management programs in 2019 and is not proposing changes to OMS criteria for 2020 at this time. CMS is accepting feedback from Part D plans on ways to improve the OMS criteria and identify potential at-risk beneficiaries for 2021 and beyond.

CMS Remains Concerned About Opioid Potentiator Drugs

Given the risk of opioid potentiator drugs to increase an individual's risk of overdose and death when used concurrently with an opioid, CMS continues to expect Part D plans to decrease inappropriate concurrent use through targeted initiatives. Specifically, CMS remains concerned about the increased use of gabapentin and pregabalin among opioid users.

CMS notes that MTM services can play an important role for beneficiaries who are at risk of adverse events due to opioid overutilization or opioid users who are also taking potentiator drugs. AMCP agrees with CMS that these beneficiaries may benefit from MTM services including a CMR, targeted medication review, and interventions with their prescribers.

Part D Opioid Overutilization Policy Results Shows Steady Decrease in Beneficiaries Using Opioids

CMS continues to track the impact of its opioid overutilization policy. Some highlights include the following: The percent of Medicare Part D beneficiaries using opioids steadily decreased by 14% (36.3% to 31.3%) between 2010 and 2017, with the largest decrease (5%) from 2016 to 2017, despite a 34% increase in Part D enrollment between 2012 and 2017. As a result of the implementation of opioid care coordination safety edits, the absolute number of Part D enrollees receiving at least one day at 90 MME is at its lowest value in 2017 and CMS expects to see continued progress in 2019. CMS notes that while results are positive, more effort must be made, and it will continue to work with stakeholders to address the opioid epidemic.

CMS Considering Proposing Revisions to the Medication Therapy Management (MTM) Comprehensive Medication Review (CMR) Standardized Format (SF)

In an effort to optimize the utility of the CMR summary for beneficiaries and reduce burden on Part D plans, CMS is planning to propose revisions to the standardized format. CMS will accept public comment on the planned changes for approval in 2020 in a future proposal with notice and comment. The current version of the SF is approved by the Office of Management and Budget through August 31, 2020. CMS will release a memo when its proposal is available for review.

AMCP is pleased to see that CMS is planning to propose revisions to the MTM CMR SF. AMCP's Medication Therapy Management Advisory Group (MTMAG) has been doing important [work](#) in this area to include research that is soon to be published in JMCP. AMCP has met with CMS regarding this issue and we will continue to share the work of the MTM Advisory group with CMS and provide recommendations for inclusion in a future proposal on SF enhancements.

2020 Part D Benefit Parameters – Benefit Review

For 2020, CMS is proposing to maintain the minimum monthly cost-sharing out-of-pocket costs (OOPC) difference between basic and enhanced PDP offerings at the \$22 threshold. Additionally, CMS strongly encourages plans to ensure that all Part D benefit and formulary changes are part of their meaningful difference evaluation prior to submission of final bids and formularies. Benefit Parameters for 2020 Threshold Values can be found in Table 23 on page 181-182 of the Call Letter.

Cost Sharing for Applicable Drugs in the Coverage Gap

In 2020, CMS is proposing that the coinsurance for applicable beneficiaries under basic prescription drug coverage is reduced to 25 percent for non-applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After applying the 70 percent manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage is reduced to 25 percent for applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2020. These proposals stem from key changes in the [Bipartisan Budget Act of 2018](#) impacting the coverage gap that require reducing the standard beneficiary cost sharing in the coverage gap from 30% to 25% and increasing pharmaceutical manufacturers' discount in the Coverage Gap Discount Program (CGDP) from 50% to 70% of the negotiated price of applicable drugs.

Part D Mail Order Auto-Ship Modifications

After soliciting feedback on possible modifications to the mail order auto-ship policy in the 2019 Call Letter, CMS is proposing to permit interested Part D sponsors to offer an opt-in voluntary auto-ship program for refills of established therapies beginning in 2020.

Enhancements to the 2020 Star Ratings and Future Measurement Concepts

CMS is proposing enhancements to the 2020 Star Ratings in addition to soliciting feedback on possible future measure updates and concepts. Starting with the 2021 Star Ratings, any changes in the methodology for calculating the ratings, in addition to new measures and substantive measure changes, will be proposed and finalized through rulemaking.

In December, 2018, AMCP [submitted comments](#) to CMS on the 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.

Measure Updates for 2020 Star Ratings

Reminders for 2020 Star Ratings

Plans must alert CMS to errors or anomalies immediately to resolve before first plan preview period.

CMS is proposing to make updates to the following measures for 2020:

- Medication Adherence (ADH) for Cholesterol (Statins) (Part D)

- Would exclude patients with end-stage renal disease (ESRD) as adopted in the final CY 2019 Call Letter.
- Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D)
 - Would include a new denominator rule in order to accurately account for all CMRs received as adopted in the final CY 2019 Call Letter.
- Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D)
 - CMS proposes to exclude beneficiaries who elected to receive hospice care at any time in the measurement period and apply this change to the 2020 Star Ratings.
- Statin Use in Persons with Diabetes (SUPD) (Part D).
 - CMS proposes a weight of 3 as is standard practice for an intermediate outcome measure for the 2020 Star Ratings and subsequent years as opposed to 1.
- Improvement measures – measures proposed to be used to calculate the 2020 improvement measures (Part C & D)
 - See list of proposed improvement measures in Table 1 on pg. 110.

CMS is proposing to temporarily remove one measure from the 2020 Star Ratings:

- Controlling High Blood Pressure (Part C)

2020 Star Ratings Program and the Categorical Adjustment Index (CAI)

CMS continues to identify work related to adjusting measures due to socioeconomic status and has contracted with NCQA and PQA to review and determine if measures are sensitive to the composition of plan enrollees and whether modifications to the specifications would be appropriate.

PQA has developed recommendations for risk adjustments for the three medication adherence measures which will be submitted through the NQF endorsement process. CMS notes that if endorsed by NQF, it would consider how to implement PQA recommendations for three adherence measures for 2021 or beyond. In the meantime, CMS plans to test the inclusion of stratification by age, gender, dual eligibility/LIS status and disability status in the Medication Adherence Patient Safety Reports in 2019.

CMS is proposing to expand the adjusted measure set for 2020 CAI measure determination and is proposing that all measures identified as candidate measures will be included in the 2020 CAI value determination. The candidate measure set for the 2020 CAI follows:

Adult BMI Assessment	Annual Flu Vaccine	Breast Cancer Screening	Colorectal Cancer Screening	Diabetes Care – Blood Sugar Controlled
Diabetes Care – Eye Exam	Diabetes Care – Kidney Disease Monitoring	Improving Bladder Control	Medication Reconciliation Post-Discharge	MTM Program Completion Rate for CMR
Monitoring Physical Activity	Osteoporosis Management in Women who had a Fracture	Plan All-Cause Readmissions	Reducing the Risk of Falling	Rheumatoid Arthritis Management

Medication Adherence for Diabetes Medications	Medication Adherence for Hypertension	Medication Adherence for Cholesterol	Statin Therapy for Patients with Cardiovascular Disease	Statin Use in Persons with Diabetes
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Adjustments to the Extreme and Uncontrollable Circumstances Policy

CMS notes the adverse effects that extreme and uncontrollable circumstances can have on plans and their ability to provide accurate performance measurements in the Star Ratings program. Therefore, it is proposing to adjust the 2020 Star Ratings to consider the effects of these circumstances that occurred during the performance period using a similar methodology to the one provided in the 2019 Call Letter with two exceptions:

- CMS proposes to eliminate the difference-in-difference adjustment for survey data as it showed no consistent, negative impact of extreme and uncontrollable circumstances in the 2019 Star Ratings.
- CMS proposes to clarify rules around measures with missing or biased data in the prior or current year.

Updates for 2020 Display Measures

CMS is proposing new display measures for 2020, including:

- Transitions of Care (Part C)
- Emergency Department Visit Follow-Up for Patients with Multiple Chronic Conditions (Part C)
 - MPF Price Accuracy (Part D)
 - As stated in the 2019 Call Letter, CMS proposed enhancements to the MPF Price Accuracy measure to be first published as a display measure in 2020, and then to be considered to be applied to the Star Rating measure for 2022, pending rulemaking. Pending such a change, the current MPF measure will continue in the Star Ratings using the same methodology used for the 2019 Star Ratings.

CMS is proposing to retire one display measures for 2020:

- Transition Monitoring Program Analysis (TMPA) and Formulary Administration Analysis (FAA) (Part D).
 - CMS proposes to discontinue this measure as a result of improvement in formulary administrations and transition practices since the beginning of oversight projects to monitor.

CMS is proposing changes to existing display measure for 2020, including:

- Use of Opioids at High Dosage and from Multiple Providers (OHDMP) and Antipsychotic Use in Persons with Dementia (APD) (Part D)
 - CMS is proposing to implement an updated methodology for the 2020 display page measures (based on 2018 data) that calculate total days supply.
 - When calculating days supply, the following will be applied:
 - Any days supply that extends beyond the end of the measurement period will be excluded.
 - In the case of multiple prescription claims with the same date of service, total days supply will only include the supply of the claim with the longest days supply, and

- In the case of multiple overlapping claims with different dates of service, there will be no adjustments for early fills or overlapping days' supply.
- This change also applies to the following:
 - Use of Opioids at High Dosage (OHD) and Use of Opioids from Multiple Providers (OMP) measures.
 - Concurrent Use of Opioids and Benzodiazepines (COB),
 - Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH).
 - Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) measures.
- Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage Disenrollment Reasons Survey composite measures (Part D)
 - CMS is proposing to pool the two most recent years of survey data for these composites and their component items for all contracts so that each of these composites would include two years of data instead of one.

Removal of Measures for 2020

CMS proposes to remove the following measures from the 2022 Star Ratings:

- Adult BMI Assessment (Part C)
- Appeals Auto-Forward (Part D), Appeals Upheld (Part D)
 - These two measures will be removed for their low reliability over time.

CMS Introduces Potential Changes to Existing Star Ratings and Display Measures in 2020

- Plan All-Cause Readmissions (Part C)
- Medication Reconciliation (Part C)
- Osteoporosis Measures (Part C)
- Care for Older Adults – Functional Status Assessment Indicator (Part C)
- Hospitalization for Potentially Preventable Complications (Part C)
- Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D)
 - Beginning with the 2019 measurement year for the 2021 Star Ratings, CMS proposes to include Skilled Nursing Facility (SNF) stay data from the Common Working File (CWF) if available for MA beneficiaries and MA-PDs.
- Antipsychotic Use in Persons with Dementia (APD) and Statin Use in Persons with Diabetes (SUPD) (Part D)
 - CMS proposed to apply this change to the 2021 measures base on PQA clarification of the specifications to state that that the eligible population received ≥ 2 prescription claims on different dates of service.
- Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) (Part D)
 - CMS began reporting these measures in the Patient Safety reports for the 2018 measurement year. CMS plans to add the measures to the display page for 2021 (2019 data) and 2022 (2020 data). They will consider this measure for the 2023 Star Ratings (2021 data), which would be proposed through rulemaking.

- Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D).
 - PQA finalized changes to the three opioid measures for the 2019 measurement year in the 2019 PQA Measure Manual to better align with the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain as follows:
 - **Measure 1:** Use of Opioids at High Dosage in Persons without Cancer (OHD): The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) over a period of ≥90 days.
 - **Measure 2:** Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The percentage of individuals ≥18 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.
 - **Measure 3:** Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.
- High Risk Medication (HRM) and Diabetes Medication Dosing (DMD) (Part D)
 - CMS will retire these two display measures for 2021 and no longer report these measures in the Patient Safety reports for the 2019 measurement year in an effort to focus on the Polypharmacy measures.

CMS Introduces Potential New Measure Concepts for the Future

- Cross-Cutting Topic – Measure Digitalization (Part C)
- Cross-Cutting Topic – Exclusions for Advanced Illness (Part C)
- Physician/Plan Interactions (Part C & D)
 - CMS is interested in feedback from stakeholders on alternative methods to measure interactions of providers with plans on behalf of beneficiaries., specifically related to plan coverage and payment decisions, claims processing issues, and other common administrative processes.
- Interoperability Measures (Part C)
- Patient-Reported Outcome Measures (Part C)
- Pain Management (Part C)
- Adherence to Antipsychotic Medications for Individuals with Schizophrenia (Part C)
- Antibiotic Utilization Measures (Part C)
- Diabetes Overtreatment (Part C)