February 10, 2025
Filed electronically via federal eRulemaking Portal: http://www.regulations.gov.

Ms. Stephanie Carlton
Acting Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Dear Acting Administrator Carlton:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) Advance Notice of Methodological Changes for Calendar Year (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.[1]

PCMA is the national association representing America's Pharmacy Benefit Manager (PBM)s, which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

We offer in this letter comments on the five main areas addressed below, focusing mostly on Part D benefit redesign and Stars quality measures:

- ***Calculation methodologies for the Annual Percentage Increase (API) and Consumer Price Index (CPI):*** CMS should consider how the impact of Part D benefit changes, including the resultant induced utilization, will be reflected in Prescription Drug Event (PDE) data, and the potential for this to raise the API to unsustainable levels.
- **Part D Premium Stabilization:** CMS should consider providing demo-related bid details prior to the June bid submission deadline. Additionally, CMS should also allow plans to sign up for the demo in Year 2 even if they did not sign up in the initial year.
- **RxHCC Risk Adjustment Model:** CMS should provide additional information and collaborate with plans before the Advance Notice is published so that stakeholders have sufficient time to provide meaningful feedback on different models being considered by CMS.

[1] https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents/2026-advance-notice **2026 Advance Notice**

- **Normalization Factors for the RxHCC Models:** CMS should remain mindful of the risk of creating instabilities in the Part D market and ensure the continued viability of a strong standalone Part D program. To this end, CMS should hold the differentials between MA-PDs and PDPs at current levels.
- **Part C and D Star Ratings and Future Measurement Concepts:** PCMA supports all the recommended measure simplification processes, with some caveats for consideration. We also recommend that CMS create a website that tracks all past, present, and future Star Ratings measures.

I. Calculation methodologies for the Annual Percentage Increase (API) and Consumer Price Index (CPI)

Each year, the numerical thresholds applying to the standard Part D benefit increase by the rate of growth in gross Part D program spending or by the rate of overall inflation. However, we are concerned that CMS's definition of incurred costs for beneficiaries enrolled in plans with enhanced benefits is accelerating the API beyond the actual market-driven changes in pricing for prescription drugs due to this induced utilization of brand and high-cost drugs. For instance, per the CMS Office of the Actuary, private health insurance gross expenditures on retail prescription drugs are projected to increase 3.2% in 2026 and 4.0% in 2027, compared to 12.0% and 11.1% in Medicare, respectively.[2]

In light of these concerns, we ask that CMS consider ways to mitigate the impact on enrollees. While we understand that the API could change as 2025 PDEs are made available, we believe these PDEs could potentially exacerbate the issue by increasing, rather than decreasing, the API. The new maximum Out-Of-Pocket (OOP) and CMS's interpretation of how the $2,000 is achieved through the standard benefit is likely to induce additional spending growth. Further, the Medicare Prescription Payment Plan is also likely to increase utilization of high-cost brand-name drugs.

While we appreciate that the statute requires use of the API to increase benefit parameters, we believe that CMS nevertheless has sufficient flexibility in its calculation of the API to address these concerns. CMS should also consider ways to provide an offramp for enrollees from the premium demonstration so that there is a deceleration in premium increases without a concurrent reduction of benefits offered by plans. Significant increases in the API of 4-5% or higher effectively reduce the richer Part D benefits intended by Congress through the passage of the IRA. For example, the $2,000 Maximum OOP (MOOP) in 2025 is proposed to become $2,100 in 2026 and will only grow from there as the induced utilization beginning in 2025 is reflected in PDE data and so fuels the growth in the API. Thus, the very Part D program changes that are intended to ease the OOP burden for Part D enrollees will, through induced utilization and other Part D program design changes, push up Part D costs and, subsequently,

[2] Source: Projected NHE, Table 11, available at https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected

OOP costs through a higher API. We are concerned that over time, these increases will become unsustainable for enrollees on fixed incomes.

***PCMA Recommendation*: CMS should consider how the impact of Part D benefit changes, including the resultant induced utilization, will be reflected in PDE data, and the potential for such changes to raise the API to unsustainable levels. A prohibitively high API will severely impact access for Part D enrollees most in need, such as those who are on a fixed income but do not qualify for the low-income subsidy.**

II. Part D Premium Stabilization Demonstration Program

In 2025, the Medicare national average monthly bid amount (NAMBA) rose from $63.45 in 2024 to $179.45.[3] The root cause of this increase was Part D redesign changes going into effect that shifted substantial risk from the federal government to Part D plan sponsors. In response to this almost 180% increase from 2024 to 2025, CMS offered standalone Part D plans a new voluntary demonstration program (demo) aimed at stabilizing the market during the IRA's implementation phase.

The intent of the demo is to stabilize the Medicare Part D market by mitigating premium increases and preventing excessive beneficiary churn, specifically within low-income subsidy populations (LIS). However, the demo was only offered after PDP bids were submitted. Plan participation choices made absent knowledge of the demo resulted in a marked decrease in PDP offerings, including leaving some markets with a single benchmark.

To facilitate an increase in PDPs, CMS's Office of the Actuary (OACT) should consider providing demo-related bid information prospectively, in the Final Notice in April. Additionally, CMS should consider allowing new plans to enroll in Year 2 of the demo even if they did not enroll in Year 1, to incentivize plan sponsors to return to the PDP market. These process and programmatic changes could lead to an increase in benchmark plan variety after years of shrinkage.

Any concern CMS may have regarding prospective publication of the demo's details are accounted for in the existing risk corridor reconciliation process.[4] PCMA strongly encourages OACT to release demo-related bid information early this year to allow for plans to consider submitting PDP bids and to build their actuarial bid models with a level of certainty that was unavailable during the CY 2025 bid cycle. Additionally, to the extent that CMS finalizes other significant policy changes in Part D for 2026, such as those related to changes in the coverage of anti-obesity medicines, as proposed in the CY 2026 MA and Part D proposed rule, CMS may need to further expand the premium stabilization demonstration and risk corridor policies, including MA-PDs, due to destabilization of the MA market.

---

[3] https://www.cms.gov/files/document/july-29-parts-c-d-announcement.pdf

[4] CMS begins reconciling these upfront payments with actual benefit costs of plans and applies a statutory formula for risk corridors. The following information elucidates this point clearly. Between 2009 and 2013, between $700 million and $1.1 billion was returned yearly by plans as a rectification of overpayments through risk corridors. *chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf

***PCMA Recommendation*: CMS should consider providing demo-related bid details prior to the June bid submission deadline. Additionally, CMS should also allow plans to sign up for the demo in Year 2 even if they did not sign up in the initial year.**

III. RxHCC Risk Adjustment Model

CMS proposes to implement updates to the RxHCC risk adjustment model in 2026 and provides the option of two alternative models — one that includes the MFP and one that does not. However, there has been no assessment of the differences between the two models. We request more information on the potential changes to risk scores from one model to the other.

When proposing payment changes in Medicare FFS, CMS typically publishes detailed impact analyses that allow providers to understand the implication of their changes. However, for plan payment changes, CMS does not provide any of the tools plan providers need to understand the changes, nor is any information provided that allows plans to provide thoughtful and meaningful responses in regard to alternative approaches.

The published RxHCC model coefficients for the two models by themselves are not sufficient, and the predictive ratios, because they are sorted on predicted rather than actual costs, are also not sufficiently informative. Moreover, CMS should have a consistent approach across Part D for policy changes that reflect net cost. Specifically, CMS should ensure that the model reflects appropriate costs for all drugs, including MFP for both selected drugs and for the generics or biosimilars that get substituted for selected drugs.

***PCMA Recommendation*: CMS should provide additional information and collaborate with plans before the Advance Notice is published so that stakeholders have sufficient time to provide meaningful feedback on the different models being considered by CMS.**

IV. Normalization Factors for the RxHCC Models

CMS states that it will continue calculating separate normalization factors for risk scores used to pay MA-PD plans and PDPs because MA-PD and PDP risk score trends continue to diverge. CMS states that just as for CY 2025, this will ensure that risk scores more accurately reflect Part D costs in each of these two sectors of the Part D market that are driven by a variety of market-based variables, including the overall benefits that they are able to manage, the strategies available for managing Part D costs, and the inability of PDPs to affect the submission of diagnoses in FFS. CMS also states that based on its modeling, it found that MA-PD plan costs tend to be overpredicted, while PDP costs tend to be underpredicted.

The changes in the Part D program caused by the IRA continue to be implemented, causing ongoing benefit design changes throughout the Part D market. Further, the changes to normalization factors are relatively new — taking effect in January 2025 — and the effects of the numerous policy changes, including the calculation of separate normalization factors, are still emerging. Therefore, PCMA believes that the proposed adjustments for 2026 are premature and would widen the differential between PDP and MA-PD payments significantly, before the

results of the first year of differential payments can begin to be understood. We urge CMS to hold the differentials between MA-PDs and PDPs at current levels and not adjust further until CMS has had an opportunity to gather the data and do a thorough analysis of all the contributing factors and impacts on both the MA-PD and PDP markets.

PCMA Recommendation: CMS should remain mindful of the risk of creating instability in the Part D market and ensure the continued viability of a strong standalone Part D program. CMS should hold the differentials between MA-PDs and PDPs at current levels and refrain from adjusting further until it has had an opportunity to gather the data and do a fulsome analysis of all the contributing factors and impacts on both the MA-PD and PDP markets.

V. Part C and D Star Ratings and Future Measurement Concepts

Methodological Considerations

PCMA would like to recommend that any proposed changes to the Star Ratings program should be focused on improving stability, predictability, and the proper measurement of quality and performance. The Tukey outlier deletion methodology has destabilized the Star Ratings program by removing guardrails and setting unattainable cut points. PCMA encourages CMS to put the Tukey outlier deletion policy on hold until it has further evaluated whether the policy is necessary if the guardrails remain in place. Should the agency move forward, we recommend that it delay removal of the guardrails to provide itself an opportunity to determine whether any unintended consequences materialize from the implementation of the Tukey outlier deletion methodology.

PCMA Recommendation: CMS should discontinue use of the Tukey outlier deletion that is applied to certain Star Rating measures currently.

Efforts to Simplify and Refocus the Measure Set to Improve the Impact of the Star Ratings Program:

Given the expansion of measure concepts, PCMA recommends that CMS rely on the Partnership for Quality Measurement (PQM) for initial measure endorsement and maintenance to ensure that new quality measures in the Star Ratings are reliable, feasible, equitable, and meaningful. Only then should CMS submit measures to the Measures Under Consideration (MUC) list for consideration. This judicious process will help CMS identify appropriate measures for the Universal Foundation of quality measures. This universal core set of measures should be aligned across all quality- and value-based care programs throughout the entire care continuum.

As part of the consideration, the proposal to remove operational measures from the Star Ratings program is not widely accepted, as many of these measures provide meaningful and direct feedback on performance. While Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures member experience, these measurements are often too broad to clarify to a plan exactly what is directly contributing to member perceptions. While compliance

monitoring can keep some things in check, the Star Ratings program can influence strategic direction that directly benefits members. PCMA recommends maintaining operational measures but re-evaluating the specific measures. We agree that measures like MPF and contact center measures have topped out in usefulness and now provide diminishing value.

Once a measure has established tenure and stable cut points set by industry performance over the course of several years, CMS could consider transitioning those tenured measures to a pre-determined cut point model — this approach would keep important measures on the Star page in a "maintenance" mode to ensure that performance remains high. Adherence measures, for example, will remain critical to measure outcomes and help to offset avoidable medical costs, but once cut points get to the high 80s and 90s, gameability and waste become a higher risk. There is a tipping point at which higher performance cannot be reasonably expected, given the many clinically appropriate reasons why a member may discontinue therapy.

As part of this simplification process, CMS is also recommending the retirement of process measures such as the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D). PCMA agrees that assessing MTM program outcomes will benefit CMS, plans, and beneficiaries more than capturing completion rates only. However, we recommend that CMS weigh the validity of an outcomes measure against a current measure when more details emerge and validate the comparative utility of the two types of measures.

Concurrent Use of Opioids and Benzodiazepines (COB) (Part D)

Pharmacy Quality Alliance (PQA) updated the COB measure specifications in the draft 2025 PQA Measure Manual to exclude beneficiaries with cancer-related pain treatment diagnosis during the measurement year to align with the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain (2022 CDC Guideline). CMS is proposing to align with the PQA through a non-substantive update under § 423.184(d)(1)(iii) because it updates the clinical codes with no change in the target population or the intent of the measure. PCMA supports this change and encourages CMS to gather stakeholder input first through review of the 2025 PQA Measure Manual.

Medication Adherence for Diabetes Medications/ Medication Adherence for Hypertension (RAS Antagonists)/ Medication Adherence for Cholesterol (Statins)/Statin Use in Persons with Diabetes (SUPD)/COB/Polypharmacy: Use of Anticholinergic Medications in Older Adults (Poly-ACH) (Part D)

For this measure**,** CMS is proposing a non-substantive update to align with the PQA measure changes that exclude contracts with fewer than 30 enrolled members from the measure rate calculations. Contracts with 30 or more enrolled members will be included in the measure rate calculation starting with the 2025 measurement year (2027 Star Ratings). PCMA supports this

change and encourages CMS to gather stakeholder input first through review of the 2025 PQA Measure Manual.

CMS has finalized a deadline for administrative review of underlying data. PCMA asks that CMS consider two deadlines, similar to the preview periods later in the year to review Star scores. The first deadline in May can be the first administrative review, but a second review will be required following PDE close to ensure that all discrepancies due to a lag have been resolved. We recommend a second, later deadline or clarification that the preview periods will provide an opportunity to resolve any remaining PDE discrepancies.

***PCMA Recommendation*: PCMA supports all the recommended measure simplification processes, including measure alignment with PQM, non-substantive updates, and retirement of the current MTM measure. Further, CMS should create a website that tracks all past, present, and future Star Ratings measures.**

Display Measures

Polypharmacy: Use of Multiple CNS-Active Medications in Older Adults (Poly-CNS) (Part D)

PQA updated the Poly-CNS measure specifications and added the skeletal muscle relaxant class of medications. This change was made to align with the 2023 updated American Geriatrics Society Beers Criteria's recommendation to avoid concurrent use of three or more CNS-active medications in older adults because of the increased risk of falls, fractures, and confusion. CMS is proposing to align with the PQA measure specification updates and add the new skeletal muscle relaxant class of medications to the Poly-CNS measure for the 2025 measurement year (2027 display page). Given that a new class of medication is the alignment-related change, PCMA recommends that CMS re-engage in rulemaking and keep the measure on the Display page for at least two years.

Use of Opioids at High Dosage in Persons Without Cancer (OHD)/Initial Opioid Prescribing for Long Duration (IOP-LD) (Part D)

PQA updated the OHD and IOP-LD measure specifications to exclude beneficiaries with cancer-related pain treatment diagnosis during the measurement year to align with the 2022 CDC Guideline. CMS is proposing to align with the PQA measure specification updates and will incorporate this exclusion beginning with the 2025 measurement year (2027 display page). We recommend that any measure changes be preceded by stakeholder review of the 2025 PQA Measure Manual. We strongly suggest that the focus on opioids prescribing also include intensive prescriber education.

***PCMA Recommendation*: PCMA supports all the proposed non-substantive measure updates to align with the most current measure specifications, with the caveat that decision is based on information gathered during stakeholder review of the 2025 PQA Measure Manual. CMS should calculate and provide information to the public on the differences in measure scores even if they consider changes to be non-substantive.**

Financial Reasons for Disenrollment (Part C & D)

This measure captures a variety of reasons related to the cost or affordability of services for leaving a plan. CMS is proposing to replace one general cost-related leave reason (i.e. found a plan that costs less) with three more specific cost-related reasons: 1) found a plan with a lower copayment for prescription drugs (MA & PDP); 2) found a plan with a lower copayment for doctors' visits (MA); and 3) found a plan with a lower monthly premium (MA & PDP). CMS states that the updated measure is currently being tested and will be available for the 2026 Display Page that covers the 2024 measurement year. PCMA supports this measure clarification, given that the measure change will increase the granularity of data and help ascertain the exact reason for a participant's disenrollment.

***PCMA Recommendation*: PCMA supports the proposed measure clarification.**

Health Equity (Part C and D)

CMS is considering adding social risk factors (SRFs) to the Health Equity Index (HEI) reward via an assessment of geography (e.g., rural or urban). PCMA encourages CMS to prioritize the stability of the HEI given all the changes instituted through several recent rules, including the 2025 Rate Announcement and the 2026 Proposed Rule. If geography is added to the HEI reward, we encourage CMS to apply an already existing evidence-based definition of geographic areas. PCMA is concerned that "rural versus urban" may be too broad a definition. Instead, the Area Deprivation Index (ADI) should be considered as an option, even though recent research has pointed out a flaw in the ADI methodology regarding rescaling for housing prices.[5] Additionally, it would be helpful if the urban-rural classification used by the Census Bureau could be improved by including regional segmentation beyond the current urban and rural definition.

***PCMA Recommendation*: CMS should evaluate the impact of all the HEI measure changes before adding a geographic assessment.**

VI. Conclusion

[5] Hannan, Edward L., Wu, Yifeng, Cozzens, Kimberly, and Anderson, Brett. The Neighborhood Atlas Area Deprivation Index for Measuring Socioeconomic Status: An Overemphasis on Home Value, Health Affairs (May 2023): https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2022.01406

We thank CMS for the opportunity to provide comments on methodological changes related to the Part D program redesign. If you need any additional information, please reach out to Tim Dube at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube, SVP, Policy & Regulatory Insights

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA