March 1, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically to PartDRedesignPI@cms.hhs.gov

Re: Draft CY 2025 Part D Redesign Program Instructions.

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the proposed rule titled Draft CY 2025 Part D Redesign Program Instructions.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Changes in True Out-Of-Pocket Costs (TrOOP)

AMCP believes that the true out-of-pocket limit (TrOOP) should predominantly be based on actual payments made by enrollees. TrOOP limits serve as a fundamental safeguard for Medicare beneficiaries, ensuring financial protection against excessive out-of-pocket expenses for prescription drugs. TrOOP limits are designed to cap the total amount that individuals must pay for covered medications within a benefit year, providing relief from the burden of high drug costs. By predominantly basing these limits on actual payments made by beneficiaries, TrOOP provisions aim to offer a transparent and equitable system, wherein beneficiaries can accurately track and manage their healthcare expenditures. This approach also mitigates the risk of third-party payment arrangements distorting the calculation of out-of-pocket thresholds, thus maintaining the integrity and reliability of TrOOP limits. As a cornerstone of Medicare Part D coverage, TrOOP limits play a pivotal role in promoting affordability and accessibility to essential medications for millions of beneficiaries nationwide.

Third-party payment arrangements should not be counted toward the out-of-pocket threshold, except to the extent specifically enumerated in statute or in previously existing regulations (such as amounts reimbursed by supplemental coverage, LIS cost-sharing support, qualified State

Pharmacy Assistance Programs, Indian Health Service and certain other Native American organizations, and AIDS Drug Assistance Programs). AMCP agrees with CMS' decision to not count any other third-party arrangements for 2025 and we encourage CMS to maintain this position in future years.

Given the technical nature of the updates and time needed for Part D sponsors to update their systems to ensure that TrOOP accumulators appropriately account for incurred costs in 2025, AMCP requests that CMS provide CY 2025 PDE reporting instructions as soon as possible to allow for the greatest possible turnaround time in which to make these updates.

Definition of Enhanced Alternative Benefit Design

AMCP is concerned about Part D plans' limited ability to continue to offer enhanced alternative (EA) plans and encourages CMS to consider how best to allow continuing flexibility for these plans to meet the needs of beneficiaries. EA plans encompass a pivotal aspect of Part D plans, offering tailored coverage options to meet the diverse needs of beneficiaries. EA plans need the flexibility to innovate and customize benefits to enhance access to essential medications and improve overall health outcomes. By allowing for greater personalization and specialization in coverage, EA plans play a crucial role in addressing the unique healthcare requirements of individual beneficiaries, ultimately contributing to a more comprehensive and effective healthcare system.

AMCP applauds CMS' reconsideration of how to define an EA benefit design by estimating the value of the EA plan relative to the value of the defined standard (DS) Part D drug benefit. AMCP agrees that not establishing a specific threshold for this value is the right approach.

PDP Meaningful Difference

AMCP supports establishing an absolute percent threshold for evaluating Prescription Drug Plan (PDP) meaningful difference. The meaningful difference standard is a critical metric used to evaluate the distinctiveness and value of different plans available to Medicare beneficiaries. An absolute percent threshold for assessing meaningful difference would hold PDPs to a standard that ensures meaningful variations in coverage and benefits. This approach eliminates the need for annual inflation adjustments, providing consistency and clarity in plan differentials over time. Additionally, it underscores the importance of formulary robustness and benefit design by ensuring that the coverage provided by PDPs is not only different but also comprehensive and beneficial to beneficiaries. By promoting competition and innovation among plans, PDP meaningful difference safeguards beneficiary choice and encourages the development of plans that truly meet the diverse healthcare needs of Medicare enrollees.

Medical Loss Ratio (MLR)

AMCP's members appreciate the clarification from CMS that the Discount Program payment and the Inflation Reduction Act Subsidy Amount (IRASA), must be excluded from the denominator of the MLR calculation, and associated expenditures excluded from the numerator of the MLR calculation. This approach will help to ensure that the Discount Program payment and the IRASA do not distort the MLR calculation. As the ratio of healthcare expenditures to premium revenue, MLR provides insights into how efficiently insurers are utilizing funds to provide healthcare services to enrollees. This transparency and accountability in spending

ultimately benefits consumers by promoting fair pricing, quality care, and financial stability within the healthcare system.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer