



September 20, 2023

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 via regulations.gov

Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans:
Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the
Social Security Act for 2025, and Solicitation of Comments

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thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the draft guidance titled “Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments” (Draft Part One Guidance) issued on August 21, 2023.

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.

AMCP commends CMS for its continued efforts to reduce out-of-pocket costs for patients. AMCP shares CMS’ commitment to ensuring access to low-cost medication to improve the health outcomes of patients.

Implementation

AMCP and its members are concerned about ensuring timely implementation of the Medicare Prescription Payment Plan (MPPP) given the complexity of the requirements and the short turnaround time before the effective date. While the Draft Part One Guidance notes that it will be finalized by spring 2024 and that a draft part two guidance will be issued in early 2024 and finalized by spring or summer 2024, AMCP is concerned that CMS’ timeline does not give plans enough time to adequately prepare for implementation by January 1, 2025. Plans need to complete a variety of technical changes, including but not limited to creating opt-in, billing, and payment processes; drafting and finalizing communications to MPPP participants (Participants)

and prospective Participants; coordinating with pharmacies regarding claims processing changes; and implementing new data submission requirements. Given the heavy lift needed for this implementation, plans need information and guidance from CMS as soon as possible. AMCP urges CMS to accelerate its timeline for issuing guidance such that all final operations guidance is given to plans with sufficient time to implement all facets of the MPPP by the effective date.

Because of this difficulty with implementing a new program in a short timeframe, AMCP also urges CMS to use its enforcement discretion during the first year of the MPPP for plans that have made good faith efforts to comply with its requirements. AMCP asks for understanding that plans are moving as quickly as possible to implement this complex program with limited resources while awaiting final guidance on important aspects of the MPPP.

Participant Billing Requirements

AMCP applauds CMS for encouraging Part D sponsors to offer multiple payments methods, such as electronic funds transfer (EFT), cash, or check. AMCP encourages CMS to expand on these enumerated options by expressly listing pre-pay and auto pay mechanisms in its final guidance. These options would reduce the likelihood of missed payments. AMCP also encourages CMS to allow Participants to deduct payments from Social Security. AMCP urges that CMS should encourage as many payment options as possible.

The Draft Part One Guidance notes that, while Participants may pay more than the maximum monthly cap, Participants cannot pay more than their total out-of-pocket costs incurred. AMCP encourages CMS to allow Participants the option to pay up to the maximum out-of-pocket (MOOP). The Part D sponsor would then use the financial reconciliation outlined in Section 1860D–2(b)(2)(E)(v)(III)(gg) of the Inflation Reduction Act (IRA) to adjust for any overpayment. This approach would give each Participant the greatest amount of flexibility and control when determining the payment options that work best for their individual circumstances.

Requirements Related to Part D Enrollee Outreach

AMCP supports the development of a uniform, national communication strategy to educate Medicare enrollees and others. The overall approach should incorporate a variety of tools and messengers to ensure the broadest reach. AMCP's members would welcome additional guidance, model documents, and training materials to assist them in their outreach efforts. Standardized communications for insurance plans, pharmacies, pharmacists, and providers would help to ensure consistency and clarity.

AMCP encourages CMS to update the Medicare.gov Plan Finder website to include information about the MPPP and the out-of-pocket cap to help beneficiaries when selecting a plan.

We suggest that CMS provide educational materials and guidance to pharmacies while encouraging pharmacies to provide education programs to alert front-line pharmacy employees about the MPPP. This would help to alleviate the potential for confusion for these employees, Participants, and prospective Participants alike. Front-line pharmacy employees need to understand how the MPPP will work so that they can adequately respond to inquiries from prospective Participants. They also need to learn how to correctly process MPPP claims. If a point of sale (POS) election option is implemented, these employees will also need to

understand any new processes to ensure that patients are able to opt in while interacting with the front-line pharmacy employees.

Prohibition on Part D Enrollee Discrimination

AMCP's mission is to improve Americans' health by ensuring access to high-quality, cost-effective medications and other therapies.¹ For this reason, AMCP supports CMS' prohibition on discriminating against or inhibiting access to the MPPP for any Part D enrollee, including those eligible for the Low-Income Subsidy (LIS). Eligibility for the LIS is based on an enrollee's income and other assets, which must be below specified levels. The goal of the LIS program is to increase access to needed prescription medications and to support medication adherence by lowering the cost barrier. AMCP believes that all Part D members should be able to avail themselves of the potential benefits of the MPPP.

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

¹ One of AMCP's strategic priorities is to address health disparities in medication use and access. See <https://www.amcp.org/about/about-amcp/amcp-strategic-priorities> for more information.