



March 15, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to provide comments on the part two guidance on select topics related to the Medicare Prescription Payment Plan (MPPP).

The American Lung Association is the oldest voluntary public health association in the United States, representing the more than 34 million individuals living with lung disease. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

Approximately 25% of seniors report difficulty affording their medications and three in ten adults have not taken their medication as prescribed due to costs.¹ The Lung Association strongly supported the out-of-pocket (OOP) cap in Medicare Part D and related policies to spread patients' prescription drug costs over the year included in the Inflation Reduction Act. If implemented well, these policies will be a huge step forward in improving the affordability of medications for seniors in Medicare Part D, especially for people with lung disease who often rely on multiple medications to manage their conditions. The Lung Association looks forward to working with you on the implementation of these policies and offers the following comments on the part two guidance.

Outreach, Education, and Communications Requirements for Part D Sponsors (Section 30)

The Lung Association appreciates the outreach and education requirements outlined for Part D sponsors in the draft guidance. A robust outreach and awareness strategy will help patients and other stakeholders understand the OOP cap and their ability to spread payments out over a calendar year, especially since recent polling suggests that only one third of seniors are aware of the upcoming annual OOP prescription drug limits for people with Medicare coverage.² As outlined below, CMS should broaden the outreach and education efforts required for Part D sponsors in the draft guidance to ensure that as many patients as possible understand the availability of the MPPP and can make informed decisions on whether or not they benefit.

Targeted Outreach and Education Requirements for Part D Sponsors (Section 30.2)

Identifying patients likely to benefit from the MPPP prior to the beginning of the plan year or as early as possible in the plan year will be critical to the success of the program. The Lung Association supports the requirement that Part D sponsors conduct outreach to enrollees likely

to benefit from the MPPP based on their OOP costs in the previous plan year, specifically patients who reached the \$2,000 threshold by September of the previous plan year.

However, many patients will not realize that they will benefit from the MPPP until faced with high OOP at the pharmacy. In the final part one guidance, CMS set the threshold for when pharmacists must notify patients about the MPPP at \$600 for a single prescription. This is significantly higher than the threshold the Lung Association recommended in our comments on the part one guidance.³ Additionally, by considering only considering the costs of a single prescription, rather than the cost of all prescription the patient is collecting at the pharmacy that day or their OOP costs to date, the policy will significantly limit program enrollment. We encourage CMS to reconsider this approach and adopt a broader threshold for determining which patients will likely benefit from enrollment and must receive additional information about the MPPP.

Communications with Program Participants and Model Materials Requirements for Part D Sponsors (Section 30.3)

The Lung Association appreciates the list of model documents that CMS will develop for Part D sponsors and looks forward to providing additional feedback on those later this spring. A strong set of model document documents will be essential to reduce patient and consumer confusion about this program. We recommend that CMS conduct user testing with diverse stakeholders to directly collect feedback from patients and others who will be assisting patients with enrollment. Additionally, CMS should require Part D sponsors to promptly follow up with enrollees within specific timeframes to collect any missing information to complete election requests. CMS should also require Part D sponsors to put review and appeal processes in place before terminating enrollment, as well as provide robust support services to help patients navigate enrollment and request assistance with financial difficulties.

Beyond these notices, the Lung Association recommends that CMS require Part D sponsors to provide additional tools to help patients understand the MPPP and determine whether they will benefit. For example, simple online calculators and other similar tools that allow patients to input expected prescription drug costs and determine whether opting into the MPPP makes sense for them should be available for the upcoming open enrollment period. CMS should also include guidance to Part D sponsors about additional communications tactics, such as information sessions and community events, to educate patients about the MPPP, especially in the first few years of implementation when the most robust education and awareness efforts will be needed.

Language Access and Accessibility Requirements (Section 30.4)

The Lung Association supports the language access and accessibility requirements outlined in the draft part two guidance, including requirements for translating documents, sharing information about free interpretation services, and complying with website accessibility requirements. While these are important steps for helping patients with limited English proficiency and people with disabilities enroll in the MPPP, additional activities are needed to ensure the program reaches a diverse population. CMS should encourage Part D sponsors to invest in meaningful efforts to reach underserved populations and partner with community organizations with relevant expertise to educate patients about the MPPP.

CMS Part D Enrollee Education and Outreach (Section 40)

The Lung Association appreciates CMS's commitments to develop new educational resources and modify existing Part D resources to include information about the MPPP. Additional detail

on these communications will help outside stakeholders, including the patient advocacy community, plan for the upcoming open enrollment period and support our patients throughout this process. CMS should adopt the same recommendations outlined above for Part D sponsors about developing additional tools like monthly OOP calculator and committing to specific education and awareness efforts to reach underserved populations as part of the agency's own education and outreach plan. We encourage you to work with patient groups and their call center staff, state health insurance assistance programs and other key stakeholders in the patient and consumer advocacy communities to maximize their networks and outreach.

Other Implementation Issues

Strong monitoring and oversight will be important during this period of significant change for Medicare Part D. In addition to our previous recommendations about closely monitoring the impact of the MPPP and other parts of the Part D redesign to address potential unintended consequences for patients,⁴ CMS should closely monitor outreach and enrollment efforts to track uptake of the program, including collecting and releasing data on the demographics of enrollees, and identify any barriers to enrollment to address in future years.

Finally, the final part one guidance confirms that point of sale enrollment will not be in place for 2025. The Lung Association continues to believe that point of sale enrollment is an essential feature of successful MPPP implementation and encourages CMS to implement this as soon as possible. Without a point of sale enrollment option, some patients unable to afford a prescription will simply not fill it, jeopardizing management of their health condition and putting them at greater risk for emergency room visits and other negative health outcomes.

Conclusion

Thank you for the opportunity to provide these comments. We look forward to continuing to partner with you on the implementation of these critical policies to help reduce patients' prescription drug costs in Medicare.

Sincerely,



Harold P. Wimmer
President and CEO

¹ KFF, Public Opinion on Prescription Drugs and Their Prices. Updated August 21, 2023. Available at:

<https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>.

² KFF, KFF Health Tracking Poll July 2023: The Public's Views Of New Prescription Weight Loss Drugs And Prescription Drug Costs. August 4, 2023. Available at: <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs/>.

³ American Lung Association, Comments to CMS 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. September 19, 2023. Available at:

<https://www.lung.org/getmedia/50c0f560-442a-466c-9f12-13bbbd2da5f3/American-Lung-Association-MPPP-Guidance-Comments.pdf>.

⁴ Id.