



September 20, 2023

Sent Electronically

Meena Seshamani, M.D., Ph.D.

Deputy Administrator and Director, Center for Medicare & Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244

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 Deputy Administrator Seshamani,

Thank you for the opportunity to provide comments on this draft part one guidance on a select set of topics related to the Medicare Prescription Payment Plan (MPPP). Our organizations represent millions of people living with severe and chronic health conditions such as cancer, multiple sclerosis, lung disease, epilepsy, cystic fibrosis, arthritis, and many rare diseases.

Many of the patients we represent will save thousands of dollars each year due to the Inflation Reduction Act's (IRA) annual \$2,000 out-of-pocket cap. Yet, while the annual cap is a landmark new patient protection, many Medicare enrollees will not see its benefits if they cannot afford to fill their initial prescriptions due to high upfront out-of-pocket costs. **That's why the MPPP is so important: it ensures every Medicare enrollee has an opportunity to eliminate upfront costs at the pharmacy point-of-sale and thereby unlock the benefits of every other provision intended to lower the cost of prescription drugs.**

The stakes are high. If implemented effectively, we are confident the MPPP will greatly benefit our patients, increase medication adherence, and break down the barrier of upfront costs that contribute to health inequity and too often prevents beneficiaries from accessing needed care. At the same time, if CMS falters in implementing critical aspects of the MPPP, patients will continue to be forced to leave even lifesaving prescriptions unfilled, and many enrollees will never experience the benefits of the IRA's landmark Part D benefit reforms. As you undertake this important work and finalize the draft guidance, we offer the following perspective on three critical priorities for the patients we represent: protecting patients from being locked out of the MPPP, facilitating pharmacy point-of-sale election in 2025, and promoting robust communication to enrollees about this new program.

Protecting Patients from “Lockout”

Section 11202 of the IRA included a “lockout” provision allowing Part D plans to preclude an individual patient from electing into that plan’s MPPP in a subsequent year due to a missed monthly payment. Many of our organizations worked closely with Congress as they crafted this provision and related provisions of the IRA, and **we applaud CMS for implementing this provision in line with Congress’s intent to provide plans the flexibility to prevent enrollees with overdue monthly payments from accruing additional obligations while simultaneously protecting access to the MPPP for enrollees who have paid all overdue monthly payments.**

Specifically, our organizations applaud CMS for outlining a framework that, first, provides consumer protections that will help prevent patients being penalized for unintentionally missing a monthly payment and, second, clearly protects enrollees who have repaid all owed MPPP payments from being barred from their plan’s MPPP. Regarding the former, we appreciate CMS requiring part D plans to provide individuals with comprehensive notice regarding a missed payment, establish and offer a dispute process, and ensure a grace period of at least two months when an individual has failed to pay by the due date before disenrolling them from the payment program. Regarding the latter, we strongly support CMS’s draft guidance provisions in section 80.3 establishing a clear standard that requires Part D plans to permit an enrollee to opt in to the MPPP after the enrollee has paid off outstanding balances.

We urge CMS to preserve this framework in the final guidance, both to ensure alignment with Congressional intent and to establish clear, consistent rules for facilitating access to MPPP for Part D enrollees.

Point-of-Sale Election

As we previously stated, a clear and orderly enrollment process is one of the most important elements to ensure that every Medicare Part D enrollee has the opportunity to benefit from the MPPP. Maximizing opportunities for Medicare beneficiaries to elect into the MPPP is key, given the enormous challenge of educating all Part D enrollees on the MPPP and what it would mean for their changing circumstances. As such, we appreciate the Centers for Medicare & Medicaid Services (CMS) for including language in the draft guidance that requires plans to allow patients to elect into the Payment Plan before the plan year begins, during the plan selection and re-enrollment process, when switching between plans, and throughout the plan year.

At the same time, we consider it unacceptable that the draft guidance contemplates no point-of-sale election mechanism in 2025 and even expresses openness to delaying point-of-sale election beyond 2026. To be clear, **without point-of-sale election, many Medicare enrollees will fail to experience a benefit from the IRA’s other provisions, including the annual out-of-pocket cap and other reforms intended to lower the cost of prescription medications.**

Congress included the MPPP as a core component of the 2025 Part D redesign because lawmakers were keenly aware that patients were leaving necessary, often lifesaving, prescriptions at the pharmacy because they could not afford the upfront costs. Without a point-of-sale election process, many Medicare patients will be left behind—unable to fill critical, time-sensitive medications when they need it most. These Medicare enrollees would face the same decision they faced prior to the IRA: Pay thousands of dollars upfront for their prescription or leave it behind.

Importantly, our organizations anticipate point-of-sale election as being even more integral in 2025 than in later years. Particularly as the program is new in 2025, fewer patients will elect to participate until they are faced with a costly prescription and understand how the MPPP protects them from upfront costs. Given the novelty of this program, enrollees in 2025 may not understand or trust that an urgent election request would be processed in a timely way and may not return to the pharmacy to get their medication. As a result, we would continue to see high rates of prescription abandonment due to upfront costs at the pharmacy—the very issue Congress sought to address by establishing the Medicare Prescription Payment Plan in 2025.

We strongly urge CMS to swiftly implement a POS enrollment solution for 2025 instead of waiting until 2026. We recognize that, to achieve this goal in 2025, CMS has two key issues to address: the logistics of facilitating election at the point-of-sale and how to avoid disruption to the workflow at dispensing pharmacies.

To address the issue of logistics, we urge CMS to leverage one or more existing Part D program mechanisms to facilitate point-of-sale election. The IRA already requires pharmacy staff to inform enrollees of the fact that they may benefit from opting into the MPPP. If an enrollee having received this information would like to avail themselves of the lower upfront costs provided by the MPPP, CMS should establish a process building on the existing “transition fill” process used to facilitate access to medications when an enrollee switches plans or the existing “Best Available Evidence” process that allows point-of-sale enrollment in LINET, or an altogether new mechanism that automatically informs the enrollee’s plan of the enrollee’s decision to opt into MPPP and allows the enrollee to secure their prescription with zero-dollar upfront cost sharing. At a minimum, real-time enrollment via telephone should be available for enrollees who need to enroll at the point-of-sale. Regardless of which approach is used, there is no need for complex math during the enrollee-pharmacy interaction because the election of MPPP always results in the same upfront, point-of-sale cost-sharing: \$0.

To address the issue of pharmacy workflow, we recommend that CMS consider a first-year implementation strategy that focuses on ensuring point-of-sale election in specialty and mail-order pharmacies. Specialty pharmacies represent a small fraction of all US pharmacies. This small subset of total pharmacies are already accustomed extended patient-pharmacy staff interaction at the point-of-sale, including discussions about out-of-pocket cost, and routinely dispense the types of medications most often associated with high out-of-pocket burden. In contrast, retail community pharmacies see a much greater share of patients who have less-expensive medications and thus face lower upfront out-of-pocket costs under the traditional Part D benefit design. A point-of-sale election policy that facilitates point-of-sale election at specialty pharmacies is less than ideal, but it would promote access to this critical benefit to the patients likely to face the highest out-of-pocket costs while causing no workflow disruption for the vast majority of US pharmacies.

Outreach and Education

Communicating the MPPP program to Medicare enrollees ahead of and during the 2025 plan year will be a monumental task, requiring CMS to partner with a myriad of stakeholders to promote consistent and helpful outreach and education efforts. Beneficiaries, plans, pharmacies, and other patient and consumer resources—such as State Health Insurance Assistance Programs (SHIPs) and nonprofit patient organization call centers—will need extensive engagement with CMS to fully understand MPPP election and its implications. We applaud CMS for outlining outreach responsibilities for each of these entities

and look forward to part two of this guidance that will include model language, supporting materials, and specifics on outreach and education by plan sponsors, pharmacies, and CMS.

As CMS prepares for the second part of this guidance, our groups urge you to prioritize a shortlist of important components. We urge CMS to specify which Part D plan education and promotional materials must include information on the MPPP (such as Annual Notice of Change and Evidence of Coverage documents on Part D plan websites). The Medicare Plan Finder can be an excellent resource to educate beneficiaries who are exploring their plan options about the MPPP program. We strongly encourage CMS to include MPPP information in the Medicare Plan Finder tool. We also recommend CMS provide extensive, proactive consumer education ahead of and during the 2025 plan year open enrollment, including mailed notices, email notices, prominent Medicare website notices, and other mechanisms.

As it relates to this guidance, in Section 40 of the draft guidance, CMS outlines the extensive list of information that must be included in MPPP billing statements to ensure MPPP participants understand the program and their responsibilities. As CMS finalizes this list and provides plans guidance on structuring these statements, we urge CMS to emphasize that communication regarding participants monthly payments should prioritize clear, actionable information on the first page. We suggest that the first page of plan communication regarding program payments be simple and emphasize: the total payment amount required for the month; consequences for failing to pay on time, including the required grace period; a simple breakdown of any changes from last month's payment and expected payment for the following month; and a reminder that the consumer will pay no more than \$2,000 in prescription costs for the year.

Conclusion

We look forward to working together with CMS to ensure the successful implementation of the MPPP, and we welcome the opportunity to meet and discuss our recommendations further. If you have any questions or would like to follow up in any way, please contact Beverly Hart at Beverly.Hart@lls.org.

Sincerely,

The Leukemia & Lymphoma Society
American Cancer Society Cancer Action Network
American Lung Association
Arthritis Foundation
Cystic Fibrosis
Epilepsy Foundation
National MS Society
National Organization for Rare Disorders