

**March 15, 2023**

**VIA ELECTRONIC SUBMISSION — PartDPaymentPolicy@cms.hhs.gov**

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**RE: Medicare Prescription Payment Plan Guidance – Part Two**

Dear Dr. Seshamani,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the *Medicare Prescription Payment Plan: Draft Part Two Guidance*.<sup>1</sup> PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly \$101 billion in 2022 alone. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

Medicare Part D represents an unparalleled success in health care policy, with more than 90% of seniors consistently reporting satisfaction with the program<sup>2</sup>. In the two decades since it was created, the program – grounded in competition among competing Part D plans - has consistently come in below initial cost estimates, with annual spending growth in recent years lower than other parts of Medicare.<sup>3</sup> At the same time, the program supports coverage and access to critical treatment advances for over 50 million beneficiaries. Thanks to its competitive structure for market negotiation, the average cost per prescription in Medicare Part D fell from \$57 in 2009 to \$50 in 2018,<sup>4</sup> while improved beneficiary access and adherence to prescribed therapies has reduced other health and caregiver expenses like costly hospitalizations.<sup>5</sup>

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<sup>1</sup> CMS, 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, Feb. 2024

<https://www.cms.gov/files/document/medicare-prescription-payment-plan-draft-part-two-guidance.pdf>

<sup>2</sup> Medicare Today. Senior Satisfaction Survey 2023. Found at: <https://medicaretoday.org/resources/senior-satisfaction-survey/>

<sup>3</sup> See CBO Medicare Baselines available at [www.cbo.gov](http://www.cbo.gov).

<sup>4</sup> CBO. Prescription Drugs: Spending, Use, and Prices. January 2022

<sup>5</sup> De Avila, J. L. M., D.O.; Zhang, J.X. (2021). Prevalence and Persistence of Cost-Related Medication Nonadherence Among Medicare Beneficiaries at High Risk of Hospitalization. In JAMA Network Open (Vol. 4, pp. e210498)

Major benefit design changes were included as part of the Part D redesign provisions of the Inflation Reduction Act (IRA), including a maximum annual cap on out-of-pocket (OOP) costs, paired with a maximum monthly cap on cost sharing program in which Part D enrollees may elect to participate. This program, which CMS named the Medicare Prescription Payment Plan (MPPP), represents an opportunity to build on the fundamental strengths of the Part D program and further improve affordable access to the range of medicines needed by beneficiaries, particularly those facing multiple costly diseases and conditions. Ensuring successful implementation of the MPPP requires careful policy development and effective outreach to beneficiaries likely to benefit from the program, and we appreciate the opportunity to provide input.

Further, these provisions of the IRA, the OOP cap coupled with spreading costs over time (“smoothing”), have a history of broad bipartisan support from a wide range of stakeholders. To that end, PhRMA has long supported increased affordability and predictability of patient OOP costs – including with an OOP cap and smoothing policy in Part D<sup>6</sup> – in an effort to increase access to medicines. Moreover, many other stakeholders have also recognized the affordability challenges of Medicare beneficiaries and called for the OOP cap on Part D costs coupled with the ability to “smooth” those costs out over time.<sup>7</sup> Further, numerous drug pricing reform bills in recent years<sup>8</sup> included an approach to capping OOP costs in Medicare Part D, coupled with the smoothing concept.

Thus, as the Administration moves forward with laying out the rules, operational mechanics, and outreach and education parameters of MPPP, we wish to call attention to the program’s history of bipartisan support and remind the Administration that implementing the program is a rare opportunity for bipartisan collaboration towards an important, patient-centered policy goal. In this context, PhRMA first submitted comments on the MPPP program in June 2023 as part of our response to CMS’ HPMS email, *Solicitation for feedback on IRA Part D Redesign*<sup>9</sup> and again in September 2023 in response to the draft *Medicare Prescription Payment Plan Guidance – Part One*.<sup>10</sup> In both sets of comments, we encouraged CMS to develop key education and outreach tools for beneficiaries on the program, to keep beneficiary protections at the forefront of operational calculations and effectuation decision-making, and not to delay decisions related to infrastructure and effectuation details. Our comments were intended to ensure the program meets its goal of improving affordability for Medicare beneficiaries.

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<sup>6</sup> [https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/Better-Way-Assets/Better-Way\\_Proactive-Agenda1.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/Better-Way-Assets/Better-Way_Proactive-Agenda1.pdf)

<sup>7</sup> <https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/>; <https://www.medicarerights.org/medicare-watch/2022/04/14/further-evaluation-of-potential-caps-in-part-d-shows-promise-for-beneficiary-impact>; <https://www.urban.org/research/publication/capping-medicare-beneficiary-part-d-spending-2000-who-would-it-help-and-how>

<sup>8</sup> See H.R. 19 and S. 3129 in the 116<sup>th</sup> Congress

<sup>9</sup> <https://phrma.org/resource-center/Topics/Medicare/PhRMA-Comments-to-CMS-on-the-Calendar-Year-CY-2025-Part-D-Redesign>

<sup>10</sup> [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-Comments-on-MPPP-Guidance\\_Final-92023.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-Comments-on-MPPP-Guidance_Final-92023.pdf)

We appreciate the opportunity to comment on Part Two of the Draft Guidance and provide feedback on outreach and education by CMS, plans, and pharmacies. We also appreciate that CMS has released the MPPP Model Documents and we will provide comments on those through the ICR process.

While successful implementation of the MPPP program is important to improve beneficiary affordability for needed medicines, these improvements will not deliver any benefit if patients cannot gain access to needed treatments due to coverage denials or restrictive utilization management. To that end, in parallel with effective implementation of the MPPP program, we urge CMS to give increased attention to the growing access barriers faced by beneficiaries as a result of formulary exclusions, prior authorization requirements and step edits imposed by Part D plans.<sup>11</sup> While these tools play a role in plan negotiation with manufacturers to manage program costs, there is growing concern that provisions of IRA, including the “Maximum Fair Price” provisions, will lead to increased, cost-based UM restrictions that prevent patients from gaining access to beneficial treatment options. PhRMA has addressed these concerns in more detail in separate comments to the Agency on its MFP guidance for IPAY 2026,<sup>12</sup> and other Part D guidance and rulemaking opportunities.<sup>13</sup> We urge the Agency to take steps to ensure beneficiaries continue to enjoy access to a range of treatment options in Medicare Part D.

PhRMA would like to address the following issues and make these recommendations to CMS in the MPPP Draft Part Two Guidance. Specifically,

- CMS should launch robust education and outreach program to beneficiaries on MPPP and other changes to Part D program, with targeted MPPP materials as well as updated Medicare educational resources.
- CMS should create and finalize an interactive calculator to assist Medicare beneficiaries in understanding how the MPPP could change their costs.
- MPPP model documents should be standardized, to ensure consistent information is available to Medicare beneficiaries across plans and to ensure efficiency in rolling out MPPP communications.
- CMS should require plan sponsors to notify beneficiaries who are likely to benefit from MPPP in advance and throughout the plan year, including those with costs at the LTB threshold and also those who could benefit from MPPP due to their cumulative OOP costs.

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<sup>11</sup> Joyce G, Blaylock B, Chen J, VanNuys K. Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2010-2020. *Health Affairs* 2024; 43(3) 391-397.

<sup>12</sup> <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/PhRMA-Comments-on-CMS-Initial-Guidance-on-Medicare-Drug-Price-Negotiation-Program22948.pdf>

<sup>13</sup> <https://phrma.org/resource-center/Topics/Medicare/PhRMA-Comments-to-CMS-on-the-Calendar-Year-CY-2025-Part-D-Redesign>

- CMS should reconsider the pharmacy POS threshold as a \$600 per script threshold for LTB is too high. In addition, the MPPP LTB notification should also include educational information and instructions for opting in to MPPP.
- CMS should monitor beneficiary complaints and grievances on MPPP and also monitor plan bids for predicted loss calculations.

Please see our detailed comments and recommendations below.

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## **Section 30. Outreach, Education, and Communications Requirements for Part D Sponsors**

### ***30.1 General Outreach and Education***

Part D beneficiaries have different financial situations and many choices for prescription drug coverage today, resulting in highly varied OOP costs for medicines. For this reason, general outreach and education on the MPPP program as well as the other significant changes to the Part D program will be critical to ensuring that beneficiaries have a clear understanding of the current benefit structure and how opting into the MPPP may impact their monthly OOP costs. As noted by CMS, the program is likely to offer significant benefit to many enrollees in improving drug affordability but will not offer the same benefit to all enrollees. Successful implementation of MPPP will require broad education to raise awareness of the program and clearly explain the potential benefit and how to elect the program. Further, because enrollee election into MPPP is voluntary, beneficiary education and outreach will be a critical factor in both the uptake and the success of the program, especially in the early years of MPPP implementation.

To that end, we reiterate earlier comments that **CMS should launch a robust education and outreach campaign to all Medicare beneficiaries on the many changes to the Part D program**, well in advance and independent of the annual open enrollment education and outreach activities conducted by CMS each year to ensure the new benefit structure and affordability improvements in Part D are well understood by all Part D beneficiaries.

In addition, PhRMA supports CMS' requirement to include information about the MPPP program in specific plan materials provided to prospective and current Part D enrollees (e.g., the Membership ID Card, Evidence of Coverage [EOC], Annual Notice of Change [ANOC], Explanation of Benefits [EOB]).

The statute requires that Part D sponsors provide notifications and educational materials about participation in the MPPP program to current and prospective Part D enrollees. CMS states it will provide model educational materials to support Part D sponsors but also allow sponsors to develop their own materials if they "accurately convey" program information to satisfy education and outreach requirements. PhRMA disagrees with this approach. Given the lack of clear, prescriptive guidance from CMS, PhRMA is concerned individually created content

by each plan sponsor could lead to significant variation across Part D plan materials and cause confusion for beneficiaries. **To ensure that every Part D beneficiary has access to clear and consistent educational materials regarding the MPPP, CMS should clearly specify the exact program language Part D sponsors must include in their educational materials. Also, as described in more detail in section 30.3, CMS should require further standardized language in model notices – particularly language conveying the fundamentals of the program – to ensure all Medicare beneficiaries receive the same information about the MPPP. Given the importance of the program and other recent actions by CMS to strengthen oversight of plan communications to Part D beneficiaries, deferring to health plans to “accurately convey” program information is not a suitable approach.**

Additionally, PhRMA concurs that the statutory requirement for Part D sponsors to include information about the MPPP in enrollee educational materials includes providing information on their websites. However, because plan websites vary across sponsors, **PhRMA encourages CMS to require a standardized, easily accessed location for MPPP information on plan websites.** Specifically, PhRMA recommends that CMS require plans to include a notification about the MPPP program on the plan’s home page, linking to more detailed information and any CMS-developed tools to illustrate potential beneficiary OOP costs, such as a real-time calculator. CMS should also provide clear guidance on the form and manner in which MPPP enrollment election is presented to beneficiaries. Such a requirement would ensure that information about the program is not buried in a hard-to-reach location on the sponsor’s website, will assist in building awareness of the MPPP program, and is more likely to offer beneficiaries likely to benefit the ability to opt in before the point-of-sale at the pharmacy.

CMS also requires that Part D sponsor websites provide several examples of how the program calculation works. **PhRMA encourages CMS to create standardized example calculations for use on plan websites – for example, adjusting the example calculations provided in the draft Part 1 guidance to be easily understood by beneficiaries – to ensure consistent information and calculations are shared by all plans and accessed by all beneficiaries.**

## **Section 30.2 – Targeted Outreach and Education Requirements for Part D Sponsors**

### ***30.2.1 Notice for Part D Enrollees Likely to Benefit***

PhRMA supports the development of a standardized document to notify beneficiaries who are deemed likely to benefit (LTB) about opting into the MPPP to ensure consistent and uniform awareness of the program and its advantages, regardless of a beneficiary’s choice of Part D plan. In addition to requiring use of the standardized LTB notice, CMS should ensure the notice also includes both substantial educational information about the program along with instructions of immediate actions the beneficiary may take, including:

- Personalized information regarding why that beneficiary is receiving the LTB notice (e.g., costs in prior year at catastrophic level vs. being prescribed a higher cost medicine and notified by plan during UM process vs. at pharmacy with \$600 threshold);
- A clear description of steps necessary to opt into the program;
- Clear instructions if additional documentation or forms are needed for this election; and
- Where to receive more information and patient resources on the program and its benefits

### **30.2.2.1 Identifying Part D Enrollees Likely to Benefit Prior to the Plan Year**

PhRMA supports the requirement for Part D plan sponsors to engage with beneficiaries that are LTB prior to the start of the 2025 plan year. We note that targeted outreach by plans is most likely to be effective when it occurs prior to the point of sale and the advance notification can also ensure beneficiaries have time to understand the program in advance and seamlessly elect into the MPPP.

**While we support CMS' requirement for plans to assess beneficiary costs based on their 2024 OOP spending, and notify beneficiaries accordingly, PhRMA urges CMS to consider the implications of not assessing a full year of OOP cost data in identifying beneficiaries likely to benefit for MPPP in 2025.** Failing to review OOP costs in the last quarter of 2024 will exclude beneficiaries who reached the \$2,000 target OOP maximum in the last quarter of 2024, even though their total OOP costs would demonstrate that they may still benefit from participating in the MPPP.

We therefore **urge CMS to require plans to assess and notify beneficiaries with \$2,000 in OOP costs both in September and also again at the end of the plan year.** A 2023 ADVI analysis found that 40% of non-low-income subsidy (non-LIS) Part D beneficiaries who reached \$2,000 in OOP costs did so between September and December of the plan year.<sup>14</sup> Thus, if plans stop aggregating OOP expenditures in September, a significant number of individuals likely to benefit from MPPP would not be notified proactively by the plan.

**CMS should clarify that the requirements on Part D plan sponsors to identify beneficiaries as LTB should apply regardless of whether the beneficiary will be enrolled in the plan the following year.** Specifically, Part D plan sponsors should be required to notify LTB beneficiaries about the MPPP based on their 2024 OOP costs, even if the beneficiaries elect to switch to another plan for 2025 during open enrollment.

In addition, the timing of LTB notices will be crucial to ensuring beneficiaries have the time to evaluate MPPP and make a decision on both plan choices and election. CMS states Part D plan sponsors must notify beneficiaries identified as LTB beginning in October 2024 (based on their OOP costs through the end of September 2024), but no later than December 7, 2024. **PhRMA encourages CMS to use an earlier deadline than December 7, which coincides with the last day of the Part D Annual Election Period (AEP). CMS should either require notification**

<sup>14</sup> <https://www.advi.com/wp-content/uploads/2023/09/ADVI-AMCP-Nexus-2023-Poster.pdf>

**earlier during AEP or allow beneficiaries LTB to make a one-time plan change following receipt of the notification (between December 7 and 31<sup>st</sup>).** Specifically, some beneficiaries with high OOP costs might make a different plan enrollment choice once they understand more about the MPPP and its interaction with the new OOP cap, but in order to preserve this option, beneficiaries must be notified within a timeframe for making plan enrollment decisions during the AEP.

### ***30.2.2.2 Identifying Part D Enrollees Likely to Benefit During the Plan Year***

#### *Requirement for Plan Outreach During the Plan Year*

The IRA includes a number of changes to the Part D benefit, including the creation of the MPPP. However, polling shows that awareness of these changes is low, with only 25 percent of older Americans aware of the new OOP cap in Part D.<sup>15</sup> It is therefore essential that Part D plan sponsors have multiple mechanisms to assess if beneficiaries are LTB during the year and to notify them accordingly. To that end, **PhRMA supports CMS' efforts to establish outreach requirements during the plan year for beneficiaries who are LTB, in addition to notifying beneficiaries prior to the plan year as described in section 30.2.2.1.**

Part D plan sponsors have direct interaction with plan enrollees and complete access to prescription costs incurred by enrollees throughout the plan year. **As such, PhRMA recommends CMS establish more robust requirements for Part D plan sponsors to notify Part D beneficiaries about the MPPP and whether they may be LTB from the program during the plan year.** Specifically, Part D plan sponsors should be required to conduct more targeted and detailed communications to beneficiaries who reach the LTB threshold (\$600 identified in the Part One Final Guidance) on cumulative prescriptions, particularly to those beneficiaries with higher Part D OOP costs in the previous year. PhRMA previously commented that beneficiaries are best notified prior to reaching the pharmacy counter. This notification is even more important given that CMS is not requiring a point-of-sale (POS) election process at the pharmacy counter in 2025 and also finalized a very high single prescription \$600 POS notification threshold in the MPPP Part One Final Guidance, which will only benefit 1 million individuals, leaving behind many millions of other individuals who may have cumulative costs of \$2,000 over the year.<sup>16</sup> While we recognize CMS' desire to avoid false positives (individuals notified when they are not LTB), it is also important, perhaps even more so, to avoid false negatives (individuals not notified about MPPP when they would be LTB).

#### *Plan Notifications as part of UM transactions*

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<sup>15</sup> Kaiser Family Foundation. The New Help for Medicare Beneficiaries with High Drug Costs that Few Seem to Know About. Dec. 12, 2023. <https://www.kff.org/policy-watch/the-new-help-for-medicare-beneficiaries-with-high-drug-costs-that-few-seem-to-know-about/>

<sup>16</sup> <https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf> p 66. We note that the Part One Guidance says the \$600 single prescription threshold will identify 1.0 million as LTB, while a \$500 threshold would identify 1.7 million and a \$400 threshold would identify 2.9 million.

As MPPP is implemented, it is important for Part D plan sponsors to have multiple recurring methods to identify enrollees in their plan who may benefit from MPPP and communicate with these individuals about the program. **While PhRMA supports using routine plan-beneficiary interactions like utilization management processes as an opportunity for triggering potential LTB notification requirements, we request CMS clarify Part D plan sponsors' notification requirements during utilization management processes.** Specifically, CMS should clarify that the intent is not for Part D plan sponsors to add additional utilization management on medicines specifically to trigger MPPP notifications during the plan year, but instead to utilize routine interactions already taking place with beneficiaries to serve as an opportunity to identify and communicate with those LTB from the MPPP.

In addition, we note that beneficiaries could have significant OOP expenditures if they routinely fill multiple mid-cost prescription medicines over the course of the year. **PhRMA recommends CMS require Part D plan sponsors to look retrospectively at the total/cumulative claims data throughout the plan year to identify and provide notice to beneficiaries who are LTB from MPPP based on their total OOP costs.** PhRMA is concerned that limiting targeted plan outreach to beneficiaries using the UM process or pharmacy notifications of LTB for individuals with a single prescription at the \$600 OOP threshold will leave behind substantial numbers of individuals with recurring levels of significant OOP costs that fall under these thresholds. Thus, we recommend CMS also adopt a measure for plans that considers the cumulative patient OOP costs across multiple medicines at a similar dollar threshold. Specifically, **PhRMA recommends CMS add a requirement that the Part D plan sponsor provide an LTB notice to an enrollee who meets the pharmacy LTB notification dollar threshold across all prescription claims in the previous month (e.g., in 2025, OOP costs of \$600 across all prescriptions in a month).**

While, for 2025, CMS finalized a single prescription \$600 threshold at the POS, we are concerned **this threshold is much too high. PhRMA's comments on the MPPP Draft One Guidance recommended a \$400 threshold per day, or even lower.** Research shows high cost-sharing faced by Medicare beneficiaries in Part D can lead to poor adherence and abandonment of medicines at the pharmacy counter.<sup>17</sup> In fact, research shows that rates of abandonment for Part D beneficiaries average 55 percent for all prescription drugs with cost-sharing higher than \$250, no matter how critical the medicine.<sup>18</sup> This abandonment or lack of adherence to prescribed medicines can worsen health outcomes and further widen existing health disparities.<sup>19</sup> Thus, in order to achieve the affordability goals of MPPP, CMS must recognize the affordability challenges of the Medicare population and set a level much lower than \$600 for future plan years.

In addition, we note that the threshold for LTB notification by pharmacies should not be a static dollar threshold. Instead, it should change year over year to remain proportionally aligned with the maximum OOP costs under Part D. As the MPPP continues to evolve, the LTB

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<sup>17</sup> [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/Addressing-Disparity-Report\\_v3p1.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/Addressing-Disparity-Report_v3p1.pdf)

<sup>18</sup> <https://www.iqvia.com/locations/united-states/blogs/2021/11/understanding-the-impact-of-cost-sharing-in-pharma>

<sup>19</sup> [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/Addressing-Disparity-Report\\_v3p1.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/Addressing-Disparity-Report_v3p1.pdf)



dollar threshold amount should also be refined to consider the month in which the beneficiary is opting in and whether the prescription is a recurring fill.

### *Oversight and Accountability*

In efforts to ensure the MPPP is implemented effectively and assist with CMS oversight of the program, PhRMA emphasizes the importance of CMS collecting data on identified LTB enrollees and whether or not they elected MPPP. We note that in the draft Part D Data Reporting Requirements ICR, CMS proposes to collect data on the total number of individuals identified during the reporting period as LTB, including those who did not elect to participate in MPPP.<sup>20</sup> However, CMS proposes collecting information only in aggregate and does not propose to break down information such that the agency is able to evaluate the subset of enrollees identified as LTB who opt into the program. We encourage CMS to collect detailed information and use it to identify plans that may be outliers in terms of the percentage of LTB beneficiaries who have opted into the program. We recommend CMS conduct periodic audits of plans to ensure they are meeting notification requirements.

#### ***30.2.2.3 Requirements for Identifying Part D Enrollees Likely to Benefit at POS***

**PhRMA supports the requirement that Part D plan sponsors notify the pharmacy when an enrollee incurs OOP costs greater than the threshold amount that make the beneficiary LTB from the MPPP, although as noted earlier, we believe the single prescription \$600 threshold is too high.** We ask CMS to require Part D plan sponsors to provide qualifying beneficiaries with accompanying robust educational materials and information about next steps to elect MPPP, in addition to the LTB Notice, particularly as CMS does not require pharmacies to provide any additional education, resources, or counseling on the MPPP.

To ensure beneficiaries are not abandoning urgent and necessary medicines at the pharmacy due to delays in processing their MPPP election, **PhRMA strongly supports every effort that moves towards effectuating a POS election option for 2026.** We note the POS election option could include a combination of pharmacy requirements at the POS, as well as notifications that plans could provide to patients via automated phone call, email, or text message once they have received a notification from a pharmacy.

#### ***30.3 Communication with Program Participants and Model Material Requirements for Part D Sponsors***

**PhRMA supports the election requirements detailed in the MPPP Draft Part Two Guidance for paper, telephone, and website program election options.** We emphasize the importance of having multiple communication and education mechanisms available for beneficiaries to elect in the MPPP prior to and during the plan year.

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<sup>20</sup> 89 Fed. Reg. 7399 (Feb. 2, 2024); <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/prl-listing-items/cms-10185>.

We appreciate CMS' efforts to create model "notice" materials to support Part D sponsors. We also support CMS' encouragement for Part D sponsors to provide beneficiaries supplemental information about next steps or information about plan processes as they relate to the MPPP program. At a minimum, we strongly encourage CMS to require more standardized language in the model notices to ensure that all beneficiaries receive the same information about the MPPP, regardless of the Part D plan in which they are enrolled.

Specifically, **PhRMA encourages CMS to standardize all the notices and require Part D sponsors to use the materials provided. Beyond standardized language, CMS should provide guidance to plans** on the form and manner in which MPPP enrollment is presented to beneficiaries, both at the time of plan election and subsequently when MPPP communications are presented to beneficiaries during a plan year. Should plan sponsors prefer to use their own additional branded materials, CMS should, at minimum, standardize the key content and require sponsors to use the exact same descriptive language provided in the CMS model notices. This standardization will increase efficiency and simplify the outreach and education requirements which may ease concerns about implementing the MPPP in a timely manner. In addition, it may also ease potential burdens on plans and pharmacies and minimize any timing delay associated with each plan developing its own educational and outreach documents. Additionally, standardizing the content on LTB, education, and election forms will reduce confusion when beneficiaries shift between Part D plans over time, and also facilitate a more streamlined communication experience if Medicare Part D beneficiaries reach out to 1-800-Medicare or State Health Insurance Assistances Programs (SHIPs).

Separately, we are concerned that the naming conventions used for CMS materials may elicit confusion among beneficiaries. Specifically, the "Notice of Termination of Participation in the Medicare Prescription Payment Plan" may be mistaken by beneficiaries as disenrolling from their Part D plan. Therefore, we recommend that CMS clarify and streamline their naming conventions to avoid potential confusion as well as engage with patient groups to conduct beneficiary testing of the naming conventions to ensure that they are clear and understandable.

### ***Section 30.4 Language Access and Accessibility Requirements***

PhRMA agrees with CMS on the importance of developing accessible educational and outreach materials regarding the MPPP. **We urge CMS to ensure the language of the materials provided is written in a way that is understandable and accessible to all beneficiaries, in keeping with existing regulatory requirements.**

## **Section 40. CMS Part D Enrollee Education and Outreach**

### ***Section 40.1: Information on the Medicare Prescription Payment Plan***

PhRMA applauds CMS for seeking input on the tools and decision supports that will be most beneficial to Part D beneficiaries as they determine whether to opt in to MPPP.

CMS notes that it will develop an “educational product” for beneficiaries on Medicare.gov and through other Medicare communication channels. PhRMA believes CMS-developed educational resources will play a vital role in education on the MPPP, not just in directly educating beneficiaries and their caregivers, but also educating other stakeholders such as Part D plans, pharmacies, providers, and patient advocacy organizations. While beneficiary circumstances and understanding of plan options may vary, broad-scale, easily understandable messaging and consistent communication to all beneficiaries will be important to successful MPPP implementation. This will empower beneficiaries to make informed choices about participation in the program.

**PhRMA encourages CMS to provide clarity on the content of the educational product, and the process for the development of this product, including opportunities for stakeholder comment, dissemination plan, and timeline for its release. PhRMA believes that stakeholder input and comment on the CMS educational product will be critical to ensuring that the necessary information about the program is included** in a way that is easily accessible and digestible to the broad Medicare population. The accessibility needs of Medicare beneficiaries vary greatly, and stakeholders with direct experience with different beneficiary communities will be best positioned to ensure materials are accessible and easily understood by all beneficiaries.

While information on the MPPP may be a central focus for the educational product, it will also be important for beneficiaries to understand how the MPPP interacts with other recent and forthcoming changes in the Part D program. **PhRMA therefore believes that within the MPPP educational product, CMS should also include a brief explanation of other recent changes in Part D.** This explanation should also cover: the elimination of cost-sharing in Part D for Advisory Committee on Immunization Practices (ACIP)-recommended vaccines, the \$35 monthly cap on covered insulin products, restructuring of the Part D benefit phases, the new Part D OOP cap (at \$2,000 in 2025), and the expansion of eligibility for Extra Help (the Part D LIS program). PhRMA agrees with CMS that LIS enrollees are not likely to benefit from the MPPP. The MPPP educational product should therefore provide information on how beneficiaries qualify and can apply for LIS, and clearly state that LIS enrollees are not likely to benefit from participation in MPPP.

**PhRMA urges CMS to consider how the educational product can be disseminated through multiple channels to ensure that it is accessible to all beneficiaries and stakeholders,** including paper communications and online platforms, such as Medicare Plan Finder. Specifically, the agency should consider opportunities to enhance functionalities of the educational product depending on the channels it is provided through (e.g., interactive educational videos or modules for online resources vs. graphic depictions in paper communications). CMS should also ensure materials on online platforms are easily accessible and clear.

**We also recommend that CMS evaluate how educational resources and outreach can be extended to and optimized for other members of a beneficiary’s care team, including**

**caregivers, providers, and pharmacies.** While CMS encourages plans to provide information on the MPPP to contracted providers and pharmacies, we urge CMS to develop targeted materials and conduct its own outreach to providers, particularly those in specialties that are more likely to prescribe therapies for which a patient would benefit from participation in the MPPP. CMS can leverage existing provider communication channels (e.g., the Medicare Learning Network) to provide education and information on the MPPP. Given the lack of POS election for 2025, providers will play a critical role and may be the first point of contact in alerting beneficiaries about the MPPP before the patient arrives at the pharmacy, which can prevent delays in treatment.

**PhRMA strongly urges CMS to release the MPPP educational product(s) as early as possible.** Given the significant number of changes to the Part D program that begin in 2025, and the lack of awareness among seniors about significant changes in the Part D benefit,<sup>21</sup> early education will give beneficiaries sufficient time to understand these materials and make informed choices ahead of the Part D AEP. Early release will also allow other stakeholders, such as patient advocacy groups and other senior organizations like Area Agencies on Aging and SHIPs, sufficient time to leverage this resource as part of their own education and outreach efforts, which will broaden beneficiary outreach, ensure more consistent communication about the program and prevent beneficiary confusion.

#### ***Section 40.2: Modifications to Existing Medicare Part D Resources***

PhRMA applauds CMS for its commitment to modifying and updating routine Medicare resources and tools with information on the Part D program changes, including the MPPP. However, **we seek additional clarity on the resources CMS will update and the process for these updates, including if CMS will provide opportunity for stakeholder input.**

PhRMA believes it is critical that resources such as Medicare.gov, the Medicare & You handbook, and Plan Finder be updated with information about the MPPP. However, **PhRMA is concerned that CMS did not explicitly commit to a set of Part D resources that it will update, nor did it provide information on how these resources will be updated, particularly regarding Medicare Plan Finder.** We note that Plan Finder is a crucial venue for MPPP education, as beneficiaries and their families routinely use Plan Finder as a resource to make choices about coverage and costs. To ensure that beneficiaries have the appropriate tools to make informed plan and MPPP election choices, **PhRMA urges CMS to incorporate the interactive calculator tool in Medicare Plan Finder mentioned by CMS in its technical memo on MPPP<sup>22</sup> and the draft part one guidance.** PhRMA asks CMS to provide more detail on its progress in developing this interactive calculator tool, as we believe it will be a critical forecasting tool (both inside and

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<sup>21</sup> Kaiser Family Foundation. The New Help for Medicare Beneficiaries with High Drug Costs that Few Seem to Know About. Dec. 12, 2023. <https://www.kff.org/policy-watch/the-new-help-for-medicare-beneficiaries-with-high-drug-costs-that-few-seem-to-know-about/>

<sup>22</sup> CMS. Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost Sharing Payments Under Prescription Drug Plans. July 2023. <https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf>.

outside of Plan Finder) in helping beneficiaries understand how the MPPP could change their OOP costs throughout the plan year once they opt into the program. This is especially important for beneficiaries on fixed incomes who may need to budget accordingly as well as beneficiaries with lower cost sharing who could inadvertently accumulate monthly payments that exceed the original cost share amount later in the year. Without the calculator tool, beneficiaries may rely on general calculation examples that may not apply to their individual situation, which could cause confusion.

**PhRMA strongly encourages CMS to engage stakeholders and seek public comments on updates and adjustments to Medicare resources.** While PhRMA appreciates the opportunity to comment on this guidance, we believe it is vital that all stakeholders, including patients, caregivers, patient advocacy organizations, providers, and manufacturers can comment on the content of updates to ensure they are appropriate, clear, and accessible to all beneficiaries.

**PhRMA also encourages the agency to clarify how it will ensure that callers to 1-800-MEDICARE get the information they need on the MPPP,** such as new training requirements for the customer service representatives that staff the hotline. This could include scripted materials for representatives to explain the MPPP in a consistent way and additional tools and training for staff to answer questions about an individual beneficiary's circumstances as it relates to their medication needs. Model scripts could also be shared with plan sponsors to promote consistent explanations and assistance for beneficiaries, regardless of which call center they contact.

### ***Section 40.3: National Outreach and Education Efforts***

PhRMA appreciates CMS' commitment to working with interested partners to spread awareness of changes in Medicare Part D, including the new OOP cap and the MPPP. **PhRMA encourages CMS to conduct this engagement directly with stakeholders, such as patient advocates, providers, and other groups that engage in Medicare enrollment efforts (i.e., State Health Insurance Assistance Programs, Medicare Rights Center) as early as possible.** Early engagement will allow for stakeholders to provide robust input on the development of educational resources and to provide timely and effective communication about the program to beneficiaries. This is particularly important as education, outreach, and communication strategies may vary depending on the targeted beneficiary group.

### **Section 50: Pharmacy Process**

PhRMA supports requirements for Part D plans to require pharmacies to provide the standardized "Medicare Prescription Plan Likely to Benefit Notice" to beneficiaries who incurred costs that trigger the pharmacy POS notification threshold. However, **PhRMA is disappointed that CMS finalized for 2025 a threshold in Part One Guidance at the higher end (\$600) of the proposed range, and that this threshold will be based on per script incurred costs rather than costs in a single day.** This will mean that beneficiaries who may fill multiple, moderate cost

scripts and who would still benefit from the MPPP may not be aware of the program. By CMS' own estimates, this will leave out an additional 1,818,000 enrollees who would likely benefit from the MPPP. This number of additional enrollees who would likely benefit from the MPPP is higher based on CMS' updated estimates using 2022 Prescription Drug Event (PDE) data.<sup>23</sup>

**PhRMA therefore strongly urges CMS to reconsider the POS notification threshold for future years.** The high POS notification threshold also underscores the importance of robust CMS and plan outreach and education to beneficiaries prior to and during the plan year, to ensure that others whose single prescription fill will not trigger LTB notification still receive general information about the program.

Pharmacies and providers are on the front line of patient care and represent an important part of a patient's care team. Since the pharmacy POS notification could be the first-time beneficiaries are made aware of the program, **PhRMA emphasizes the need for requirements that plans provide educational materials on the MPPP (or links to CMS materials) to contracted pharmacies and providers.** As previously stated, outside of requirements for plans to provide these materials, CMS should develop targeted educational materials for pharmacies (including specialty pharmacies) and providers and to make these materials easily accessible.

Further, regarding mail-order pharmacies (Sec 50.3.3) we ask CMS to consider requiring, rather than encouraging, mail-order pharmacies to delay processing payment for LTB members in order to provide time for outreach related to the MPPP program, as appropriate. We suggest the delay be required for up to 48 hours.

Given the short timeframe for implementing the MPPP ahead of the 2025 plan year, we again note that requiring plans to use standardized materials on the MPPP, particularly educational materials, will reduce the burden on pharmacies and providers in their engagement with patients and will ensure consistent messaging on the MPPP. For example, it will be less burdensome if there are standardized forms and materials pharmacies receive from all Part D plans rather than receiving different resources and requirements from each plan. To ease potential burden on pharmacies in answering questions on the MPPP from patients and to maximize the utility of information provided to beneficiaries, **the "Medicare Prescription Payment Plan Likely to Benefit Notice" should also include clear and concise educational information** on the MPPP and instructions on where beneficiaries can obtain additional information, as noted in the model documents.

## **Section 60: Part D Sponsor Operational Requirements**

CMS notes that plan losses from MPPP non-payments will count toward administrative costs in the denominator of the medical loss ratio (MLR) and not count as claims expenses in

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<sup>23</sup> CMS. 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. Available <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>

the numerator. Given the importance of the MLR, PhRMA is concerned that the proposed treatment of these costs may incentivize plans to underpredict potential losses from the MPPP to achieve an MLR at or just above the 85% minimum. **PhRMA urges the agency to monitor plan bids as they relate to predicted losses from the MPPP and MLR compliance, and to consider issuing guidance in the bid instructions on how plans should calculate predicted losses.**

**In addition to the bidding dynamics, PhRMA is concerned that this proposed approach to the MLR may give plans reason to be wary of MPPP in its early years, creating further incentives for plan sponsors to structure benefits and MPPP marketing strategies to discourage participation by certain beneficiaries.** For example, due to the impact on MLR, plans may have incentives to avoid participation by enrollees in the MPPP who they believe are less likely to pay amounts owed.

### ***60.3 Monitoring and Compliance***

We appreciate CMS states it will monitor and collect data about beneficiary complaints/grievances; that it expects sponsors to incorporate MPPP into their compliance programs; and that CMS and/or its contractors may conduct specific audits of Part D sponsors' implementation. We recommend that CMS pay careful attention to:

1. Whether LTB notices are being sent to all those eligible for such notices.
2. The timeliness of processing election requests.
3. Whether notices of failure to pay are routinely preceding any involuntary termination.
4. Sponsors' use of the lock-out provisions.

PhRMA is concerned that plans may discriminate against certain beneficiary groups, including those believed to have lower incomes, but are not eligible for LIS, or who otherwise may have more difficulty meeting MPPP payment obligations. We encourage CMS to ensure that plans are providing outreach and education on the MPPP in an equitable way to all beneficiaries and should closely monitor participation trends by different demographic groups.

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PhRMA appreciates the opportunity to provide feedback on the Medicare Prescription Payment Plan Draft Part Two Guidance and look forward to opportunities for continued collaboration with CMS in implementing this important beneficiary affordability improvement in Part D.

We are happy to discuss these comments and provide any further details or supplemental materials that you may request.

Sincerely,



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Rebecca Jones Hunt  
Deputy Vice President, Policy & Research

/s/

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Judy Haron  
Deputy Vice President, Law



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