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VIA ELECTRONIC SUBMISSION — PartDPaymentPolicy@cms.hhs.gov

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RE: Medicare Prescription Payment Plan Guidance – Part One

Dear Dr. Seshamani,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the *Maximum Monthly Cap on Cost-Sharing Payments Program Draft: Part One Guidance.*[1] 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).

It has been nearly two decades since enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). In that time, Medicare Part D has brought medical advances and breakthroughs to more than 50 million seniors and disabled persons. Beneficiaries have received a constantly evolving array of medicines, greatly improving treatment across a range of illnesses. Even as treatments have expanded, improved, and become more personalized, Medicare Part D costs have remained steadily below original projections, and with annual spending growth in recent years smaller than other parts of Medicare.[2] Moreover, medicine usage has been found to reduce other health care spending.[3]

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[1] CMS, Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments, Aug. 2023.
https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf

[2] See CBO Medicare Baselines available at www.cbo.gov.

[3] 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. The Maximum Monthly Cap on Cost-Sharing Payments Program, now known as the Medicare Prescription Payment Plan (MPPP), requires careful policy development and thoughtful implementation of key operational details.

PhRMA first submitted comments on this program in June as part of our response to CMS' *Calendar Year (CY) 2025 Part D Redesign* guidance.[4] In those 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 the infrastructure and effectuation details. Our comments were intended to ensure that the program is able to meet its goal of improving affordability for Medicare beneficiaries.

PhRMA appreciates the opportunity to expand on those earlier comments and provide feedback on the Part One draft guidance for the MPPP, which also builds on the "Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans" released in July.[5]

To that end, our comments here include feedback on a number of policies associated with Part One of the MPPP guidance, including but not limited to program calculations, outreach and education, program election, both in advance and at the point-of-sale (POS), and beneficiary protections. We also look forward to commenting on part two of the MPPP draft guidance in the future.

In addition, while we strongly support these MPPP provisions in the IRA, which will improve beneficiary access to medicines through patient affordability, we are equally concerned that other elements of the IRA -- including "Maximum Fair Price" provisions authorizing government price-setting for certain drugs in Medicare -- could undermine these gains by disrupting Part D plan and formulary designs and increasing patient barriers to medicines through formulary exclusions and utilization management (UM) restrictions. PhRMA addressed these concerns in more detail in separate comments to the agency on its MFP guidance for IPAY 2026, and we urge the agency to take steps to ensure beneficiaries continue to enjoy access to a range of treatment options in Part D.

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[4] https://phrma.org/resource-center/Topics/Medicare/PhRMA-Comments-to-CMS-on-the-Calendar-Year-CY-2025-Part-D-Redesign

[5] 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.

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Section 20 – Overview

We recognize that the Part D annual OOP cap, coupled with a monthly cost-sharing cap, are significant affordability improvements to the Part D benefit, which PhRMA has long advocated.

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 not only require broad education to raise awareness of the program and clearly explain the potential benefit and how to elect the program, but also necessitate changes in Part D plans and pharmacies' financial and operational workflows.

Further, as noted in the draft guidance, because beneficiary 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 implementation.

To that end, ***CMS should launch a robust education and outreach campaign to all Medicare beneficiaries on the many changes to the Part D program,*** independent of the traditional beneficiary education and outreach activities each year related to open season, to ensure the new benefit structure and affordability improvements in Part D are well understood by Part D beneficiaries.

The MPPP will have varying effects, depending upon the variability and level of a beneficiary's monthly out-of-pocket costs as well as their individual financial situations. While there will be a clear benefit for those who may hit their MOOP early in the year, for others, there may not be a benefit. As such education and outreach are critical, and ***we applaud 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.***

We acknowledge the concern that for some months, the statutory formulary could result in MPPP costs that exceed what a patient may otherwise have paid in cost sharing at the pharmacy. For that reason, ***it will be important for CMS to develop an interactive tool, as referenced in CMS' technical memo,[6] that accurately models a beneficiary's unique month-to-month MPPP cost-sharing.*** This tool should include estimates of a beneficiary's likely prescription fills during the year, and comparisons of OOP costs with and without the MPPP.

Section 30 – Program Calculations and Examples

The MPPP is a significant step forward in improving affordability for Part D beneficiaries, especially for those taking higher cost specialty medications who may hit their MOOP early in the year after one or just a few fills. For these individuals, the statutory formula in the MPPP is a

[6] 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.

straightforward calculation that produces a generally consistent payment from month to month, after the initial month calculation*. Therefore,* ***PhRMA supports CMS's beneficiary-focused approach to the MPPP, specifically CMS's approach to calculating monthly costs to make those as low as possible for beneficiaries.*** The multiple examples provided by CMS are helpful illustrations of the various forms this program may take, with varied levels of monthly benefit as applicable based on a participant's unique circumstances.

PhRMA commends CMS for its proposed interpretation that the "months remaining in the plan year" in the calculation would include the current month. As noted in our prior comments on Part D Redesign,[7] we view this option as more patient friendly, since it spreads costs over an additional month, resulting in lower monthly payments for participants. ***We also commend CMS for including participant costs in the deductible phase, which we believe accords with the statute, as well as Congressional intent.***

<u>Section 40 – Participant Billing Requirements</u>

The IRA includes few details on the process for billing patients for their MPPP amounts. However, given the wide variety of MPPP billed amounts, there is a clear need for structured billing guidelines.

PhRMA concurs with CMS' proposal to specify the operational requirements for patient billing statements in a manner that is patient-centered and consistent across all Part D plans. We also support encouraging multiple payment options for participants (i.e., electronic and paper billing, multiple means of payments, and flexibility on dates of withdrawal).

PhRMA agrees that billing statements must incorporate specific content, including clearly presenting the MPPP cost-sharing amounts. This level of detail will be critical to providing all MPPP participants with a consistent experience and ensuring participants understand the factors that contribute to the calculation of their billed amounts. Additionally, PhRMA interprets the statute as requiring monthly billing statements as CMS proposes. Given each participant's unique circumstances and the variance in their incurred drug costs each month, monthly bills are critical as a policy matter as well. ***PhRMA also urges CMS to build on these clear standards by requiring the plan to inform the participant once they have achieved their MOOP,*** both to note that milestone and to clarify that the participant's payments under the MPPP will remain fixed for the remaining months of the plan year.

Understanding and using the MPPP to a patient's advantage is inherently complex and requires a high degree of health insurance literacy. Patients enrolled in the MPPP should clearly

[7] https://phrma.org/resource-center/Topics/Medicare/PhRMA-Comments-to-CMS-on-the-Calendar-Year-CY-2025-Part-D-Redesign

understand the charges on their monthly billing statements and how these contribute to a patient's total OOP costs each year. Therefore, in an effort to ensure that participants in the program have comprehensive knowledge about their statements and their current liabilities, ***PhRMA suggests that CMS work with patient groups and advocates to draft and pre-test billing documents in advance of 2025.*** This way CMS can determine whether these billing statements are clear and can be understood by all participants in the program, regardless of their background and health literacy level.

Section 50 – Pharmacy Payment Obligations and Claims Processing

PhRMA supports CMS' goal of developing claims processing methodologies that ensure an individual's MPPP participation does not affect the amount paid to pharmacies, and results in "timely, uniform, and seamless implementation for all parties."

PhRMA appreciates CMS' interest in building a claims processing methodology for the MPPP that would leverage existing coordination of benefits transactions based on existing National Council for Prescription Drug Programs (NCPDP) standards. While we are currently evaluating the implications of this methodology on patients, pharmacies, and plans, we believe it is likely to offer a reasonable approach to achieving the goal noted above.

In addition, ***we urge CMS to continue developing processes to ensure that plans and pharmacies offer beneficiaries the choice of opting in at the POS or, in the initial year of the program, otherwise process elections within 24 hours.*** As CMS develops a claims processing methodology, it will be important to ensure that any changes to pharmacy workflows and claims processing can occur seamlessly and in conjunction with the POS election mechanism and 24-hour election processing standards.

We also encourage CMS to engage in outreach to various pharmacy types (e.g., specialty, long-term care, mail-order, and home infusion pharmacies) to ensure that patients can seamlessly opt into the MPPP at the POS, or in the initial year can have their elections processed within 24 hours. If specific pharmacy types experience difficulties effectuating election at the POS due to operational or financial burdens, we encourage CMS to provide technical assistance and if necessary, issue guidance relevant to specific pharmacy types delineating unique payment or claims processing standards.

Section 60 – Requirements Related to Part D Enrollee Outreach

PhRMA agrees with CMS that enrollee education and outreach are essential to the success of the program. This education and outreach should be multifaceted and involve not only CMS, plans, and pharmacies, but also collaborations with other key third-party patient and senior stakeholders (e.g., providers, pharmaceutical manufacturers, patient advocates, senior groups,

and patient assistance programs, etc.). ***We urge CMS to specify, in the "Part Two" MPPP guidance, the exact requirements for such outreach.***

60.1 General Part D Outreach Requirements

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 to all Part D beneficiaries will be critical to ensuring that beneficiaries have a clear understanding of how opting into the MPPP may impact their monthly OOP costs.

CMS should broadly explain the new benefit enhancements in Part D to Medicare beneficiaries as part of a comprehensive Part D education campaign prior to the fall 2024 open enrollment for Calendar Year (CY) 2025, as this will be integral to building awareness on the many changes in Part D. In addition, CMS should conduct outreach to beneficiaries prior to and during the plan year on the MPPP, as this represents a vital opportunity to ensure that beneficiaries who are likely to benefit can sign up before they reach the pharmacy counter.

The statute requires that both CMS and plans provide MPPP information and educational materials to prospective participants in MPPP, and that CMS provide such information within general Medicare Part D program materials. Plan sponsors must notify prospective enrollees of the MPPP option in promotional materials during annual open enrollment and include information on the MPPP within standard Medicare educational materials. Therefore, the Explanation of Benefits could be utilized as a supplemental avenue for plan education and outreach as it should be updated to include standard language on the MPPP, as stated in our previous comments on the Explanation of Benefits ICR.[8]

Additionally, the statute also requires tailored notification requirements. Specifically, Part D plans must have a mechanism to notify a pharmacy if a beneficiary has OOP costs that make it likely that the beneficiary would benefit from the MPPP. Plans must also have a mechanism to ensure that pharmacies then inform the beneficiary of the notification. However, the statute is not prescriptive as to the content of the educational materials or notifications, nor how the information must be communicated to potential participants.

PhRMA recommends that CMS take all actions within its authority to ensure robust communications and outreach, including that every Medicare Part D beneficiary has consistent and clear outreach and education materials on the MPPP, as individual beneficiary circumstances and choices could vary widely. Simple, effective, and broad-scale communication to beneficiaries, paired with tools to enable them to easily and quickly opt in, will ensure beneficiaries understand the potential new benefit and engage as active decision-makers. While we share CMS' concern that the statutory formula could, toward the end of the year, produce a

[8] PhRMA Comments, Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453), August 7, 2023.

monthly bill higher than the OOP costs a participant might otherwise face during that month in the absence of the MPPP, the calculators CMS is developing should partially address this issue.[9] Beneficiary financial situations are highly individualized and subject to change, and there is no one-size-fits-all definition of who benefits from MPPP. For example, a beneficiary may opt into the MPPP at the beginning of a plan year to smooth their annual deductible and then choose to voluntarily withdraw later in the plan year.

More broadly, ***CMS must work to update current education and outreach materials associated with annual Part D open enrollment (e.g., Medicare & You handbook, 1-800-Medicare, CMS websites)***. This will ensure these materials include a robust, clear explanation with various illustrative scenarios of what a beneficiary's OOP costs could be under the MPPP. Additional maximum monthly cap examples would be helpful to supplement what CMS has already described in the Part One draft guidance and July 2023 technical memorandum, including the addition of an example of a participant who opts in to MPPP to spread out the costs of their annual Part D deductible and then withdraws later in the plan year.

Separately, the Medicare Plan Finder will also need to be updated to include information on MPPP, with careful attention to how the Plan Finder displays MPPP election and whether the Plan Finder can be adjusted to display the impact MPPP may have on estimated beneficiary monthly OOP costs. ***PhRMA recognizes that the technical updates to Plan Finder that account for MPPP variables may require more lead time to be ready for CY 2025. We therefore urge CMS to move forward on finalizing the policy standards of MPPP so that the Plan Finder can be updated in time for CY 2025 open enrollment.***

60.2 Targeted Part D Enrollee Outreach Requirements

While the statute does not define "likely to benefit," it does place requirements on plans to notify pharmacies when a Part D enrollee incurs OOP costs that make it likely the enrollee may benefit from MPPP. CMS states in the draft guidance that plan enrollees incurring higher OOP costs in the early months of the year are "generally more likely to benefit" and also proposes a range of $400-700 as the potential "likely to benefit" threshold (discussed in more detail below).

Targeted outreach by plans is most likely to be effective when it occurs prior to the point of sale. Targeted outreach will need to include both direct outreach to beneficiaries and a robust pharmacy notification process. As noted above, while the law requires plans to have a mechanism for pharmacies to notify Part D enrollees if they are "likely to benefit" from MPPP, the best time for them to be notified is actually before they reach the pharmacy, particularly if CMS does not establish a strong POS election mechanism for 2025.

[9] 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.

For example, ***Part D plans should be required to conduct more targeted and detailed communications to beneficiaries who have had higher Part D OOP costs,*** including those with OOP costs both approaching and also exceeding the Part D maximum out of pocket cap in recent years or beneficiaries who had opted into the MPPP in the previous year. This proactive communication to a population of beneficiaries likely to benefit would provide important advance notification of MPPP and more lead time for potential participants to opt into the program (and for plans to process the enrollment). Plans could make this determination by accessing historical medicine costs for individual enrollees in their plans.

PhRMA also supports standardized communications, codeveloped with multiple stakeholders including patient advocates, to ensure the new benefit and affordability improvements are explained in language that can be well understood by Medicare populations. CMS should partner with patient advocacy groups and other organizations like Area Agencies on Aging and State Health Insurance Assistance Programs to leverage their proven ability to reach their communities. CMS should also work with pharmacists and pharmacy groups to identify how MPPP information can be appropriately communicated to patients during pharmacy encounters without causing significant disruption to pharmacy workflows.

We commend CMS for seeking input from interested parties on the kinds of communication tools and decision supports to offer to help Part D enrollees decide whether the program is right for them, as well as CMS' commitment to further address this issue in Part Two of its MPPP guidance. As CMS develops tools (e.g., model documents and training materials) and considers which communication materials would benefit from templates, the Agency should create model language that can be used by third parties that interact directly with Medicare beneficiaries, including, for example in patient advocacy group materials as well as manufacturers' patient assistance programs.

***CMS should also extend outreach on MPPP beyond beneficiaries, and target caregivers and health care providers*.** Caregivers and other family members often help with healthcare decision making for elderly patients with Medicare. Similarly, providers also play a vital role in a beneficiary's healthcare team. As such, we urge CMS to identify and take advantage of opportunities to enlist these team members in MPPP education and outreach efforts, so they can assist in identifying patients likely to benefit and navigating the election process. CMS should also consider developing targeted materials that could be used in physician offices, including in specialties that often prescribe higher cost specialty medicines to effectively treat a wide range of conditions and comorbidities.

Targeted outreach at the POS and identification of those "likely to benefit"

Due to the novel nature of the MPPP and its implementation in 2025, it will be important for CMS to ensure that plans and pharmacies play meaningful, appropriate roles in educating and notifying beneficiaries.

Once a beneficiary has been notified by pharmacies at the POS that they may be likely to benefit from election into MPPP, plans should follow up with the beneficiary and send more detailed information about the program to supplement the information received at the POS, both for those beneficiaries that opt into MPPP at the pharmacy and also those who do not opt in.

Proposed standard for beneficiaries "likely to benefit" from MPPP

PhRMA commends CMS for proposing standards for identifying beneficiaries "likely to benefit" from the MPPP that balance the goal of ensuring all potential participants are identified while setting an accurate metric. We also appreciate the agency soliciting comment on key elements of this threshold, including whether notification to the beneficiary should be based on OOP costs for a single prescription or all prescriptions filled within a single day.

PhRMA urges CMS to maintain a pro-beneficiary posture and to set standards for calculations of the "likely to benefit" threshold that would identify larger numbers of Medicare beneficiaries. We also urge CMS to set the threshold based on the total OOP costs filled for a single day (particularly, if filled in one pharmacy encounter). Based on CMS' retrospective modeling of PDE data, the draft guidance notes an additional 200,000 beneficiaries would meet the "likely to benefit" standard if the threshold were based all prescriptions filled in a single day. This broader definition would be worthwhile.

In addition, the draft guidance proposes a range of $400 - $700 as the potential "likely to benefit" notification threshold, with more beneficiaries that would be notified at lower dollar thresholds. We recognize that lower OOP thresholds may increase the probability that those who would receive the notification would face costs under the MPPP in some months that are more than what they would pay outside of MPPP; however, we note that actual beneficiary financial circumstances can vary widely, and with a high threshold, there will be beneficiaries who could benefit from MPPP who are not notified.

CMS projects that at a $400 threshold, just over 2 million Part D beneficiaries would be identified as likely to benefit from the MPPP. This translates to 4 percent of Part D beneficiaries, based on a total number of 50 million beneficiaries in 2022.[10] ***PhRMA recommends CMS use a relatively low threshold for notification at the POS, either the $400 level or even lower,*** in order to ensure that a larger pool of potential MPPP participants are identified. For example, the threshold could be $400 for prescriptions for an extended supply (i.e., 90 days), but lower for those filling 30-day prescriptions.

We also note that even $400 can represent an unaffordable level of cost-sharing for many Part D beneficiaries and there is ample evidence to support a relatively low notification threshold. Research shows high cost-sharing faced by Medicare beneficiaries in Part D can lead to poor

[10] https://www.medpac.gov/wp-content/uploads/2023/03/Ch12_Mar23_MedPAC_Report_To_Congress_SEC.pdf

adherence and abandonment of medicines at the pharmacy counter.[11] In fact, research shows 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.[12] This abandonment or lack of adherence to prescribed medicines can worsen health outcomes and further widen existing health disparities.[13]

As such, ***we urge CMS to assess the number of beneficiaries who would be notified if CMS established a "likely to benefit" threshold that is lower than $400.*** For example, CMS could model PDE data and make public such modeling, to present the range of outcomes based on different thresholds, including the level of variation for billed MPPP amounts using a lower threshold. Presenting a more robust data set would allow patients, clinicians, caregivers and other stakeholders to weigh in on how CMS should balance the costs and benefits of a particular threshold. Affordability and adherence gains are important not just for those enrollees with the highest costs, but also for beneficiaries with lower and modest incomes, who could benefit from the MPPP.

We appreciate the need for a clearly defined notification threshold at the point of sale. However, given the variability of beneficiary situations as noted above, a more tailored, formulaic approach should be used when plans proactively notify beneficiaries before and during the plan year (not at the POS).

We note also that the dollar threshold triggering notification at the POS may be the standard for 2025. However, this should change over time to stay aligned with the maximum out of pocket cost in Part D. Also, as the program continues to grow and evolve in the coming years, this "likely to benefit" dollar threshold could be refined to also take into account the month of election and whether the prescription is a recurring fill.

In summary, ***CMS should provide a clear distinction between what targeted outreach looks like at the POS (pharmacy counter) versus outside of the POS (in advance of and throughout the plan year) for both CMS' outreach and plans' obligations for notifying pharmacies of individuals "likely to benefit" from the MPPP. CMS should create model language and distinct outreach and education materials that are used by CMS, plans, and pharmacies that align with their different notification expectations.***

In addition, ***CMS should develop model language and educational materials to be used at the POS upon notification that a beneficiary stands to benefit from MPPP election.*** We are concerned that if CMS does not specify any requirements for this pharmacy notification, or if requirements are inadequate, it could result in little beneficiary interaction (e.g., if the

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[11] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/Addressing-Disparity-Report_v3p1.pdf

[12] https://www.iqvia.com/locations/united-states/blogs/2021/11/understanding-the-impact-of-cost-sharing-in-pharma

[13] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/Addressing-Disparity-Report_v3p1.pdf

notification is via a written description of the MPPP attached to the bag containing a medication after a prescription is filled), which would make it more challenging for the beneficiary to act on the notification and opt into MPPP.

The new MPPP can have a meaningful impact on patient affordability. However, its success is tied to the ability to broadly educate on this new benefit.

Section 70 – Requirements Related to Part D Enrollee Election

70.2 Interactions Between LIS and Medicare Prescription Payment Plan

We support CMS' proposal to leverage beneficiary communications regarding the MPPP to remind patients in Medicare of the potential to qualify for the low-income subsidy (LIS) program. We share CMS' concern that too many Part D beneficiaries who may qualify for extra help through the LIS program are unaware of the program and remain unenrolled in LIS. In 2019, only 68 percent of Part D beneficiaries eligible for LIS subsidies were enrolled in the program, representing nearly 5 million putatively eligible lower income Medicare beneficiaries who did not receive extra help to access their prescriptions.[14] Therefore, when beneficiaries inquire about electing the MPPP to improve their affordability in Part D, it makes sense to first determine whether they are aware of the LIS program (and whether they may qualify).

Beyond this information sharing on LIS and eligibility guidelines, however, CMS may also wish to consider proposing a policy regarding outreach for LIS beneficiaries who seek to opt into the MPPP. Specifically, CMS could ensure that any current LIS beneficiary who has elected the MPPP receives a telephone call from their Part D plan to ensure that they understand both LIS and MPPP and have appropriately evaluated whether they would financially benefit from the MPPP.

70.3.5 Processing Election Request During a Plan Year

In the draft guidance, CMS proposes that plans must process election requests within 24 hours for requests made during a plan year, consistent with the timeframe CMS uses today for processing expedited coverage determinations in Part D. CMS seeks comments on interim solutions that Part D plan sponsors could implement to prevent those who have opted into MPPP from waiting 24 hours to receive their prescription at no cost-sharing, while waiting for their plan to formally process their election into the program.

CMS' request for comments sheds light on the problems that arise if a POS election option is not available to Medicare beneficiaries on day one of the MPPP. In fact, much of the benefit of Congress' requirement that pharmacies notify individuals that they would be likely to benefit

[14] Loh E., Stuart B., Negari M., Hunt R.J., Dougherty S. Maximizing Enrollment is Key to Success for the Inflation Reduction Act's Medicare Low-Income Subsidy Provisions. AcademyHealth ARM Conference 2023. Poster. Available at: https://academyhealth.confex.com/academyhealth/2023arm/meetingapp.cgi/Paper/60230

from MPPP will be lost if the individual cannot act on that notification to elect to participate and avoid the high OOP payment that otherwise could prompt them to abandon their prescription(s). PhRMA appreciates CMS' recognition of this remaining challenge in the draft guidance and interest in solutions to address it. ***We strongly support every effort that moves towards effectuating a POS option at the start of the program in 2025, which would eliminate the complications and confusion for beneficiaries not having $0 cost-sharing while program election is processed.*** This can and should be done in real-time, using the POS options spelled out below.

In addition, we recommend CMS explore requiring POS election where feasible at an earlier point in time, such as in cases where pharmacies are owned or affiliated with the plan sponsor, for specialty pharmacies that deliver prescriptions to beneficiaries, and for mail order prescriptions.

70.3.7 – Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours and 70.3.8 – Standards for Urgent Medicare Prescription Payment Plan Election

In the draft guidance, CMS proposes a retroactive election process when plans fail to process a beneficiary's election into the MPPP within required timeframes, due to no fault of the beneficiary.

PhRMA agrees on the importance of timely and proper election into the MPPP as patient OOP burdens and access are exacerbated by any delay. We also appreciate CMS proposing a mechanism for plans to effectuate retroactive election into the MPPP when a beneficiary has an urgent prescription fill(s) and has already paid OOP costs for medicines before the election into MPPP was processed.

PhRMA believes that CMS should include information and model language about the retroactive election option in educational and outreach materials on MPPP to help inform beneficiaries about the option and ensure that beneficiaries are not abandoning urgent and necessary medicines at the pharmacy due to delays in processing their election. While the retroactive election option is a helpful transition, we do not believe that it replaces our primary goal of working towards POS election as soon as practicable (ideally in 2025). Even with a retroactive and urgent election option, patients may still face affordability challenges at the pharmacy, as they will be required to pay the cost-sharing up front (which can be significant). For example, studies show abandonment rates in Part D at 55 percent when OOP costs are greater than $250;[15] thus, any delay of election into the MPPP and the resulting exposure to high OOP costs (even temporarily) at the POS will have a significant impact on beneficiaries and adherence.

CMS should also develop clear standards to ensure that plans cannot deny an urgent MPPP election within the defined standards of the draft guidance.

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[15] https://www.iqvia.com/locations/united-states/blogs/2021/11/understanding-the-impact-of-cost-sharing-in-pharma

While we appreciate CMS taking the important first step to propose plans be required to reimburse beneficiaries for OOP costs within 45 days of the date for which the beneficiary should have been admitted into the MPPP, ***PhRMA recommends that the refunds to beneficiaries should be processed in fewer than 45 days***. This is particularly important if the amount of OOP costs incurred by the beneficiary is well-above the threshold CMS uses for "likely to benefit."

If CMS cannot fully implement a POS election option for 2025, ***PhRMA believes that CMS should have clear procedures and mechanisms available for beneficiaries to opt into the MPPP during the plan year,*** including the 24-hour election requirement for plans to process opt-ins (as laid out in Section 50 of the guidance) and the retroactive and urgent election processes described here.

Section 70.3.9 – Request for Information on Real-Time or Near-Real-Time POS Election and other POS needs

In its Part One draft guidance on the implementation of the MPPP, CMS includes a request for information on three options to effectuate real-time or near-real-time election into the MPPP at the POS without any delay or with only a nominal delay between the election request and effectuation. CMS states "a POS enrollment option is not likely for 2025", thus the POS election options CMS proposes for consideration are expected to begin in 2026 or later. The three methods CMS proposes are: (1) telephone-only, (2) mobile or web-based applications, and (3) a new clarification code submitted on claims.

CMS also seeks feedback on whether one method could reasonably be implemented for 2026 and then replaced or supplemented by a different or additional method in future years. CMS also seeks input on other potential approaches.

As noted above, PhRMA appreciates CMS' recognition of the potential problems that arise when beneficiaries lack a real-time POS election option. PhRMA also notes that Congress' requirement for notification at the pharmacy counter that a beneficiary is likely to benefit from the MPPP is largely meaningless without an ability to simultaneously opt into the program. Although we are disappointed that CMS is not considering a full effectuation of the POS election in 2025, we appreciate the opportunity to provide feedback on potential approaches to MPPP POS election. Regardless of the process ultimately selected, ***PhRMA urges CMS to effectuate POS election in 2025 if possible, and no later than 2026, as further delays in implementation will have negative consequences on beneficiaries and significantly diminish the achievements of the MPPP*****.**[16] ***PhRMA further encourages CMS to optimize the benefits of the MPPP by establishing multiple mechanisms in which beneficiaries can opt into the program***, as effectuating more than one proposed election method will reduce barriers to participation and may increase program uptake.

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[16] Dusetzina SB, Huskamp HA, Rothman RL, et al. Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions. Health Affairs. 2022; 41(4). https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01742

Overall Considerations for POS Election

We encourage CMS to ensure that all requirements and proposals throughout this guidance and future guidance regarding the MPPP are in agreement with one another, and do not pose any contradictory actions while under consideration.

PhRMA's detailed comments for each of CMS' proposed methods for POS election, including operational opportunities and implementation challenges, can be found in **Appendix A**. To simultaneously address the opportunities and challenges identified for each POS option in Appendix A, we strongly believe CMS should provide beneficiaries with multiple mechanisms to opt in year-round. These processes should be developed with beneficiary preference in mind, encompass a wide range of accessibility considerations, and prevent barriers to participating due to variability in technical proficiency, infrastructure limitations, language barriers, and disabilities. Particularly in the early years of the program, enrollees may also benefit from CMS and Part D plan sponsors deploying several different election options over time, based on feasibility, time to deploy, and resources needed to implement.

An approach using several successive implementation approaches will allow all stakeholders to realize incremental benefits over time – the delay in offering POS election for beneficiaries would be minimized while also giving the industry the time needed to develop and implement more robust technology systems. Based on the information presented on the three options proposed by CMS in this guidance, ***we encourage CMS implement a POS election option using a new clarification code on pharmacy claims.*** This option would minimize the disruption to current workflows for pharmacy staff and place minimal burden on the beneficiary. However, while the clarification code approach may provide a way to process a point-of-sale election via a pharmacy transaction, we note additional clarity is needed from CMS on the plan's processing of the participant election in MPPP using this approach. Simultaneously, ***we encourage CMS to develop a supplemental POS election option, like a mobile/web-based application, that may require more time but provides beneficiaries with more robust functionality and enhanced capabilities compared with the clarification code option.***

While we recognize the benefits of and support CMS offering beneficiaries multiple options for election, it will be important to ensure this does not inadvertently lead to different standards and requirements for participation based on when a beneficiary opts into the program or the mechanism they use to make the election. In Section 70.3.1 of the guidance, titled *Format of Election Requests*, CMS requires the beneficiary's signature (or electronic signature) to be captured on the options where appropriate (e.g., on paper election forms and website applications). For the telephone option, a verbal attestation of the intent to opt into the MPPP is captured and recorded during the call, in place of a signature. The Part D plan sponsors are then required to provide beneficiaries with evidence the election request was received (e.g., "confirmation code") during the election process. However, in the option for POS election using a clarification code, it is unclear if these same requirements are being satisfied. ***We encourage CMS to ensure that the same required elements are in place for beneficiaries whether***

requesting election before the plan year or during the plan year at POS and are consistent across all mechanisms for MPPP election.

PhRMA appreciates CMS providing extensive requirements and recommendations for various elections procedures under the MPPP. However, we note that there is a noticeable lack of guidance on re-election in the MPPP for participants who would like to continue in the program for the following year. Therefore, we ask that CMS provide clarification or request comment in Part Two of the guidance on whether election in the MPPP should automatically carry over from year to year, consistent with current standards on Part D enrollment. Additionally, we ask that CMS require that education and outreach materials, from both CMS and plans, clearly provide information on how beneficiaries are able to continue their participation in the MPPP from year to year, regardless of whether this is an automatic carryover from the prior year or participants must choose to elect each year.

Section 80 – Procedures for Termination of Election, Reinstatement, and Preclusion

PhRMA commends CMS for proposing protections in the draft guidance that ensure that Part D enrollees benefit from the MPPP, balancing beneficiary access and patient protections with plan operational and financial considerations. Specifically, we appreciate CMS' policies that create a grace period of at least two months, the ability to voluntarily opt out and pay outstanding amounts over the remaining months of the year, allowing reelection after payments are made, and the reinstatement policy for good cause for certain participants who do not pay billed amounts within the grace period due to uncontrollable or unforeseen circumstances.

We also encourage CMS to take additional steps to protect beneficiaries. Specifically, ***we strongly encourage CMS to create model language on beneficiaries' rights and responsibilities associated with terminating MPPP election to ensure that information is clear and consistent across all Part D plans. We also urge CMS to work with patient groups and senior advocacy organizations to ensure that the education and outreach materials on the MPPP clearly explain the participant rights and responsibilities under the program in a manner that is understandable and inclusive for all Part D beneficiaries across diverse backgrounds***. To that end, ***we encourage CMS to consider standardizing language in all beneficiary communications under the MPPP*** that informs and reminds participants of their option to voluntarily opt out from the MPPP at any time (while confirming that beneficiaries would continue to owe outstanding incurred costs to the plan), and that doing so may avoid potential adverse effects like involuntary termination. ***We also recommend that CMS measure outcomes associated with MPPP outreach, such as potential disparities in MPPP election among disadvantaged groups.*** If discrepancies are found, CMS should develop a plan to address these unintended consequences.

Additionally, the draft guidance indicates that plan sponsors may use different preclusion policies for different plans. ***We encourage CMS to ensure that plans use consistent language across all plans on reinstatement and the ability for Medicare beneficiaries to opt in to the MPPP in future years by repaying balances.***

Section 90 – Participant Disputes

PhRMA generally supports CMS's proposal to use existing Part D appeals and grievance procedures as delineated in section 1860D-4(h) of the Social Security Act and 42 CFR § 423.562 to adjudicate disputes regarding election requests, billing requirements, and termination-related issues. That said, it would be helpful for CMS to update its existing dispute resolution guidance to provide examples of how various MPPP-related disputes might be categorized and which resolution timeframes would apply. ***Given the 24-hour timeframe proposed in the draft guidance for processing mid-year elections, we suggest that CMS also adopt a 24-hour timeframe for resolving most election-related disputes.***

We urge CMS to conduct oversight of dispute resolution procedures and perform audits to ensure that plans properly resolve disputes between MPPP participants and their Part D plans. We also urge CMS to conduct additional outreach to MPPP stakeholders once the program has been fully implemented to determine if additional regulatory actions should be taken to strengthen current dispute resolution policies and processes.

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PhRMA appreciates the opportunity to provide feedback on Part One guidance on a select set of topics for the Medicare Prescription Payment Plan.

If you have additional questions about the topics discussed in our comments or are in need of further information, please feel free to contact Rebecca Jones Hunt at 202-835-3400. We are happy to discuss these comments and provide any further details or supplemental materials that you may request.

Sincerely,

/s/

Rebecca Jones Hunt
Deputy Vice President, Policy & Research

Judy Haron
Deputy Vice President, Law

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Daniel Fellenbaum

Senior Director, Policy & Research

Appendix A. Technical Feedback on POS Election Options for 2026 and Beyond

POS Election Option 1. Telephone-Only

Operational Opportunities: Telephone Option

We acknowledge that a telephone-based POS election approach would offer an option that is quick to deploy and require minimal technical education or expertise for beneficiaries. The beneficiary experience may be optimized by utilizing interactive voice response technology and designing a standardized voice-service menu, in multiple languages, to navigate at POS, providing a consistent, quick, and reliable process for MPPP election. Consistency in the steps/actions the beneficiary takes once calling the Part D sponsor's respective phone number would support pharmacy staff in assisting patients to navigate the election process at POS.

There is also an opportunity for this option to have a text-based functionality that could help further streamline this option in that any necessary notifications or documents about the program could be sent to beneficiaries through text. This option could be leveraged to alert beneficiaries "likely to benefit" about the MPPP and provide links to information about the program.

Implementation Challenges: Telephone Option

While establishing new phone numbers may be relatively simple from an infrastructure perspective, the process of communicating these new numbers to pharmacies and patients would need to be standardized across Part D plans. Creating a new phone number could cause confusion among beneficiaries and hinder uptake in MPPP. Therefore, this telephone option should be effectuated using an already established plan customer service number, i.e., the same number provided on insurance cards or plan documents, with a new menu option to opt into the MPPP.

If CMS uses a telephone option to achieve POS enrollment, Part D plan sponsors will need to develop internal processes and standard operating procedures (SOPs) that allow plans to receive beneficiary phone calls, triage inquiries, and effectuate MPPP elections made in real-time, including for calls that may come in outside of traditional business hours.

Additional implementation burden and increased demands may also be experienced by pharmacies, as beneficiaries are likely to be at the pharmacy counter when making the POS election via telephone. As a result, a telephone-based process could result in bottlenecks at the pharmacy counter as beneficiaries wait on hold with their plan sponsor unless the process is carefully structured to avoid disrupting other pharmacy workflow. In addition, a telephone-based process could potentially compromise beneficiary privacy, if beneficiaries engage in a conversation about their health status and prescriptions in a public pharmacy setting. We also note that relying on a non-automated process creates significant variability in the total time to process MPPP election and a lack of consistency in the process across pharmacies and Part D plan sponsors. If these factors are not controlled for in the process by Part D plan sponsors, the uncertainty and variability in the telephone method for POS election could create barriers to the ability of Part D beneficiaries to adopt MPPP election at POS.

While telephones are relatively more accessible and user-friendly forms of technology than other potential approaches, there will still be some beneficiaries who face technical barriers while utilizing this election method. CMS should take into account the technical and infrastructure limitations faced by some beneficiaries, including those requiring accommodations due to a disability and non-English speaking beneficiaries, when considering feasible options for effectuating POS election into the MPPP. For example, beneficiaries may not have access to a personal mobile phone to place the call to the Part D plan sponsor, and the pharmacy may not be able to provide access to a phone for the beneficiary to use. Particularly in rural or remote areas, beneficiaries may not have access to cell phone service or a landline. As such, ***PhRMA reiterates the importance of establishing multiple mechanisms in which beneficiaries can opt into the program, to account for the wide range of circumstances representative of all beneficiaries.***

POS Election Option 2. Mobile or Web-Based Application

Operational Opportunities: Mobile/Web-based Application Option

Implementing a mobile/web-based application would give beneficiaries access to multiple tools and functionality to assist with financial decision-making and managing their prescriptions, all through a single platform. In addition to allowing beneficiaries to opt into the MPPP, the same mobile/web-based application could provide beneficiaries with additional capabilities that help manage their medications, care, and health-related finances.

While a multi-functional application could provide significant value to beneficiaries, Part D plan sponsors could also benefit by utilizing the same application and incorporating additional functionality that supports compliance with CMS' other requirements related to the MPPP. For example, a single application could be developed to offer beneficiaries the option to elect into the MPPP, but then also be used by Part D plan sponsors to send program participants monthly electronic billing statements, calculate monthly maximum caps, establish a mechanism to notify pharmacies of beneficiaries with OOP costs that are likely to benefit from MPPP, conduct targeted outreach directly to individuals, and/or incorporate other real-time benefit tools.

We note that there is precedent for payer organizations and PBMs to develop and deploy mobile apps and web-based applications that are currently used to engage with members to provide useful information, access helpful tools, and facilitate the exchange of data/information and payments. While we recognize not all payers/plan sponsors may have mobile/web-based applications actively deployed today, ***CMS and Part D plan sponsors should strongly consider utilizing existing mobile/web-based applications where possible and modifying them to support MPPP needs, instead of developing completely new health information technology (HIT) applications.*** Leveraging existing health infrastructure and adapting it for the MPPP program could save a significant amount of development time and resources, and also allow the end product to be put into operation for beneficiaries much earlier than if a technology was developed from scratch.

The industry can also benefit from referencing historical use cases of HIT applications when considering the development, implementation, and adoption of new applications and software. We encourage CMS and all those involved in the development of mobile/web-based applications in relation to this Guidance to apply the learnings from other HIT platforms including electronic health records, digital health platforms, and telehealth applications. The industry has made significant strides in interoperability and adopting standards to allow for data sharing between technologies and IT platforms. If CMS pursues this mobile/web-based approach, it will be vital to the success of the applications and the MPPP to ensure these new applications are not developed in silos, freely allow for the exchange of information, and integrate with other existing, widely used applications and platforms to fully maximize the potential benefits to patients and the MPPP.

Implementation Challenges: Mobile/Web-based Application Option

While we recognize the opportunities the mobile/web-based application option can bring to beneficiaries participating in the MPPP, we acknowledge the implementation challenges and concerns with operationalizing this method. One challenge of utilizing mobile or web-based applications to effectuate MPPP election at POS is the time required to design, develop, test, implement, and adopt these applications. With the goal of effectuating POS election into MPPP no later than beginning in 2026, all stakeholders should be aligned on the collaboration and cooperation needed to achieve this goal – as well as the importance of the goal itself. In order to accomplish the necessary steps to develop a functioning application and virtually achieve universal adoption in approximately two years, we anticipate this would require significant governmental oversight and governance, as well as the use of third-party organizations to outsource the development and testing of the platforms.

In addition to the timeline and governance needed to support an expedited implementation of new applications, the variability in functionality, user experience, and user interface design between platforms will need to be accounted for and controlled. With an undefined number of potential applications being developed by Part D plan sponsors and available for beneficiaries to use, ***CMS should establish clear guidelines and recommendations for the development of the technology applications to minimize the risk of significant inconsistency and variability in beneficiary experience.*** For the development and updating of electronic health record (EHR) technology, the Office of the National Coordinator for Health Information Technology (ONC) develops the infrastructure, establishes standards, and defines functional requirements that is adopted industry wide for EHRs, resulting in a more uniform market with consistency and an assurance of quality. When evaluating the potential of the mobile/web-based application for the MPPP, CMS should recognize the lessons from the EHR/ONC relationship and evaluate the applicability to MPPP applications. CMS should seriously consider the implications to the MPPP and viability of POS election if these applications are developed in the absence of universally adopted standards and proper oversight.

Larger health plans, pharmacy benefit managers, and Part D plan sponsors will likely have more historical experience with deploying mobile/web-based applications and will likely have more resources to bolster the development, implementation, and educational requirements that

support the adoption of their platform. These organizations likely have already implemented proprietary mobile/web-based applications that are currently used to manage their lines of business and engage with their members, while also providing enhanced functionality to their beneficiaries. This inequity in historical experience and current technological infrastructure could disadvantage other Part D plan sponsors who do not have the same resources, and subsequently negatively impact their members who may not be able to benefit from the same robust applications and resources that other payers and large, retail pharmacy chain stores may be able to offer.

Similar to the concerns voiced for technical literacy and infrastructure limitations faced by certain beneficiaries in assessing the telephone election option, we reiterate heightened concerns with the mobile/web-based application election option. The varying technical proficiency in end-users (i.e., patients and pharmacists) has the potential to have a negative impact on adoption and utilization of the applications within these populations. Furthermore, infrastructure limitations may exist, such as limited access to internet service in rural areas, or no access to a smart phone with connectivity to download an app/access the webpage.

We also note that any new mobile or web-based option must have appropriate data controls and confidentiality guidelines in order to protect the sensitive health and financial information for participants in the MPPP.

Again, ***CMS should take into account the technical and infrastructure limitations faced by beneficiaries when considering feasible options for effectuating POS election into the MPPP.*** PhRMA reiterates the importance of establishing multiple mechanisms in which beneficiaries can opt into the program, to account for the wide range of circumstances representative of all beneficiaries.

POS Election Option 3. Clarification Code

Operational Opportunities: Clarification Code Option

Pharmacies, Part D plan sponsors, PBMs, and other entities involved in the processing of Part D prescription drug claims are required to use the NCPDP standards for exchanging HIPAA-sensitive prescription drug data and submitting financial transactions. Since the initial implementation and universal adoption of NCPDP's pharmacy claim standards, these standards have been subject to several changes and updates effectuated by CMS final rules issued over the years. When updating the current standards to accommodate new MPPP POS election clarification codes, the industry can benefit from having a known, well-defined process through established rulemaking and statutory-defined procedures.

Based on the brief description of the workflow provided in the Part One draft guidance, the clarification code option would largely be an automated process, in that it requires minimal input from the end users (beneficiary making election decision and pharmacy staff appending clarification code to claim). With the exception of making the decision to elect into the MPPP and notifying the pharmacy of such decision, the beneficiary's role in the pharmacy process

would be significantly eased (virtually eliminated) at the POS compared to the other proposed approaches. This would significantly mitigate the burden placed on the beneficiary and reduce the potential for error.

Implementation Challenges: Clarification Code Option

NCPDP has defined multiple pathways and mechanisms for updating claim standards and incorporating new workflows, depending on the magnitude of the update, how much of the existing process the proposed update affects, and the changes necessitated by the update. Proposed updates that significantly alter current workflow may necessitate a full update to the existing NCPDP standard, requiring an updated version of the standard to be developed and released. NCPDP uses a consensus-based process for standards development, so more significant update requests may involve convening stakeholder action groups, work groups, or task groups to vote on the approval of updated standards, obtaining public comment through ballots, approvals by Consensus Voting Group, Standardization Committee, and Board of Trustees.[17] This becomes an issue with ensuring a clarification code will be developed, validated and voted on via the consensus-based process in time for a January 1, 2026 implementation date.

Regardless of whether the changes needed to accommodate new clarification codes for POS election require a full version update to claim standards or a simplified NCPDP internal process, CMS should start the process now, so that it is able to effectuate this proposed option and implement POS MPPP election by January 1, 2026.

If CMS chooses to pursue a new clarification code approach, this could require changes to existing pharmacy claims processing workflows. Use of a clarification code to effectuate point-of-sale enrollment would only likely be achieved if the appropriate code is appended on initial submission of the claim. It is our understanding that submission clarification codes today are attached to claims more on a retroactive basis, after receiving additional messaging from the plan. Thus, pharmacy staff education and training on understanding the new clarification code usage requirements and utilizing the correct clarification code value in the appropriate field will be vital in properly implementing POS election of MPPP. Omission of the new clarification code during initial claim submission of could result in incorrect billing and/or payments, the need for financial reconciliation, or a delay in the delivery of patients' medications.

As such, we reiterate the importance of pharmacy staff education, robust implementation training, and providing supporting resources to pharmacies on the identification of clarification codes and their proactive use on initial claim submissions in order to successfully effectuate this POS option.

[17] https://standards.ncpdp.org/Our-Process.aspx