



March 15, 2024

The Honorable Meena Seshamani  
Deputy Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Submitted electronically to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov).

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

Dear Deputy Administrator Seshamani:

AARP, which advocates for the more than 100 million Americans age 50 and over, appreciates the opportunity to comment on the February 15, 2024, draft part two guidance pertaining to the new Medicare Prescription Payment Plan (MPPP) created by the Inflation Reduction Act of 2022. This policy will help ensure greater payment flexibility to help make prescription drugs more affordable and accessible for seniors.

We appreciate the Centers for Medicare and Medicaid Services' (CMS) ongoing efforts to obtain feedback during the MPPP implementation process and to ensure that, starting in 2025, people in Medicare prescription drug plans will have the option to spread their prescription drug costs over the course of the plan year. This option will provide cost relief and flexibility for older Americans, particularly those with high out-of-pocket (OOP) costs earlier in the plan year. As with all of the prescription drug provisions included in the new prescription drug law, we encourage CMS to pursue a timely and robust implementation of this program with a strong focus on benefiting consumers.

AARP continues to urge CMS to prioritize consumer and family caregiver engagement and support in the MPPP program implementation process. We encourage CMS to conduct ongoing listening sessions and focus groups with diverse populations of Medicare beneficiaries, caregivers, and other patient advocates to help ensure that adequate and appropriate feedback is obtained and that MPPP education and outreach materials meet consumers' needs.

With respect to the draft part two guidance, we offer the following comments, organized in the order they appear in the proposal.

## **Outreach, Education, and Communications Requirements for Part D sponsors (section 30)**

### **1. General Outreach and Education (section 30.1)**

AARP strongly supports requiring Part D plan sponsors to update and use plan materials that are already furnished to Part D enrollees. These materials are familiar to existing enrollees and create multiple opportunities for plans to provide educational information about the MPPP. AARP encourages CMS to consider requiring the use of distinctive formatting to better differentiate MPPP information from standard plan materials.

AARP supports requiring plan sponsors to include comprehensive information about the program on their websites in a clear, conspicuous manner, including information about the Low-Income Subsidy program, and to encourage plans to link to CMS-developed educational products and resources where applicable. Such information will be integral to ensuring that consumers select the most appropriate program to meet their needs.

### **2. Targeted Outreach and Education (section 30.2)**

Not all enrollees will benefit from the MPPP, so AARP strongly supports requiring Part D plan sponsors to undertake targeted outreach, both prior to and during the plan year, for Part D enrollees likely to benefit from the program.

Prior to the plan year, AARP supports CMS's decision to require plans to focus their efforts on Part D enrollees who had annual out-of-pocket costs of at least \$2,000 through the first three quarters of the prior year, which should help identify many of the enrollees who are likely to benefit from the MPPP. AARP encourages CMS to consider regularly updating this threshold to ensure it remains aligned with the Part D out-of-pocket spending limit.

During the plan year, AARP supports CMS' requirement that plan sponsors engage in targeted outreach if they become aware of a new prescription for a Part D enrollee that would result in out-of-pocket costs that exceed \$600 and trigger the pharmacy point-of-sale notification process. Like the \$2,000 threshold above, we encourage CMS to regularly update this threshold to ensure it remains appropriate for the OOP spending limit. We also encourage CMS to consider applying this point-of-sale notification threshold to OOP costs for all prescriptions filled in a single day.

AARP also strongly supports CMS' position that the targeted enrollee outreach approach outlined in this guidance is a minimum requirement and agrees that plans should be permitted to develop supplemental strategies for identification of additional Part D enrollees likely to benefit during the plan year. However, AARP urges CMS to ensure that any emerging technologies—including artificial intelligence—used to identify Part D enrollees that may benefit from MPPP do not reinforce existing biases and disparities in the health care system. For instance, underrepresentation of minorities because of racial biases in dataset development might lead to subpar prediction results for members of those groups. Plans should continue to monitor their outreach processes to ensure they are reaching all relevant groups.

CMS should also use lessons learned from the first few years of the MPPP to identify enrollee characteristics—such as health conditions and medications—that make it more likely that they will benefit from the program and use this information to guide future outreach requirements.

Finally, AARP strongly supports efforts to educate pharmacists and other health care providers about the MPPP, as Part D enrollees will benefit from having access to guidance and information at both the point of sale and the point of prescribing. AARP encourages CMS to consider other parts of the health care system that offer additional opportunities to educate older adults about the MPPP, such as community health workers and *promotoras de salud*. A multi-pronged approach could help improve awareness and alleviate concerns about overreliance on pharmacists who may not have time to engage in comprehensive discussions about MPPP.

3. Communications with program participants and model materials requirements for Part D sponsors (section 30.3)

AARP strongly supports efforts to ensure that Part D plan sponsors offer additional information about the MPPP, including what the potential enrollee's estimated monthly payments will be under the program, to ensure that consumers understand the financial implications of participation. This information should be as individualized as possible and clearly indicate whether the enrollee may be less likely to benefit from the MPPP. Further, we wholly support the requirement for Part D sponsors to offer and accept paper, telephone, and website election options.

AARP strongly supports the requirement that plans communicate with Part D enrollees via written notices and believes such notifications should also be provided electronically. Plan sponsors should be required to utilize more than one method of communication to help ensure that Part D enrollees receive MPPP-related information.

It is imperative that all Part D plan materials and communications fully explain the MPPP enrollment and disenrollment process, including possible changes in billing procedures that could occur if they decide to disenroll. Regardless of whether an MPPP participant voluntarily terminates their participation in the program or are terminated due to lack of payment after the grace period, consumers must be informed prior to enrollment about the possibility of being asked to pay a lump sum when their participation is terminated. Relevant documents, including model notice documents, should clearly inform consumers of this possibility.

AARP also strongly supports the requirement for Part D plan sponsors to work with enrollees to determine how they will pay their outstanding benefits and supports CMS' position that Part D sponsors cannot require full immediate repayment. There must be clear consumer protections in place to ensure that enrollees can report intimidation or concerns about the repayment process, should they arise.

4. Language and accessibility requirements (section 30.4)

AARP strongly supports CMS' efforts to ensure that all MPPP-related materials are provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency or reading skills and from diverse cultural and ethnic backgrounds. AARP also supports CMS' requirement that Part D plan sponsors be responsive to Part D enrollees who speak non-English languages or require accessible formats.

## **CMS Part D Enrollee Education and Outreach (section 40)**

### **1. Modifications to Existing Part D Resources (Section 40.2)**

AARP strongly supports CMS' commitment to developing new Part D educational resources and updating existing Part D resources. We encourage CMS to conduct ongoing listening sessions and focus groups with Medicare beneficiaries, caregivers, and other patient advocates to help ensure that these materials meet their needs.

AARP also strongly supports CMS' proposal to modify to existing Part D resources, including the Medicare & You handbook, Medicare.gov, and the Medicare Plan Finder, among others. For example, Medicare Plan Finder could be updated to direct users to MPPP materials when their estimated out-of-pocket costs reach a certain threshold. Similarly, Medicare.gov and the Medicare Plan Finder could be updated to include an online calculator that allows users to view their estimated monthly payments should they enroll in the MPPP.

### **2. National Outreach and Education Efforts (section 40.3)**

AARP applauds CMS' commitment to ensure that consumers have all the resources and assistance they need to learn about the availability of the MPPP. This includes working with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates – including State Health Insurance Assistance Program (SHIP) counselors – have sufficient support and materials needed to effectively communicate the availability and nuances of the MPPP to individuals.

AARP continues to believe that online decision support tools that provide real-time, individualized assistance with enrollment could play an important role in the MPPP. Such tools should be easily accessible and understandable and ideally available on CMS and Part D plan sponsor websites.

Further, given the role that caregivers often play in assisting with Part D plan selection and enrollment, we strongly encourage CMS to ensure that the larger public is aware of the availability of the MPPP program and related educational and outreach materials.

## **Pharmacy Processes (section 50)**

### **1. Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount (section 50.1)**

In some cases, individuals may have supplemental coverage for their prescription drug costs, such as through State Pharmaceutical Assistance Programs (SPAP), charity, or other health insurance. This can reduce the final patient pay amount on covered Part D drugs. AARP agrees that Part D plan sponsors should ensure that their customer service representatives are aware of this possibility and are provided with the support and materials they need to assist Part D enrollees with such coverage who are seeking to participate in the MPPP.



## 2. Pharmacy POS Notifications Late in the Plan Year (section 50.2)

AARP strongly supports CMS' position that Part D plan sponsors should ensure that their customer service representatives are prepared for the possibility of consumers receiving a point-of-sale notification based on their OOP costs and inquiring about enrolling in MPPP late in the year. Part D plan sponsors should take steps to ensure that their customer service representatives can accurately and adequately explain the financial implications of enrolling in MPPP late in the year.

## 3. Pharmacy POS Notifications in Retail and Non-Retail Pharmacies (section 50.3)

AARP applauds CMS' requirement for the pharmacy notification process to apply in all pharmacies, regardless of setting, if a Part D enrollee identified as likely to benefit declines to complete the prescription filling process. One in five seniors skip, delay, take less medication than prescribed, or take someone else's medication because of concerns about cost,<sup>1</sup> which can lead to serious health consequences. This requirement will help ensure that no senior falls through the cracks simply because of the pharmacy they happen to utilize.

AARP also supports pharmacies' ability to develop additional strategies to provide the "Medicare Prescription Payment Plan Likely to Benefit Notice" to Part D enrollees identified as likely to benefit from the program. AARP agrees that pharmacies with disease management or medication management programs may be well-suited to include MPPP information as a component of those processes and programs.

Lastly, AARP continues to strongly encourage CMS to track downstream effects from MPPP implementation, including whether participation is considerably higher or lower than expected, if enrollees are struggling to understand and meet their financial obligations under the program, and any implications for beneficiary premiums.

Thank you again for the opportunity to comment on the implementation of this important program, which will help provide financial relief and flexibility to Medicare enrollees with high out-of-pocket prescription drug costs. We look forward to continuing to work with you on this effort. If you have any additional questions, feel free to contact me or Gidget Benitez on our Government Affairs team at [gbenitez@aarpp.org](mailto:gbenitez@aarpp.org).

Sincerely,



David Certner  
Legislative Counsel and Legislative Policy Director  
Government Affairs

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<sup>1</sup> Dusetzina SB, Besaw RJ, Whitmore CC, et al. Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022. *JAMA Netw Open*. 2023;6(5):e2314211. doi:10.1001/jamanetworkopen.2023.14211



BY ELECTRONIC SUBMISSION VIA PARTDPAYMENTPOLICY@CMS.HHS.GOV

March 15, 2024

Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director of the Center for Medicare  
Centers for Medicare & Medicaid Services  
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**RE: Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments**

Dear Dr. Seshamani,

AbbVie Inc. ("AbbVie") appreciates the opportunity to provide feedback on the February 15, 2024 draft guidance implementing section 11202 of the Inflation Reduction Act ("IRA") ("draft guidance"). This provision establishes a mechanism for individuals enrolled in Medicare Part D to cap and spread their out-of-pocket (OOP) prescription drug costs to allow for more consistent and affordable monthly payments beginning in 2025. The Centers for Medicare & Medicaid Services ("CMS") refers to this program as the "Medicare Prescription Payment Plan" ("MPPP" or "program").

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas – immunology, oncology, neuroscience, and eye care. We are pleased to share our views on the MPPP and provide our recommendations to some of the policies set out in the draft guidance.

**Overview**

AbbVie supports the robust outreach and education requirements that the Guidance would require of Part D plan sponsors ("plans") as they relate to the MPPP. We have previously submitted comments on Part One of the MPPP Guidance, in which we stressed that the ultimate goal of the MPPP must be to achieve high levels of beneficiary enrollment into and satisfaction with the program. We commend CMS for setting forth a process for establishing clear and consistent requirements for plan outreach and education to enrollees in the draft guidance, which we believe will reduce confusion and enhance the quality of the MPPP experience for enrollees across different plans, as Congress envisioned.

AbbVie's comments on the draft guidance focus on the following key recommendations:

- **Standardize All Communications From Plans Relating To MPPP** (Section 30)
  - AbbVie recommends that CMS clarify that Part D plans must only use all standardized model materials developed by CMS where applicable. At the very least, if CMS allows any flexibility in the language used to communicate with beneficiaries on MPPP, Part D plans should submit any alternative materials to CMS for prior approval.

- AbbVie recommends that CMS require Part D plans must include standardized materials with the membership ID card.
- AbbVie recommends that CMS require standardized website language related to education on the MPPP for enrollees and other stakeholders.
- AbbVie recommends CMS clarify how it will oversee Part D plans' adherence to the MPPP's education and outreach requirements.
- AbbVie recommends that CMS develop standardized educational materials that Part D plans can share with providers and pharmacies regarding the MPPP.
- **Medicare Plan Finder (Section 40)**
  - AbbVie recommends that CMS prioritize updating Medicare Plan Finder to include educational material on the MPPP, specifically by incorporating an interactive calculator tool that allows beneficiaries to estimate and compare various cost-sharing outcomes under MPPP so that they can make a more informed decision of whether they are likely to benefit from the MPPP.

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**I. CMS should clarify that the MPPP information Part D plans are required to provide with the membership ID card must be standardized content provided by or approved by CMS in advance (Section 30.1.1).**

CMS indicates that when Part D plans provide enrollees their membership ID card, the plan must also include a hard copy mailing of (1) information regarding the MPPP, and (2) an MPPP election request form. CMS requires plans to provide this information but does not require that plans use CMS-developed, standardized language to meet this requirement. Further, CMS does not require that in the instance plans do not use standardized materials, that the materials be approved by CMS in advance.

AbbVie agrees with CMS that Part D plans should include MPPP educational materials alongside the membership ID. However, AbbVie believes that every communication between Part D plans and enrollees, providers, or pharmacies regarding the MPPP should be standardized to ensure consistent education of all stakeholders. Thus, we urge CMS to require that plans only use standardized educational materials that would accompany the membership ID card. If CMS does not develop standardized educational materials, any materials sent by the Part D plan should be approved by CMS in advance.

**II. CMS should establish a standardized format for plan websites as they relate to communicating information on the MPPP (Section 30.1.5).**

CMS will require plans to include information regarding the MPPP on their websites, in addition to providing an election request mechanism for enrollees to opt into the program electronically. CMS outlines multiple pieces of content that the website must include and encourages plans to use language from the CMS-developed educational product on the MPPP and other CMS-provided resources to meet these requirements.

AbbVie urges CMS to require plans to use uniform, CMS-developed educational and outreach content on their websites. We believe the policy aim of ensuring Part D enrollees are consistently and adequately informed regarding MPPP, regardless of plan sponsor, outweighs any interest in ensuring plan flexibility. CMS has expressed a preference for standardizing content on other websites due to similar worries about inconsistencies and confusion, such as in

the case of hospital transparency requirements effective July 1, 2024<sup>1</sup> and the proposed standards for web-brokers and Direct Enrollment (“DE”) entities regarding the display of standardized qualified health plan (“QHP”) information.<sup>2</sup> Standardizing information regarding MPPP is similarly critical given the complexity of the program and the benefits that can accrue to enrollees likely to benefit. Moreover, because of the financial and operational implications of MPPP, plans may not have the same strong interest in ensuring the program is adequately described to enrollees as CMS does. Therefore, we strongly recommend that CMS require that any discussion of and reference to the MPPP on plan websites use the standardized content developed by CMS to avoid the potential confusion that non-standardized webpages containing MPPP information may create for enrollees.

### **III. CMS should clarify how it will monitor Part D sponsors’ compliance with targeted outreach requirements (Section 30.2).**

On February 2, 2024, CMS released a Paperwork Reduction Act (“PRA”) package updating the Medicare Part D Reporting Requirements for sponsors.<sup>3</sup> In the supporting materials, CMS noted that the information collected would support “oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries” and this includes various data points for the MPPP. Data collected via the Medicare Part D reporting requirements will be an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries.

However, the updated PRA for Part D reporting requirements only require plans to submit “total number of individuals identified during the reporting period as likely to benefit from the MPPP based on POS criteria (unique beneficiaries, including those who did not elect to participate in the MPPP),” not those identified prior to the plan year based on incurred costs in the current plan year or identified during the plan year via utilization management (UM)/prior authorization (PA) processes. Therefore, it is unclear how CMS will have access to the data necessary to retrospectively assess plan sponsors’ compliance with these requirements. Further, CMS does not have access to real-time data on UM/PA requests, so it is unclear how the agency would monitor compliance with these requirements in real-time. AbbVie urges CMS to clearly define how it will enforce these new targeted outreach requirements with plan sponsors to ensure that enrollees who are likely to benefit are appropriately notified both before and during the plan year.

### **IV. CMS should establish a standardized format for communications between plans and their contracted providers/pharmacies as it relates to communicating information on the MPPP (Section. 30.2.3).**

CMS believes health care providers and pharmacists can play a key role to help their patients understand and manage their prescription drug costs, and to inform them about how the MPPP can help lower their monthly out-of-pocket expenses. CMS encourages Part D sponsors to share information about the MPPP with their contracted providers and network pharmacies, and to tailor their messages to different provider specialties and pharmacy types based on the

<sup>1</sup> <https://www.cms.gov/files/document/hospital-price-transparency-file-template-webinar-january-2024.pdf>.

<sup>2</sup> 88 Fed. Reg. 82510, 82518 (Nov. 24, 2023).

<sup>3</sup> CMS-10185. <https://public-inspection.federalregister.gov/2024-02095.pdf>.

likelihood of prescribing or dispensing high-cost drugs. CMS also encourages Part D sponsors to educate pharmacies on how the MPPP works and how it can help patients.

AbbVie questions the rationale for CMS's decision not to require uniform communications between plans and their providers and pharmacies regarding the MPPP. This outreach is yet another area of the MPPP's administration that would be improved by more consistency in the educational materials that inform stakeholders of its objectives, how it works, and when enrollees are likely to benefit. We strongly urge CMS to impose standard requirements for the educational materials exchanged between plans and their providers and pharmacies.

**V. CMS should prioritize updating Medicare Plan Finder so that enrollees can use it as a one-stop shop to learn about the MPPP and compare expected OOP costs with and without the MPPP (Section 40.2).**

CMS indicates that the agency will make “appropriate modifications” to CMS-provided Part D materials, and that it “may include...the Medicare Plan Finder....” CMS does not provide any more detail on what changes the agency is considering for Medicare Plan Finder. Further, in Part 1 draft guidance, CMS noted that “CMS will develop tools to help people with Medicare Part D and their caregivers learn what monthly payments might look like under this program” and “to help Part D enrollees decide whether the program is right for them” but the agency did not provide any further details on these tools in the final guidance.

The Medicare Plan Finder is the primary source of individualized information and comparison for enrollees seeking to enroll in a Part D plan, and it is imperative that it clearly reflects the availability and implications of the MPPP option. Furthermore, the Medicare Plan Finder is a web-based platform that can leverage CMS's existing data systems and provide enrollees with tailored and dynamic information on plan costs, benefits, quality, and formulary coverage based on an individual drug list entered by enrollees or their caregivers. This individualized calculator tool already exists in the Medicare Plan Finder and could be updated to provide a clear monthly comparison of expected monthly OOP costs for beneficiaries both with and without the MPPP. The Medicare Plan Finder is therefore one of the most effective and efficient ways to educate enrollees about and their likelihood to benefit from the MPPP in a highly personalized manner.

An interactive tool also enables enrollees to make informed choices, instead of being mere recipients of Part D plan education and outreach efforts. Based on the criteria that CMS requires alone (*i.e.*, \$600 per script threshold, \$2K OOP costs in current year, UM/PA process for high-cost prescriptions), Part D plans may not effectively reach some enrollees who stand to benefit, and an interactive comparison tool on Plan Finder for the MPPP would allow them to examine their own financial situation and determine whether the program is beneficial for them, irrespective of CMS's and the plan's standard approaches for making the same judgment.

Therefore, we urge CMS to develop and implement an interactive calculator tool within the Medicare Plan Finder that allows enrollees to simulate how their cost sharing obligations under the MPPP would vary under different drug spending scenarios and under different plan options. The interactive tool must also inform enrollees of the potential benefits and trade-offs of electing the MPPP option at different points in the plan year. Further, we recommend that CMS make beneficiaries aware of this new calculator tool through beneficiary education and marketing. For example, we would recommend a pop-up screen alerting beneficiaries that there is a calculator tool for MPPP when they log into medicare.gov or Medicare Plan Finder.





CMS has swiftly made technical changes to Medicare Plan Finder in the past, such as when it updated the website to reflect the Part D Savings Model insulin-related cost-sharing limitations in roughly six to seven months.<sup>4</sup> Further, less than two months after passage of the Inflation Reduction Act (“IRA”), CMS was able to update Medicare Plan Finder to include new insulin and vaccine drug footnotes and other help features to explain the benefit changes resulting from the IRA.<sup>5</sup> By providing enrollees with this tool at the point of plan selection, CMS can facilitate informed and timely decision-making regarding the MPPP. As CMS has acknowledged in the draft guidance, the sooner an enrollee can make an informed decision about the MPPP, the more they can benefit from lower and more predictable Part D costs.

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AbbVie appreciates CMS's efforts to implement the MPPP and to ensure that Part D enrollees are well-informed of their options to lower their out-of-pocket costs for prescription drugs. However, we believe that CMS should reconsider several instances in the draft guidance where it would allow Part D sponsors to deviate from the CMS-developed standardized communication formats and content for the MPPP in certain communication channels, such as plan websites and provider/pharmacy communications. We are concerned that allowing variation in these contexts could create inconsistency and confusion among enrollees, providers, and pharmacies, and undermine the beneficiary experience with the MPPP. We urge CMS to require uniformity and consistency in the presentation and dissemination of information on the MPPP across all plans and stakeholders. Thank you for the opportunity to provide feedback on implementation of this important program for patients. If you have any questions, please contact Whitney Hubbard, Director of U.S. Policy, at [whitney.hubbard@abbvie.com](mailto:whitney.hubbard@abbvie.com).

Sincerely,

Hayden Kennedy  
Vice President, Global Policy & U.S. Access Strategies  
On behalf of AbbVie Inc.

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<sup>4</sup> President Trump Announces Lower Out of Pocket Insulin Costs for Medicare's Seniors, CMS (May 26, 2020), <https://www.cms.gov/newsroom/press-releases/president-trump-announces-lower-out-pocket-insulin-costs-medicare-seniors>.

<sup>5</sup> Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin, CMS (September 26, 2022).



March 16, 2024

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, MD 21244-8013

*Submitted electronically via regulations.gov*

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

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the Medicare Prescription Payment Plan: Draft Part Two Guidance.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

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

AMCP supports CMS' efforts to clarify the requirements around outreach and education but is concerned about the administrative burden faced by Part D sponsors in implementing these requirements and integrating them into existing processes in a short time period. The ability to send point-of-sale (POS) messaging that is specific to a particular beneficiary varies depending on the systems and technology infrastructure of individual Part D plans and their contracted pharmacies. Some plans may have the capability to send targeted POS notifications based on individual member profiles and eligibility criteria, while smaller plans may need to rely on manual interventions. AMCP encourages CMS to minimize this burden by exercising enforcement discretion during the initial year while plans determine how best to integrate the new requirements into their existing processes.

AMCP encourages CMS to continue to work closely with plans and provide ongoing guidance as they incorporate information about the Medicare Prescription Payment Plan (M3P) into their existing educational and communication materials. Plans will need to ensure that the information is clear and understandable for beneficiaries while also fitting into the limited space

available on these materials. Presenting information about the M3P program in a clear and understandable manner is crucial to ensuring that enrollees comprehend their options and make informed decisions. Part D plans must carefully craft the language and design of the outreach materials to effectively communicate the purpose and benefits of the M3P program. The effort needed to configure existing systems and the increased costs of disseminating the information will add to the cost of plan administration. AMCP anticipates that these outreach efforts will also drive traffic to plans' call centers, further increasing costs for plans. CMS should promote the use of technology wherever possible in outreach to enrollees. Utilizing online portals, mobile apps, and social media channels to disseminate information about the M3P program could reach enrollees who prefer digital communication channels and enhance accessibility to educational materials. AMCP encourages CMS to provide model language for these digital channels and to consider introducing decision aids or interactive online platforms, such as a monthly cost calculator, to help beneficiaries better understand how the M3P will help them manage their personal prescription drug costs.

### **“Likely to Benefit” Notification**

AMCP is concerned about the burdens of implementing the “likely to benefit” notifications as they may pose potential technical challenges and will require coordination between different IT platforms, specifically for smaller plans which may not already have the ability to target communications at the POS. These notifications will require the creation of efficient processes to analyze claims data as well as real-time data exchange between Part D plans and pharmacies. AMCP encourages CMS to expand the standardized tools and templates it develops for Part D sponsors to use in identifying and notifying eligible enrollees.

### **Part D Sponsors Communication with Providers/Pharmacies**

CMS should encourage consistent, effective communication with prescribers and pharmacists to enhance engagement and collaboration with providers and pharmacies in promoting the M3P program and ultimately improve enrollee awareness and participation. CMS should consider developing standardized, easy to understand primers and other educational materials specifically geared toward these front-line audiences (e.g., “a train the trainer” for prescribers).

Part D sponsors may face difficulty in communicating with pharmacies about the M3P program, specifically in ensuring consistent messaging and adequate education for pharmacies and other healthcare providers. Encouraging active engagement and participation from providers and pharmacies in promoting the M3P program may be challenging, especially given the competing priorities and limited time available for them to dedicate to education and outreach efforts. Providers and pharmacies likely already receive a significant amount of information from various sources, including pharmaceutical companies, health plans, and regulatory agencies. Adding information about the M3P program to existing communications may risk overwhelming providers and pharmacies and diminishing the impact of the message. Additionally, integrating information about the M3P program into existing provider and pharmacy workflows will potentially disrupt established processes and require additional time and resources for training and implementation. Ensuring buy-in and support from providers and pharmacies for the M3P program will require building trust, addressing concerns, and demonstrating the program's value proposition. Providers and pharmacies may be more receptive to communication efforts if they perceive tangible benefits for themselves and their patients.



Opportunities to streamline communications with providers and pharmacies about the M3P program include tailoring communication efforts to specific subgroups of providers and pharmacies based on specialty and prescribing patterns to increase relevance and effectiveness. For example, focusing on providers who frequently prescribe high-cost drugs or pharmacies that dispense specialty medications may yield better results than more generalized messaging. Leveraging existing communication channels and platforms already used by providers and pharmacies, such as electronic health record systems, pharmacy management software, or professional associations, may also help to streamline communications. CMS should consider partnering with pharmacy associations, patient advocacy groups, and provider organizations through joint educational events, resource sharing, and mutual support to enhance the reach of communication efforts.

### **Pharmacy Network Contracts**

AMCP's members are concerned about how to successfully implement and administer the M3P program, including best practices for coordinating with their pharmacy networks. Implementing the contract changes necessary for POS notice and pharmacy network requirements may pose potential difficulties for Part D plans, including negotiation, monitoring, and quality control. Requiring pharmacies to provide POS notifications to enrollees will likely require contract negotiations with pharmacy partners, some of which may be resistant to undertaking new responsibilities. Part D plans must also establish mechanisms to monitor and enforce compliance with the POS notification obligations across their pharmacy network. Part D plans will need to establish mechanisms to assess the completeness, timeliness, and consistency of notifications and address any issues or discrepancies identified.

### **Timeline for Implementation**

AMCP's members are concerned about the timeline for implementation and ensuring that Part D sponsors are not penalized despite their good faith efforts at compliance. For this reason, AMCP recommends a good faith compliance safe harbor or enforcement discretion. AMCP also recommends that all forms and educational materials be finalized by CMS as early as possible.

### **Conclusion**

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at [etunstall@amcp.org](mailto:etunstall@amcp.org) or (703) 705-9358.

Sincerely,



Susan A. Cantrell, MHL, RPh, CAE  
Chief Executive Officer



March 15, 2024

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

**RE: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025**

Dear Administrator Brooks-LaSure:

The Alliance of Community Health Plans (ACHP) applauds the Centers for Medicare & Medicaid Services' (CMS) commitment to making health care accessible, equitable and affordable. With the implementation of the Inflation Reduction Act, ACHP remains focused on lowering the price of drugs for all Americans and ensuring the cost of prescription drugs is not a barrier to care. We appreciate the opportunity to provide feedback on implementation of the new monthly Part D cap for seniors.

ACHP represents the nation's top-performing, nonprofit health plans that provide high-quality coverage and care to tens of millions of Americans across nearly 40 states and D.C. Our member companies serve diverse populations across all lines of business and support comprehensive drug pricing reform.

ACHP recognizes the complexity of implementing a program that allows enrollees the option to pay their out-of-pocket drug costs through monthly payments over the course of the plan year instead of upfront payments at the pharmacy counter. We appreciate that this guidance considers many of the challenges identified in response to part 1 of the guidance and urges that it be finalized as soon as possible.

Our comments to the draft part two guidance focus on:

- (1) Outreach, Education, and Communications Requirements for Part D Sponsors
- (2) Pharmacy Processes
- (3) Part D Sponsor Operational Requirements



### Outreach, Education, and Communications Requirements for Part D Sponsors

While section 1860D-2(b)(2)(E)(v)(III)(bb) of the Social Security Act requires Part D sponsors to notify prospective enrollees of the option to participate in the Medicare Prescription Payment Plan prior to the plan year, the timing of the requirement presents significant challenges for CY 2025. Health plans' communication materials for CY 2025 will be completed and printed in advance of finalizing Parts 1 and 2 of this guidance. While we value the importance of communicating the option and implications of the new program to beneficiaries, the requirements outlined in part 2 of the guidance present a significant challenge to Part D Plan sponsors until the CMS-developed educational product and other resources are released. The later these resources are released, the more challenging it will be to comply for this upcoming calendar year. **ACHP requests CMS provide plans a waiver for delivering the new materials by the current deadlines or allow plans to post the new materials on their plan websites to meet member notification requirements.**

The information provided in the draft guidance is helpful for understanding how to communicate with those "likely to benefit" while recognizing that each beneficiary's circumstances may change throughout the year – including clinical condition, medication status or cost-sharing. Further, utilization management systems (as referenced in 30.2.2.2) are designed to manage coverage decisions in terms of decisions, timers, documentation and storage of documents. Pricing is not part of the decision-making process and will require the creation of a new process that will be difficult to operationalize with the current timelines. **ACHP requests notice be provided as soon as possible rather than the coverage determination timing requirement as these are distinct processes. Even following the Coverage Determinations, Appeals and Grievances timeframes may not result in reaching an enrollee prior to them reaching the point of sale.** For the Notice of Acceptance of Election as outlined in 3.3.2 we request that rather than written notice, it be left to member preference. We look forward to working with CMS to balance plan requirements, effective beneficiary communication and successful program implementation.

### Pharmacy Processes

While Part D sponsors can include contracting language requiring pharmacies to provide notification to enrollees, it is not feasible for a plan sponsor to monitor or enforce this requirement. Similarly, if a prescription is abandoned as outlined in 50.3 of the guidance, it would be difficult to provide notification as the enrollee is not likely to be present in-person. In both instances, plans can make their best faith effort yet be unable to meet the requirements as outlined in the guidance.

In section 50.3.1, we appreciate the recognition that long-term care pharmacies typically do not



have a point of service encounter. However, the requirement for the pharmacy to provide notice at the time of billing has the potential to be repetitive and wasteful if the enrollee consistently meets the threshold. **ACHP requests the readjudication process outlined in 50.4 be one that the enrollee chooses and not a mandated process.**

Part D Sponsor Operational Requirements

We are pleased that the Part D bid pricing tool will be modified to reflect projected losses associated with the Medicare Prescription Payment Plan. However, it is unlikely that we will have accurate projections without at least one year of experience with the program. **ACHP requests additional projections and estimates that may be used in the calculation of bids and MLR for the initial program year.**

We appreciate CMS' continued engagement to ensure the successful implementation of the Inflation Reduction Act. Please contact Michael Bagel, ACHP Associate Vice President of Public Policy, at [mbagel@achp.org](mailto:mbagel@achp.org) or (202) 897-6121 with any questions or to discuss further.

Sincerely,

Dan Jones  
Senior Vice President, Federal Affairs  
Alliance of Community Health Plans (ACHP)



March 15, 2024

Chiquita Brooks LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dr. Meena Seshamani  
Deputy Administrator & Director of the Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

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

Dear Secretary Becerra and Administrator Brooks-LaSure:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the second draft guidance related to the maximum monthly cap on cost-sharing payments under Medicare prescription drug plans. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

In 2024, more than 2 million Americans are projected to be diagnosed with cancer.<sup>1</sup> Over 1 million of those diagnosed are age 65 or older and rely on the Medicare program as their primary source of health care coverage.<sup>2</sup> A majority of these individuals will use prescription drugs, which is why ACS CAN strongly advocated for provisions to be included in the *Inflation Reduction Act* to provide a cap on annual out-of-pocket costs for Medicare beneficiaries and the optional program to impose a monthly out-of-pocket cap (the Medicare Prescription Payment Plan program).

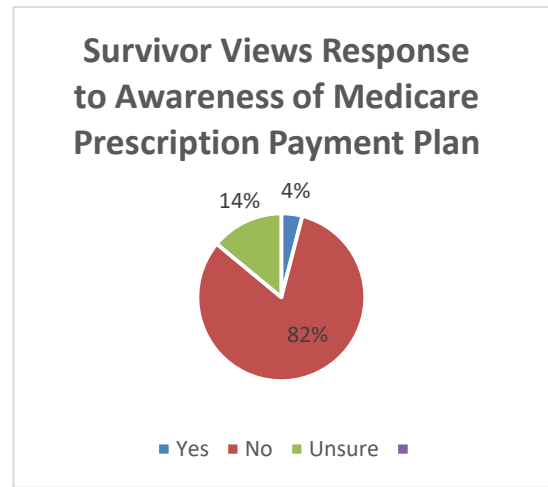
Millions of Medicare beneficiaries will benefit from the Medicare Prescription Payment Plan program but given its optional nature it is vitally important that CMS, working with stakeholders including plans, providers, and patient and consumer organizations work together to ensure that Medicare beneficiaries are provided clear, accurate information about the program and how to enroll. Unfortunately, more education and outreach is needed to realize the full benefits of this program.

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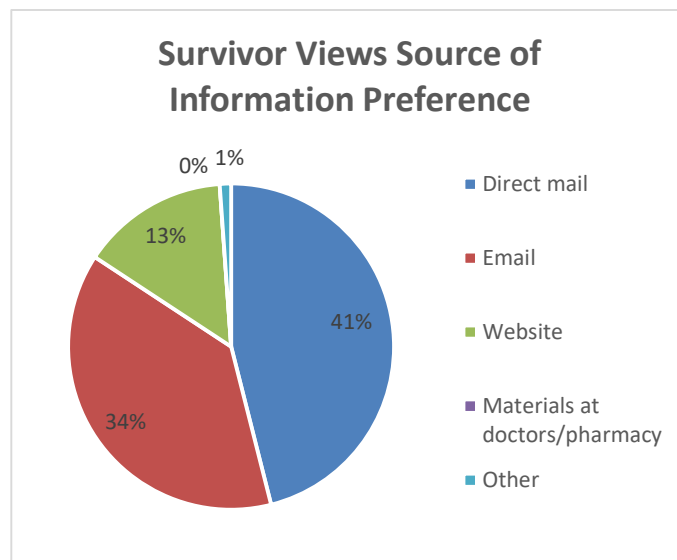
<sup>1</sup> American Cancer Society. *Cancer Fact & Figures 2024*. Atlanta: American Cancer Society; 2024.

<sup>2</sup> U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; <https://www.cdc.gov/cancer/dataviz>, released in November 2023.

In a recent ACS CAN *Survivor Views* survey, we asked Medicare beneficiaries and their caregivers whether they were aware of the option to cap their monthly Part D out-of-pocket costs beginning in 2025 and only 4% of respondents indicated they had heard anything about the new program and 82% of respondents indicated they were unaware of the new program.<sup>3</sup> This demonstrates that significant education and outreach is needed to inform beneficiaries of this optional new program. As part of the education effort, CMS, health plans, and stakeholders need to make clear that the Medicare Prescription Payment Plan program is an optional benefit in addition to and not as a replacement for Part D coverage.



In that same survey we asked respondents how they prefer to get information about changes to Medicare benefits. Almost half of respondents (41%) indicated they preferred to get information via mail. Few beneficiaries (13%) indicated a preference for information via a website and only a fraction of respondents (9%) indicated a preference for materials available in a provider's office or a pharmacy. This is not to suggest that CMS should consider educating beneficiaries solely by the use of direct mail. In fact, as the lack of general awareness discussed previously indicates, there is a general lack of awareness of the Medicare Prescription Payment Plan option and much education needs to be done. However, this information is important because it suggests that CMS will need to prioritize the use of direct mail rather than a website.

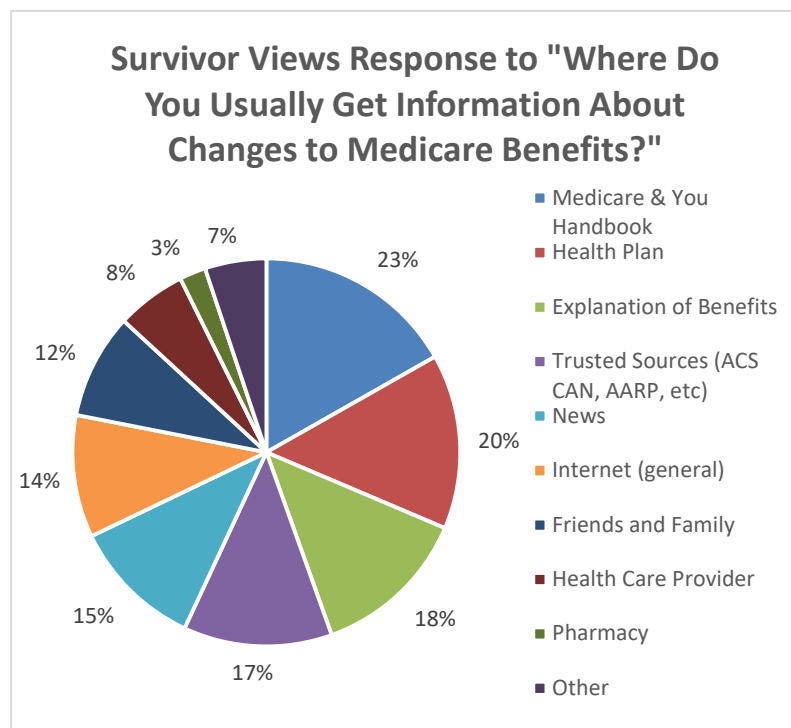


<sup>3</sup> American Cancer Society Cancer Action Network *Survivor Views* Survey. N=1,132 cancer patient and survivor Medicare beneficiaries, January 3-22, 2024.

[https://www.fightcancer.org/sites/default/files/national\\_documents/prespaymplan.pdf](https://www.fightcancer.org/sites/default/files/national_documents/prespaymplan.pdf).

As CMS contemplates how to inform beneficiaries about the new Medicare Prescription Payment Plan option, it is important to have a sense of where cancer patients and caregivers currently receive their information. According to our Survivor Views survey, most beneficiaries (23%) report receiving information directly from the Medicare & You handbook. Beneficiaries also highly rely on information from their health plan, which is why it is important to ensure that information provided by health plans is clear and accurate. Another interesting note is that roughly 14% of respondents reported getting information about changes in Medicare from the Internet. While Medicare.gov and health plan websites should contain information about the Medicare Prescription Payment Plan option, there is a concern that the Internet can also contain fraudulent information. Older adults are particularly vulnerable to fraud.<sup>4,5</sup>

As discussed in more detail below, we support many of the efforts CMS proposes to raise beneficiary awareness of this new program. However, it is clear that a significant additional investment in outreach and education is needed and we look forward to working with the Agency to assist in these efforts. As noted in our comments on the first draft guidance, we strongly encourage CMS to reevaluate its decision to not allow an option for beneficiaries to enroll at the point-of-sale. We continue to be concerned that without a point-of-sale election many beneficiaries will fail to enroll in this vitally important program.



<sup>4</sup> Yu L, Mottola G, Kieffer CN, et al. Vulnerability of Older Adults to Government Impersonation Scams. *JAMA Netw Open*. 2023;6(9):e2335319. doi:10.1001/jamanetworkopen.2023.35319.

<sup>5</sup> Protecting Older Consumers 2022-2023: A Report of the Federal Trade Commission. Oct. 18, 2023. Available from [https://www.ftc.gov/system/files/ftc\\_gov/pdf/p144400lderadultsreportoct2023.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/p144400lderadultsreportoct2023.pdf).

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

#### *30.1.1. Required Mailings with Membership ID Card Issuance*

CMS will require Part D sponsors to include with membership ID hard copy mailing information regarding the Medicare Prescription Payment Plan and a Medicare Prescription Payment Plan request form. CMS will encourage – but not require – Part D sponsors to provide the CMS-developed educational product. Part D sponsors will be permitted to use alternative informational materials in lieu of the CMS-developed educational products, provided these materials contain accurate information.

We strongly support the requirement that Part D sponsors provide information about the Medicare Prescription Payment Plan option with the enrollment card. This ensures that beneficiaries are provided notice about the program. However, given the need for beneficiary education and outreach, we urge CMS to require – not simply encourage – Part D sponsors to provide additional educational materials. If Part D sponsors choose not to use CMS-developed materials, we would suggest that CMS review plan educational materials prior to their release to ensure the accuracy of the materials.

#### *30.1.5 Part D Sponsor Websites*

CMS is requiring Part D sponsors to include on their websites information on the Medicare Prescription Payment Plan. Plans will be required to provide examples of how the program calculation works. CMS is encouraging – but not requiring – Part D sponsors to include information about the \$2,000 Medicare Part D out-of-pocket cap in 2025. Part D sponsors are encouraged – but not required – to use information from the CMS-developed educational product on the Medicare Prescription Payment Plan and other CMS-provided resources.

We support the requirement that Part D sponsors must provide information about the Medicare Prescription Payment Plan on their websites. We would encourage CMS to ensure that this information is featured predominantly on the website with detailed information available in fewer than 2 clicks. General information should be available publicly and not require the user to provide log-in information. Plan sponsors should also be required to monitor links to specific pages that contain information about the Medicare Prescription Payment Plan to ensure the links are in working order.

We also urge CMS to require – not simply encourage – Part D plan sponsors to provide beneficiaries information about the \$2,000 Medicare Part D out-of-pocket cap. This cap represents a significant policy improvement to the Part D program and beneficiaries should be made aware that regardless of whether or not they enroll in the Medicare Prescription Payment Plan option, they will be required to pay no more than \$2,000 in total annual out-of-pocket costs in 2025.

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

#### *30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year*

CMS is requiring Part D sponsors – both prior to and during the plan year – to identify beneficiaries likely to benefit from the Medicare Prescription Payment Plan program and undertake targeted outreach to inform these enrollees of the program.



ACS CAN supports CMS' clarification that Part D sponsors are required to provide notice to enrollees prior to and during the plan year. We appreciate that Medicare Prescription Payment Plan education efforts are needed during the plan year to provide relief for a beneficiary who is prescribed a high-cost medication for chronic use after the plan year has begun.

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

CMS is requiring that prior to the plan year Part D sponsors identify current Part D enrollees who are likely to benefit from the Medicare Prescription Payment Plan program and notify these individuals in writing of the availability of the program and that the beneficiary will likely benefit from enrollment in it. This outreach may be done via mail or electronically and will allow an initial notice to be made via telephone so long as the written notice and additional information is provided within 3 calendar days.

ACS CAN supports the requirement that Part D sponsors proactively reach out to enrollees who are likely to benefit from the Medicare Prescription Payment Plan based on their prior year's out-of-pocket costs. We appreciate that follow-up information is to be provided in writing or electronically. While we believe that telephone calls may serve as one way to inform beneficiaries, we do caution that telephone calls are also commonly used by unscrupulous actors. We recommend that telephone calls should be used for informational purposes only and should direct individuals to well-established sources (such as Medicare.gov, 1-800-Medicare, or their specific plan sponsor) for additional information.

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

CMS is requiring that, at a minimum, Part D sponsors must undertake targeted outreach to beneficiaries if the sponsor becomes aware in advance of a new high-cost prescription that would trigger the pharmacy point-of-service notification process, set at \$600 for a single prescription.<sup>6</sup>

While we appreciate CMS' requirement that Part D sponsors engage in active surveillance throughout the plan year to determine who could benefit from the Medicare Prescription Payment Plan, we urge CMS to broaden the proposed policy. CMS should not tie the triggering mechanism to the cost of a single prescription drug. Many beneficiaries – particularly those who have complex medical needs such as cancer medications – often take many prescription drugs each month and incur cumulative monthly out-of-pocket costs that meet or exceed \$600, even if an individual drug cost does not meet that threshold.

### **30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors**

#### *30.3.1 Overview of Election Requirements*

CMS is strongly encouraging – but not requiring – Part D sponsors to provide interested Part D enrollees with additional information about the Medicare Prescription Payment Plan, including offering a review of what their estimated monthly payments may be under the program and support tailored to the potential participant's unique situation. CMS also reminds Part D sponsors they must provide general information about applying for the low-income subsidy (LIS) program, noting that it is more advantageous than the Medicare Prescription

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<sup>6</sup> CMS Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025 (section 60.2.4). Available from <https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf>.

Payment Plan.

ACS CAN appreciates CMS' reminder to Part D sponsors to include information about the LIS program. This program has been in existence since the Part D program began and has provided millions of beneficiaries who qualify with much-needed financial relief from high out-of-pocket costs.

We urge CMS to require Part D sponsors to provide interested enrollees with information tailored to their specific needs based on their prior year's prescription drug out-of-pocket costs. As CMS notes throughout this draft guidance (and as also noted in the final version of the Part 1 guidance), not all beneficiaries will benefit from the Medicare Prescription Payment Plan, which is why the program is optional. However, in order for beneficiaries to make an informed choice they need to be given some idea of what their monthly out-of-pocket cost obligations would be under the program. This information can be provided to potential enrollees with the clear caveat that the calculations are being made based on medications filled in the prior plan year. At the same time, the information must also make clear that in no case will the beneficiary pay more than \$2,000 in out-of-pocket costs for Part D-covered drugs in 2025.

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

CMS is requiring outreach materials and communications be provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds. CMS also reminds Part D sponsors of the requirement to provide translated materials to Part D enrollees on a standing basis in any non-English language that is the primary language of at least 5% of individuals in a plan benefit package service area.

ACS CAN applauds CMS for ensuring that educational and outreach materials are provided in multiple languages and in a manner that meets the needs of a diverse population. We also encourage CMS to specifically require that any tailored material – such as that provided under section 30.3.1 – also be available in multiple languages and meet the needs of anti-discrimination requirements.

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

CMS notes some of the processes it plans to undertake to inform beneficiaries about the Medicare Prescription Payment Plan. CMS notes that it will make modifications to some of its existing materials but notes that specific resources CMS “may” modify include the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder, among others.

ACS CAN appreciates the operational challenge in educating beneficiaries and their caregivers about the new Medicare Prescription Payment Program. We urge CMS to use every tool at its disposal to accomplish this goal. As noted above, our survey found that the Medicare & You Handbook is the number one source of information for Medicare beneficiaries. While we recognize that it may require some operational tweaks, the Medicare Plan Finder tool is also popular with beneficiaries and caregivers and should display information on the new Medicare Prescription Payment Plan program. Using existing CMS materials is not only cost-effective for the Agency, but directing individuals to these resources can also help to minimize potential fraud.

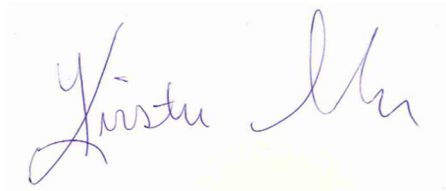
CMS notes that it intends to work with stakeholders – including Part D sponsors, pharmacies, providers and beneficiary advocates (including State Health Insurance Assistance Program (SHIP) counselors) – to bolster its education and outreach efforts. We strongly support this collaboration. We note that given the complexity of

the Medicare Prescription Payment Plan program, it will be helpful for CMS to develop as many materials as possible for stakeholder groups to use and disseminate. This will better ensure the accuracy of information being provided to beneficiaries.

### **Conclusion**

We thank CMS for offering the opportunity to comment on the Medicare Prescription Payment Plan draft guidance. We stand ready to work with CMS to develop materials that will help to educate enrollees about the option and what the enrollees' responsibilities are when they make that election. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at [anna.howard@cancer.org](mailto:anna.howard@cancer.org).

Sincerely,

A handwritten signature in blue ink, appearing to read "Kirsten Sloan", is written over a light yellow rectangular background.

Kirsten Sloan  
Managing Director, Public Policy  
American Cancer Society Cancer Action Network

March 15, 2024

Dr. Meena Seshamani  
Deputy Administrator and Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

RE: Medicare Prescription Payment Plan Guidance – Part Two

Submitted via email to: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

Dear Dr. Seshamani:

AHIP appreciates the opportunity to provide feedback on the draft part two guidance for implementing the Medicare Prescription Payment Plan (MPPP), enacted into law in section 11202 of the Inflation Reduction Act of 2022 (IRA). AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to making health care better and coverage more affordable and accessible for everyone.<sup>1</sup>

We welcome the detailed topics addressed in the draft part two guidance, which build upon the provisions included in the final part one guidance for operationalizing the MPPP. Our attached comments offer specific recommendations to clarify and improve the program.

In addition to addressing the operational components in the guidance, we continue to be concerned about the high level of uncertainty and lack of historical experience to accurately predict the risk associated with the MPPP for bid purposes, and the potential disruptive impact to plan premiums resulting from this uncertainty. We urge CMS to provide information by April 1 relating to assumptions and modeling of these impacts, which will be critical for use by Part D sponsors as part of the bid development process for the first year of the program.

In our detailed comments we also explain that we disagree with CMS' proposal to treat unsettled balances from the MPPP as administrative costs for medical loss ratio (MLR) purposes. If finalized, this could penalize Part D sponsors despite the fact they pay pharmacies the full negotiated price for a drug, including enrollee cost sharing subject to the MPPP.

We also urge CMS to apply enforcement discretion for good faith efforts made by plans for the first year of the program. Operational complexities combined with short timelines and a delayed

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<sup>1</sup> Visit [www.ahip.org](http://www.ahip.org) to learn how working together, we are Guiding Greater Health.

March 15, 2024  
Page 2

release of final model materials will make it difficult for plans to ensure full compliance despite best efforts.

Again, we thank you for the opportunity to offer comments on the MPPP. We look forward to continuing to work with CMS on IRA implementation.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Hamelburg', written in a cursive style.

Mark Hamelburg  
Senior Vice President, Federal Programs

## Section 10 – Introduction

CMS states that the draft part two guidance for operationalizing the Medicare Prescription Payment Plan (MPPP) will be finalized in summer 2024. Additionally, CMS plans to issue model materials specific to the program in summer 2024. (CMS released certain draft model notices through the Paperwork Reduction Act (PRA) process on February 29, and will release additional draft PRA model materials in the future.)

AHIP Recommendation: We appreciate CMS’ issuance of guidance and related materials on the MPPP in draft form for public comments. However, the timelines for the final part two guidance and model materials will not give plans and pharmacies sufficient lead time to operationalize process changes and revise communications materials in advance of the fall 2024 annual enrollment period (AEP) for plan year 2025. For example, some changes will require contractual changes and implementation of new processes relating to mid-year enrollee elections. Plans also need time for document development and production activities that must be coordinated with their business partners, to ensure timely mailings of beneficiary materials for the AEP. **As noted below in various sections regarding the imposing of new operational requirements, AHIP recommends that CMS provide flexibility and exercise enforcement discretion in recognition of the challenges associated with the implementation of the MPPP. In addition, given the difficulty of updating materials that will not be finalized until shortly before the AEP, AHIP requests that CMS provide flexibility to allow plans to use draft model materials for plan year 2025 and/or modify materials without CMS prior approval.**

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

### *30.1 General Outreach and Education*

CMS provides a general overview of its expectations for Part D sponsors to provide educational materials about the MPPP to Part D enrollees through existing and other Part D materials. CMS also notes that Part D sponsors may include information about the program in their marketing materials as long as these materials comply with the Medicare marketing rules.

AHIP Recommendation: We appreciate CMS providing plans with the flexibility to include information about the MPPP in their marketing materials.

#### *30.1.1 Required Mailings with Membership ID Card Issuance*

For CY 2025, CMS proposes to require plans to include information about the MPPP and the election request form with Membership ID card mailings sent to enrollees.

**AHIP Recommendation: We recommend that CMS provide plans with flexibility to send information about the MPPP and related election request form through separate mailings if the plans determine a separate mailing would improve communications to beneficiaries.**

For example, mailing MPPP information along with Membership ID cards to certain full benefit dual eligible enrollees who have no Part D cost-sharing obligations would confuse these enrollees. We also recommend that plans have flexibility to refrain from mailing information about the program as part of the enrollment process for Part D enrollees who are unlikely to benefit from opting into the program. These individuals will still receive information through other communication documents such as the EOC as noted below.

*30.1.2 Evidence of Coverage (EOC)*

*30.1.3 Annual Notice of Change (ANOC)*

*30.1.4 Explanation of Benefits (EOB)*

In the draft guidance, CMS explains that it will update the EOC, ANOC and EOB model documents to include information about the MPPP and provide plans with a comment opportunity through the PRA process. These materials will be finalized by summer 2024.

**AHIP Recommendation: We appreciate and strongly support the opportunity for public review and comment on the EOC, ANOC and EOB model documents. However, we are concerned that the release of the final documents any later than early June will not provide plans with sufficient time to implement changes and distribute to enrollees in advance of the AEP. We recommend that plans be allowed to use the draft versions of model documents for plan year 2025 and/or have the flexibility to modify the model documents to describe the program without need for prior CMS review and approval of the non-standardized language. Further, we recommend that CMS exercise enforcement discretion for good faith efforts made by plans to update these beneficiary documents and not penalize plans if they have to modify their documents with non-standardized language or issue supplemental mailings to beneficiaries in order to provide information about the MPPP.**

We also have the following additional recommendations related to beneficiary explanatory materials. First, CMS should add language about the program to the Summary of Benefits and Formulary model materials that would be optional for plans to consider adding to these documents. Second, the CMS model materials should include information about individuals unlikely to benefit from the program (such as individuals receiving low-income subsidies). Third, the materials should specify that Part B drugs are excluded from the program.

*30.1.5 Part D Sponsor Websites*

In the draft guidance, CMS reminds Part D sponsors that they will be required to include information on the MPPP on their plan's website along with an election request mechanism that

Part D enrollees can use to opt into the program as described under Section 70.3.1 of the final part one guidance.

**AHIP Recommendation: We recommend that CMS provide plans with flexibility in meeting the website requirements during the first year of implementation.** For example, we recommend that CMS permit plans to provide the election request mechanism through their member portals rather than a public facing website if the plan determines that this mechanism would minimize confusion and ensure that individuals who are not plan members do not attempt to enroll via the website. Another example of flexibility is for CMS not to require plans to provide enrollees with a confirmation number as evidence that their MPPP election request was received, during the first year of implementation. Plans should have the flexibility to accommodate this requirement through other methods.

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

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

CMS proposes requiring Part D sponsors to use the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” for required outreach to Part D enrollees who are identified as likely to benefit prior to and during the plan year, including those identified through the pharmacy notification process. (A draft likely to benefit notice was included in the PRA released on February 29.)

**AHIP Recommendation: AHIP supports CMS development of the standardized likely to benefit notice, to ensure Part D enrollees receive consistent information from Part D sponsors and pharmacies about which Part D enrollee cost-sharing circumstances indicate a higher likelihood of benefiting from participating in the MPPP.** We appreciate the Agency outlining throughout the draft part two guidance that it is also important for the likely to benefit notice to include language about individuals who are not likely to benefit from the program, including LIS enrollees and individuals enrolled in employer group waiver plans (EGWPs).

#### *30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year*

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

CMS proposes to require that Part D sponsors send the “Medicare Prescription Payment Plan Likely to Benefit Notice” no later than the end of the plan year 2025 AEP (December 7, 2024) to enrollees who incurred \$2,000 in out-of-pocket (OOP) costs for covered drugs in the first three quarters of 2024. The notice would be sent to identified enrollees via mail or electronically depending on enrollee preferences. CMS indicates that this outreach must also include additional



information about the MPPP, which can be fulfilled by including with the notice a CMS-developed educational product about the program.

In addition, CMS notes that Part D sponsors should be aware that potential changes to an enrollee's clinical condition, medication status, or cost-sharing (e.g., discontinuation of therapy or addition of supplemental payers) could affect the likelihood that a Part D enrollee may benefit from the MPPP. CMS suggests Part D sponsors should counsel enrollees accordingly based on these potential changes when contacted to discuss participation in the program.

AHIP Recommendation: We agree with CMS that targeted outreach efforts will be especially critical prior to the plan year. Identifying enrollees most likely to benefit from participating in the program prior to the plan year will help facilitate more simplified enrollment and billing processes for enrollees, as enrollments during the plan year introduce additional complexities.

**We support the threshold proposed by CMS to identify enrollees likely to benefit from the program prior to the upcoming plan year – those who incur \$2,000 in OOP costs for covered drugs through September of the current year.**

In addition, for future years, CMS should be clear in the use of “incurred costs” for the purposes of this targeted outreach requirement and the use of “incurred costs” for TrOOP accumulation purposes, which CMS separately proposes would include supplemental coverage or Other Health Insurance (OHI). We request CMS provide clarity and examples illustrating how this proposed targeted outreach requirement would apply to those with supplemental coverage or OHI.

We also agree that changes to a Part D enrollee's clinical condition, medication status, or cost-sharing could affect the likelihood that a Part D enrollee may benefit from participating in the MPPP. We request that CMS provide flexibility to Part D sponsors to not send the likely to benefit notice to enrollees affected by such changes if the sponsors become aware of the changes.

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

CMS proposes requiring that Part D sponsors put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit during the plan year. At a minimum, Part D sponsors with prior authorization or other utilization management edits in place for a drug would be required to undertake targeted outreach to an enrollee if the drug would result in OOP costs that would trigger the pharmacy point of sale (POS) notification process (\$600 for a single prescription in plan year 2025, as determined in the final part one guidance). Part D sponsors would provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the identified Part D enrollee within the same timeframe that applies to the coverage determination for the associated utilization management requirement, via mail or electronically based on enrollee preferences. CMS also encourages Part D sponsors to inform the Part D enrollee that

they are likely to benefit when contacting the Part D enrollee for other reasons, such as while communicating a prior authorization coverage determination.

**AHIP Recommendation: We recommend that CMS clarify that targeted outreach to enrollees in connection with prior authorization or other utilization management edits should apply only to approved requests.** Receiving a likely to benefit notice at the same time as a denial could create significant confusion for enrollees. We also encourage CMS to maintain flexibility on the notice process. For example, if health plans were required to provide the likely to benefit notice in the same communication as a prior authorization or utilization management coverage determination, it may present significant operational challenges for some plans.

Beneficiary confusion under this proposal could also result from potentially receiving back-to-back likely to benefit notices – one from the pharmacy, and another connected to prior authorization or other utilization management edits in place for the drug. Following a prior authorization or utilization management review, enrollees may go to the pharmacy and receive the likely to benefit notice from the pharmacy. Receiving a second notice may cause confusion and concern especially if the enrollee has already acted on the notification from the pharmacy. Further, this proposal may result in enrollees who are in fact not likely to benefit from the program receiving a likely to benefit notice. As it may not be known what quantity of the drug will be prescribed and what the day supply will be during a coverage review, there could be operational challenges and difficulties to ascertain whether an enrollee’s cost share would trigger the POS threshold of \$600 for a single prescription.

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

As noted above, the final part one guidance imposes a pharmacy POS notification requirement when OOP costs for a single prescription meet or exceed the \$600 threshold. To meet the requirement, CMS proposes that Part D sponsors require pharmacies to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice.” CMS encourages Part D sponsors to provide pharmacies with additional educational material on the MPPP. However, CMS states that pharmacies are encouraged but not required to provide educational material related to the MPPP at the time they provide an enrollee with the notice. CMS also notes that pharmacies are not required to provide additional counseling or consultation about the program to Part D enrollees.

**AHIP Recommendation: We support CMS’ proposal to have pharmacies satisfy the POS likely to benefit notification requirement by providing the “Medicare Prescription Payment Plan Likely to Benefit Notice” to Part D enrollees who meet the cost threshold.** A standardized notice used by Part D sponsors and pharmacies will ensure enrollees receive consistent and clear information and messaging about the program. However, in the first year of the program, there will be significant operational challenges for plans and pharmacies to implement this requirement. **As such, we request that CMS exercise enforcement discretion**

**for plans and pharmacies that are operating in good faith to implement the requirement to provide the likely benefit notice at the POS to enrollees who meet the cost threshold for the POS notification.**

We also request flexibility for pharmacies to provide the likely to benefit notice to enrollees based on communication preferences the individuals have indicated to the pharmacies – via paper, electronically (email or portal) or text. The utilization of email, pharmacy portals or text notifications for the delivery of the likely to benefit notice would allow Part D enrollees to potentially opt into the MPPP before picking up their prescriptions at the pharmacy. Moreover, using email, pharmacy portals or text notifications for the delivery of the likely to benefit notice can reduce burdens on pharmacies and better ensure compliance than a blanket requirement for a paper copy being provided at the point of sale. In addition, we urge CMS to couple targeted communications by Part D sponsors with CMS outreach efforts, including training and educational materials for pharmacies.

### *30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors*

CMS provides an overview of the MPPP election and termination requirements. As noted above, the new model materials released through the PRA process are currently open for comment. CMS states that the materials will be finalized by summer 2024.

**AHIP Recommendation:** We reiterate our appreciation for the opportunity to comment on the model materials, along with our concern that finalizing the materials after early June will not provide plans enough time to operationalize and print materials for open enrollment. **We recommend that CMS allow plans to utilize draft versions of the materials and not penalize plans for using earlier versions of these model documents if the materials change throughout the PRA process.**

#### *30.3.1 Overview of Election Requirements*

CMS outlines the requirements for requests made by different election mechanisms, including paper, telephonic, and website requests. Part D sponsors must accept elections received regardless of format of the request.

**AHIP Recommendation:** We appreciate CMS providing these details in the draft guidance. We have included more detailed recommendations in the sections below.

### *30.3.2 Notice of Acceptance of Election*

For elections received during the plan year, Part D sponsors must deliver notice of acceptance of election telephonically and then provide written notice to the enrollee within three calendar days.

**AHIP Recommendation: We recommend that CMS allow three *business* days for a written response to requests, rather than three calendar days.** Additionally, during the first year of implementation we ask that CMS encourage but not require plans to provide the notice of acceptance of election both telephonically and in writing. For example, plans should not be penalized if they are able to provide and document a verbal acceptance. **We recommend CMS provide plans with flexibility in meeting notice requirements and timelines given the condensed timeline for CY 2025 implementation.**

### *30.3.3 Notice of Failure to Pay*

### *30.3.4 Notice of Termination of Election Following End of Grace Period*

### *30.3.5 Notice of Voluntary Termination*

CMS indicates that it will provide plans with a comment opportunity on these model notices through the PRA process. These model notices will be finalized by summer 2024.

**AHIP Recommendation: As discussed in Section 30.3 *Communications with Program Participants and Model Materials Requirements for Part D Sponsors*, we recommend CMS allow plans to utilize draft versions of the materials and not penalize plans for using earlier versions of these model documents if the materials change throughout the PRA process given the tight implementation timeline.**

## *30.4 Language Access and Accessibility Requirements*

CMS states that Part D language access and accessibility requirements apply to all MPPP educational and communications materials. These rules require Part D sponsors to provide enrollees with translated materials on a standing basis in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area. Furthermore, materials must be provided in a non-English language or an accessible format upon request or otherwise learning of the enrollee's need.

**AHIP Recommendation: CMS routinely translates certain materials (e.g., ANOC, EOB, EOC) into several common non-English languages (Chinese, Korean, Spanish, and Vietnamese). We recommend that CMS translate these model materials related to the MPPP into these non-English languages for plan use.**

## Section 40 – CMS Part D Enrollee Education and Outreach

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

### *40.2 Modifications to Existing Part D Resources*

### *40.3 National Outreach and Education Efforts*

To educate enrollees and stakeholders about the MPPP, CMS plans to develop new Part D educational resources for enrollees and update existing Part D resources such as the Medicare & You Handbook, Medicare.gov website, and the Medicare Plan Finder. CMS also indicates it plans to work with stakeholders to ensure that they have “sufficient support and materials needed to effectively communicate the availability and nuances of this program to individuals.” Further, CMS notes under this section of the draft guidance that Part D sponsors’ use of CMS-developed educational materials will satisfy the Part D sponsor requirement to provide information about the MPPP.

AHIP Recommendation: We appreciate CMS’ plans to develop Part D educational resources and update existing Part D resources to inform enrollees and others about the MPPP. We also support CMS’ guidance that would allow Part D sponsors to satisfy the requirement to provide information about the MPPP with use of CMS’ educational materials. This approach would help promote consistent messaging and understanding about the program. To further enhance beneficiary education, we encourage CMS to also develop on-line educational videos about the program. In addition, we continue to recommend that enrollee education and communications about the program address individuals likely to benefit as well as address individuals unlikely to benefit, such as those receiving low-income subsidies. Additionally, **we urge CMS to release its educational resources as soon as possible so that Part D sponsors have sufficient time to operationalize them in advance of this year’s Fall open enrollment.**

## Section 50 – Pharmacy Processes

### *50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount*

### *50.2 Pharmacy POS Notifications Late in the Plan Year*

CMS indicates that the POS likely to benefit notification – based on a \$600 threshold for a single prescription and to be returned to the pharmacy on the primary Part D claim response from the Part D sponsor or pharmacy benefit manager (PBM) – can result in some enrollees receiving the notice who may in fact not be likely to benefit from participating in the program. For example, the POS notification is triggered based on the OOP cost on the primary Part D claim. Part D enrollees with supplemental coverage could receive a likely to benefit notice even though their actual patient pay amount on the covered Part D prescription drug claim could be reduced below the required notification threshold because of the contributions of a supplemental payer. In

addition, CMS indicates enrollees opting into the program late in the plan year following receipt of a pharmacy POS notification can result in the amount billed under the program to be equal to what they would have paid at the pharmacy counter. CMS states that Part D sponsors should ensure that customer service representatives are aware of these possibilities when receiving inquiries from Part D enrollees regarding program election.

**AHIP Recommendation: AHIP encourages CMS to include the possibilities raised in these sections of the guidance in communications and educational materials addressing Part D enrollees who are not likely to benefit from participating in the program.** Both examples should also be included on the “Medicare Prescription Payment Plan Likely to Benefit Notice” so Part D enrollees understand that in certain circumstances, it would not be to their financial benefit to participate in the program. In addition to ensuring awareness by plan customer service representatives of these possibilities, AHIP recommends that CMS provide training or other educational materials to pharmacies and pharmacy staff to ensure that they can provide counsel to beneficiaries who receive POS notifications who in fact would not be likely to benefit from participating in the program.

#### *50.4 Readjudication of Prescription Drug Claims for New Program Participants*

CMS indicates that for claims to be processed appropriately using the MPPP BIN/PCN methodology, the date of service on the primary Part D claim and the additional program-specific transaction must be on or after the date of program effectuation. As such, when a Part D enrollee leaves the pharmacy without their prescription(s) after receiving the “Medicare Prescription Payment Plan Likely to Benefit Notice,” and returns after successfully signing up for the program, CMS is proposing that the Part D sponsor must require the pharmacy to readjudicate all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary to allow for appropriate processing by the Part D sponsor and/or PBM. This includes unpaid claims for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification. The agency indicates that this same process applies when the Part D enrollee has prescriptions that have not yet been picked up and paid for at multiple pharmacies.

When the Part D claim date of service is the same as the date of program effectuation, CMS outlines that the pharmacy is not required to reverse and resubmit the Part D claim, provided that the pharmacy otherwise obtains the necessary MPPP BIN/PCN for the program-specific transaction. Overall, the Agency notes that plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the MPPP that have already been paid for by the Part D enrollee.

**AHIP Recommendation: We encourage CMS to review and reconsider its proposal for Part D sponsors to require pharmacies to readjudicate all claims for covered Part D drugs from**

**prior dates of service that have not yet been paid for and picked up by the beneficiary.**

While Part D sponsors would be aware of which claims have been adjudicated, for plan oversight purposes, they would not have insight into which prescriptions have been picked up and paid for by the Part D enrollee. In addition, the requirement to readjudicate all claims from prior dates of service that have not yet been picked up and paid for by the enrollee has the potential to be extremely burdensome for pharmacies, especially in the first year of the program. Pharmacies also may have difficulties differentiating between the claims they are required to readjudicate under this proposal, and those for Part B drugs or drugs covered via enhanced plans.

**However, if CMS retains a readjudication requirement, we have the following recommendations and requests for clarification, to improve the operational feasibility of the requirement.**

First, readjudication should be limited to the prescription(s) that trigger the POS likely to benefit notification. Part D sponsors would have some visibility into the claim(s) that triggered the notification in this case.

Second, the operational challenges would be exacerbated if the readjudication requirement applies when a Part D enrollee has prescriptions that have not yet been picked up and paid for at multiple pharmacies. Not all pharmacies at which claims have already been adjudicated would be aware of a Part D enrollee newly opting into the program; visibility into the enrollee's potential for program participation would be limited to the pharmacy or pharmacies that filled the prescription(s) that triggered the likely to benefit notification. The ability of Part D sponsors to enforce this requirement across network pharmacies would be limited, due to operational realities and the proposal's complexity. Accordingly, if CMS proceeds with its proposal to require that all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary be readjudicated after a Part D enrollee successfully opts in to the program, it should be limited to the pharmacy or pharmacies that filled the prescription(s) that triggered the likely to benefit notification.

Third, in the case of same-day program effectuation, we request that CMS clarify and provide examples illustrating its statement that the pharmacy is not required to reverse and resubmit the Part D claim, provided that the pharmacy otherwise obtains the necessary MPPP BIN/PCN for the program-specific transaction. We also seek clarification on the readjudication process applicable to long-term care pharmacies, which often dispense medications before billing the long-term care facility, Part D enrollee and/or their authorized representative.

## Section 60 – Part D Sponsor Operational Requirements

### *60.1 Part D Bidding Guidance for CY 2025*

CMS indicates that the Part D bid pricing tool (BPT) will be modified to reflect projected losses associated with the MPPP. The Agency specifies that these losses must be reflected as administrative costs in the Part D BPT.

**AHIP Recommendation: AHIP and its member plans continue to be concerned about the high level of uncertainty and lack of historical experience to accurately predict the risk associated with the MPPP for bid purposes, and the potential disruptive impact to plan premiums resulting from this uncertainty. We support modification of the BPT to reflect projected losses associated with the MPPP, which will inform CMS of the magnitude of unsettled plan balances. We also urge the Office of the Actuary (OACT) to provide by April 1 assumptions and modeling for plans to use for the first year of the program as part of the bid development process.**

In addition, given the tremendous uncertainty associated with providing the Part D benefit in CY 2025, including but not limited to operationalizing and projecting losses associated with the MPPP, **we encourage CMS to explore the use of additional mitigation mechanisms to help provide stability to the Part D program.** Specifically, AHIP reiterates our recommendation that CMS use demonstration authority to narrow the risk corridors that are applied to Part D risk sharing for the early years of implementation of the IRA Part D redesign provisions.

### *60.2 Medical Loss Ratio (MLR) Instructions*

CMS proposes to consider unsettled balances from the MPPP as administrative costs for purposes of the MLR calculation. Therefore, unsettled balances from the program would be excluded from the MLR numerator. CMS bases this interpretation on the provision in Section 1860D-2(b)(2)(E)(v)(VI), as added by the IRA, which specifies that unsettled MPPP balances “shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.”

**AHIP Recommendation: We urge CMS to treat unsettled balances from the MPPP as claims included in the numerator for purposes of the MLR calculation.** Plans are required to pay pharmacies the enrollee cost sharing subject to the MPPP. Under statutory MLR provisions that were not modified by the IRA, there is no basis to treat this payment any differently for MLR purposes than the other part of the negotiated price that plans pay for a given drug.

In addition to not modifying the MLR provisions directly, Congress did not include any cross reference to the MLR provisions in Section 1860D-2(b)(2)(E)(v)(VI). CMS should not assume



that this provision was intended to apply to MLR without such a direct reference. That is particularly the case since the intent of Section 1860D-2(b)(2)(E)(v)(VI) is to limit government liability for subsidizing unpaid MPPP balances beyond government subsidies associated with plan bids. That has no relevance to the MLR provisions, which focus on the percentage of costs that constitute claims and certain other expenses, and which apply distinct penalties when the required threshold is not met. In other words, treating unsettled balances as losses for government subsidy purposes is not inconsistent with treating them as claim payments for MLR purposes.

We also note that Section 1860D-2(b)(4)(F) provides that a MPPP participant's TrOOP-eligible costs that are paid by their Part D plan under the MPPP shall be treated as incurred costs. This is also consistent with treating unsettled balances as claims for MLR purposes.

In addition to the statutory and policy reasons for treating unsettled balances from the MPPP as claims costs for MLR purposes, it would be particularly unfair to take the proposed approach in the early years of the program given the tremendous uncertainty about the degree to which balances under the MPPP will remain unpaid. Part D plans should not be penalized for issues so clearly outside their control.

Again, for the reasons described above, **we urge CMS to treat these unsettled balances like other claims costs for MLR purposes.** However, if CMS does not take that approach, we request that the unsettled balances from the MPPP be treated the same as unpaid premium bad debt – the other primary type of administrative bad debt – for the purposes of the MLR calculation only. See 42 CFR Section 423.2420(c)(3)(i). As such, unsettled balances from the program would be excluded from both the MLR numerator and denominator.

### *60.3 Monitoring and Compliance*

Under this section of the draft guidance, CMS indicates it will require Part D sponsors to report information related to the MPPP through prescription drug event (PDE) records and new Part D reporting requirements. Additionally, CMS states it will monitor and collect data about beneficiary complaints and grievances reported through the Medicare Complaints Tracking Module (CTM) to assess Part D sponsors' compliance with the MPPP requirements, beneficiary protections, and program integrity. Further, CMS notes that it will assess whether an additional CTM category or subcategory is needed for the MPPP in future years. CMS also expects Part D sponsors to incorporate the MPPP into their compliance programs to ensure that they are meeting program requirements.

**AHIP Recommendation:** Given the complexity of this new program, we are concerned about potential increases in complaints and grievances against plans and therefore continue to recommend that CMS establish a CTM category for MPPP related complaints to help both CMS

and plans track these types of complaints, resolve them and evaluate their frequency rate and impacts. As indicated in our comments to the part one guidance for MPPP, **we remain concerned about the unanticipated impacts that implementation of this program will also have on certain Star Ratings measures and plan performance. We continue to recommend that CMS consider applying a hold harmless policy to ensure that summary and overall Star Ratings for individual plans do not go down if lower performance results are likely due to MPPP impacts. Finally, we continue to recommend that CMS apply enforcement discretion for good faith efforts made by plans to meet program requirements for plan year 2025.**

#### *60.4 Audits*

In the draft guidance, CMS indicates that the agency and/or its contractors may conduct audits of Part D sponsors' implementation of the MPPP.

**AHIP Recommendation:** **We recommend that CMS not penalize plans for good faith efforts to implement this new, complex program, especially during the first implementation year (2025).** During the initial years of implementation, CMS should also continue to hold user group calls with plans and share lessons learned and best practices and continue to respond to plan questions to help ensure common understanding of CMS' expectations and to promote compliance. **We also recommend that CMS provide more information about its audit plans through the PRA process, including providing its audit protocol for this program in draft form for public comments.** This approach would align with CMS' current process for proposing and finalizing changes to audit protocols for the MA and Part D programs. Using the PRA process also promotes transparency and supports common understanding of program rules and agency expectations.

#### *Applicability of Federal and State Consumer Protection Laws*

In the final part one guidance, CMS "reminds Part D sponsors (and any third parties Part D sponsors contract with) that actions to collect unpaid balances related to the program may be subject to other applicable federal and state laws and requirements, including those related to payment plans, credit reporting, and debt collection." AHIP recommends that CMS collaborate with federal consumer financial protection agencies to provide additional guidance about the full scope of laws that apply to the MPPP, and address the extent to which state requirements would apply to Part D given provisions in the Social Security Act that supersede state laws with respect to Part D plans (other than state licensing or solvency laws). While many of these laws and regulations were designed to protect consumers from predatory lending practices, consumer risk in the MPPP is low because Part D plan sponsors cannot charge interest, nor are they allowed to check beneficiary credit ratings or if a beneficiary has the ability to pay. Given the broad and numerous array of laws and regulations associated with consumer credit and lending, AHIP is

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concerned that a lack of clarity here will undermine the goals of the MPPP by confusing consumers and creating barriers to access.



March 15, 2024

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

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

Dear Administrator Brooks-LaSure:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### **CMS Part D Enrollee Education and Outreach (Section 40)**

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

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

### **Other Implementation Issues**

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

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

### **Conclusion**

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

Sincerely,



Harold P. Wimmer  
President and CEO

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

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

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

<sup>3</sup> American Lung Association, Comments to CMS re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments. September 19, 2023. Available at:

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

<sup>4</sup> Id.

American Society of Hematology

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March 11, 202

Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director of the Center for Medicare  
Center for Medicare  
7500 Security Boulevard  
Baltimore, MD 21244-185

Re: Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics,  
Implementation

Dear Deputy Administrator Seshamani:

The American Society of Hematology (ASH) appreciates the opportunity to submit comments pertaining to the Center for Medicare & Medicaid Services' (CMS) draft part two guidance for the Medicare Prescription Payment Plan. ASH has a longstanding commitment to improving the accessibility and affordability of high-quality, clinically appropriate care, including innovative drug and gene therapies. The Society supports this program's aim to improve health care accessibility and affordability by offering enrollees the option to pay for their out-of-pocket drug costs over the year instead of paying high costs upfront at the pharmacy.

ASH represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical (or non-malignant) conditions such as SCD, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

The Society offers comments on the following sections of the draft part two guidance in addition to general comments for consideration:

- 40. CMS Part D Enrollee Education and Outreach
- 50.2 Pharmacy POS Notifications Late in the Plan Year

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

Sections 40.1 and 40.3 focus on beneficiary educational efforts, which will be important to the successful implementation of the program. For this program to have the greatest benefit, educational materials aimed at patients, providers, and other stakeholders must effectively communicate the payment plan's availability and how it functions. Education and outreach may help facilitate enrollment and allow beneficiaries to take advantage of the potential cost savings. ASH supports the policies outlined in these sections and appreciates CMS' commitment to creating resources, such as a patient payment calculator, to assist beneficiaries in navigating this program. ASH recommends that CMS explicitly include a payment calculator as a patient decision resource in the part two guidance for this program.

The payment program is especially relevant for the practice of hematology and hematology patients, since many of these diseases are rare and require high-cost and highly specialized therapeutics. ASH members from long-term relationships with their patients due to the nature of many hematologic conditions and will be trusted advisors for their patients when evaluating participation in this program. Often patients rely on their physician or health care provider for support in understanding new programs and how they may benefit. Many patients already ask their physician about the costs of treatment when making decisions about their care plan. Therefore, ASH respectfully requests that CMS develop educational materials targeting providers so they can easily counsel their patients without adding undue burden or other administrative challenges to practice. Physicians are an important collaborative stakeholder group, and CMS must empower them to support the program's implementation by giving them the necessary tools. ASH therefore stands at the ready to be a resource to the agency in the development of materials or resources specific to hematologic conditions and treatments and in ensuring that those materials and other tools minimize additional burden on providers. The Society would also be pleased to help in the dissemination of relevant educational materials through the



pertinent ASH communication channels, including newsletters, emails, and social media posts that are distributed to our members.

## **50.2 Pharmacy POS Notifications Late in the Plan Year**

ASH appreciates CMS' consideration for educating enrollees who may benefit from this program throughout the plan year. While this program may support spreading costs for high-cost drugs over the plan year for beneficiaries who sign up early on, it is important to consider education for beneficiaries who opt-in late in the plan year. The example scenario noted in the draft part two guidance of a Part D enrollee who may benefit late in the plan year, but who would still incur a high OOP cost in the first month, helps clarify an important nuance of this program for enrollees who enroll late in the plan year. This example may come up more frequently in hematology, as patients have no way to plan for a rare hematologic diagnosis that may require a high-cost therapeutic. ASH recommends that scenarios such as this be clearly explained in laymen's terms with examples in the developed educational materials and resources. Additionally, a payment calculator may be especially helpful in scenarios such as this to help enrollees understand how they may benefit from this program. ASH is also happy to collaborate with the Agency in drafting additional example scenarios for educational materials.

The Society appreciates the opportunity to share comments and provide support for this program. ASH would also like to offer resources and expertise in development of educational materials outlined in Section 40, with example scenarios such as the one outlined in Section 50.2. We would appreciate the opportunity to meet with CMS to discuss the materials and outreach plan, as it relates to the practice of hematology. Carina Smith, ASH Manager for Health Care Access Policy ([casmith@hematology.org](mailto:casmith@hematology.org) or 202-292-0264), will reach out to request a follow-up meeting to discuss the recommendations in this letter.

Sincerely,  
Mohandas Narla, DSc  
President

Mary-Elizabeth M. Percival, MD  
Chair, Committee on Practice



Chiquita Brooks-LaSure, Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Administrator Brooks-LaSure:

Arnold Ventures welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the following guidance issued on February 15, 2024:

- *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*

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. We work to develop evidence to drive reform across a range of issues including health care, education, and criminal justice. Our work within the health care sector is driven by a recognition that the system costs too much and fails to adequately care for the people it serves.

We want to thank you and CMS staff for your important and expeditious work implementing the prescription drug provisions of the Inflation Reduction Act (IRA). We recognize the difficulty of the task you face. We appreciate the opportunity to provide comments on the implementation of the Maximum Monthly Cap on Cost-Sharing Payments Program, which is referred to in the guidance as the Medicare Prescription Payment Plan (MPPP). In addition to providing a summary of the MPPP and a description of who benefits, this letter provides comments on the following sections of the Draft Part Two Guidance:

- 30. Outreach, Education, and Communications Requirements for Part D Sponsors*
  - 30.1 General Outreach and Education*
  - 30.2.1 Notice for Part D Enrollees Likely to Benefit*

- 40. CMS Part D Enrollee Education and Outreach*

#### Summary of the Medicare Prescription Payment Plan (MPPP)

Starting in 2025, any Medicare Part D beneficiary, including those enrolled in the Low-Income Subsidy Program, may choose to participate in the MPPP established by the IRA. After joining the MPPP, a beneficiary will not pay anything to the pharmacy when filling a prescription. Instead, the Part D plan will cover the beneficiary's OOP costs at the pharmacy counter. The Part D plan then bills the beneficiary for those OOP costs, which are then gradually paid back by the beneficiary through monthly installment payments that spread those costs over the remainder of the calendar year (following a statutory formula).

The MPPP primarily benefits beneficiaries with high OOP costs incurred early in the calendar year. If a beneficiary fails to make their monthly installment payments, the Part D plan may choose to drop the beneficiary from the MPPP after providing a grace period of at least 2 months. Importantly, if a beneficiary gets dropped from the MPPP, they still retain their Part D coverage.



After being dropped from the MPPP, the beneficiary must continue to pay Part D premiums to maintain coverage and pay OOP costs to the pharmacy for any prescriptions they obtain. The Part D plan may choose not to permit the beneficiary to rejoin its MPPP until all overdue balances are paid. If past due amounts are not repaid, the Part D plan must absorb those costs.

**Only certain Part D enrollees will benefit from the MPPP.** The intent of the MPPP is to help beneficiaries that incur high monthly out-of-pocket costs earlier in the plan year (reaching the OOP threshold of \$2,000) by spreading those costs over the entire plan year through lower monthly payments. The program does not change the total amount a person has to pay over the entire year, but it changes the cadence of those payments in ways that could advantage some and disadvantage others.

Part D beneficiaries will **not** benefit from opting into the MPPP if they:

1. Are not expected to reach the \$2,000 OOP threshold and
2. Their OOP costs are already smooth over the plan year.

For example, many beneficiaries that take medications treating chronic conditions (other than specialty drugs) already have predictable monthly OOP costs (that do not reach the \$2,000 threshold by the end of the year). These beneficiaries would be made worse off if they were to opt into the MPPP because the program would make it more difficult for these beneficiaries to anticipate and budget for their monthly drug costs. Initially the MPPP would help lower costs for these beneficiaries because they would pay less early in the plan year under the MPPP than the OOP amounts set by the plan (that they would have paid at the pharmacy counter). However, under the statutory formula, their monthly payments under the MPPP would grow over time in a confusing manner and at the end of the year these beneficiaries would likely be surprised by a high balance due that could be two or three times the monthly amount that their plan would have charged in OOP costs for their monthly prescriptions.<sup>1</sup>

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

#### *30.1 General Outreach and Education*

Arnold Ventures strongly recommends that all MPPP educational materials sent out by Part D plans to their enrollees include language that describes beneficiaries that are most likely to benefit **as well as those who are least likely to benefit from the MPPP.**<sup>2</sup> We are concerned that if educational materials are not clear this way, some beneficiaries will enroll and become worse off due to the MPPP's statutory structure.

##### *30.1.5 Part D Sponsor Websites*

The guidance states that Part D sponsors must provide on their websites certain information about the MPPP including “a description of who is likely to benefit” from the MPPP. Arnold Ventures recommends that the website also **describe beneficiaries not likely to benefit** from joining the MPPP.

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<sup>1</sup> For further explanation of this issue, see <https://www.healthaffairs.org/content/forefront/medicare-part-d-s-new-prescription-payment-plan-may-not-reduce-costs-all>

<sup>2</sup> For example, AV recommends that a description of the beneficiaries that are least likely to benefit from the MPPP be added to the description of the MPPP included in the draft Explanation of Benefits issued by CMS in December.



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

Part D plans are required to identify beneficiaries that are likely to benefit from the MPPP. These are beneficiaries that meet the criteria set out in the guidance by incurring \$600 in OOP costs from a single prescription or because they reached the \$2,000 OOP cap by September of the previous plan benefit year. Part D plans are required to send these beneficiaries an “MPPP Likely to Benefit Notice.” Arnold Ventures recommends that the “election request form” be sent out to this subgroup of beneficiaries along with the “MPPP Likely to Benefit Notice”.

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

CMS will develop and provide an educational product about the MPPP for the Medicare.gov website and other communication channels. Part D plans are also encouraged to use this educational product when sending educational materials to their enrollees about the MPPP. Arnold Ventures recommends that this educational product developed by CMS contain a description of the beneficiaries that are likely to benefit from joining the MPPP **as well as those that are least likely to benefit.**

### Conclusion

Arnold Ventures is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook, Ph.D. with assistance from Andrea Noda, MPP, Vice President of Health Care at Arnold Ventures and Mark E. Miller, Ph.D., Executive Vice President of Health Care at Arnold Ventures.

Please contact Andrea Noda at [anoda@arnoldventures.org](mailto:anoda@arnoldventures.org) or Mark E. Miller at [mmiller@arnoldventures.org](mailto:mmiller@arnoldventures.org) with any questions. Thank you again for the opportunity to comment and for your important work to lower prescription drug prices for the Medicare program and its beneficiaries.

Sincerely,

Andrea Noda

March 15, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd  
Baltimore, MD 212441

Dear Administrator Brooks-LaSure,

On behalf of the Arthritis Foundation, representing the nearly 60 million American adults with doctor-diagnosed arthritis, thank you for the opportunity to comment on ***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***. Securing a Medicare Part D out-of-pocket cap was our top priority last Congress, as many of our patients continue to be negatively impacted by high Part D costs, in some cases having to switch to Part B drugs and experiencing adverse events as a result. This program has the potential to make a major impact on the ability of Medicare beneficiaries to afford their medications.

We have signed onto comments from the MAPRx Coalition and the Alliance for Aging Research that go into much greater detail on the policy components of the guidance, but we wanted to submit comments to highlight our plans for outreach and education and ways CMS can collaborate with the patient community moving forward.

Educating as many beneficiaries with arthritis as possible about MPPP is one of our top organizational priorities this year. We have established an inter-department team to design an outreach and education campaign involving staff from our advocacy, patient education, communications, and Helpline teams. We will be developing educational materials and utilizing a multi-modal method to reach our population, including newsletters, social media, webinars, in-person events, support groups, podcasts, and other channels we may identify along the way. Using patient advocacy groups as a conduit to reach beneficiaries is critical for CMS as it launches its own outreach campaign. We encourage you to work with us and other patient groups to coordinate the development of materials and the timing of our respective outreach campaigns. As there is ample opportunity for confusion about the program, we strongly suggest this approach to ensure our collective language is aligned and beneficiaries are hearing consistent messages from multiple parties.

We also strongly encourage CMS to work with the health care provider community in the same fashion, as they have the broadest and most direct touchpoints with patients, and data consistently shows that patients trust their health care providers most. We have already begun coordinating with the American College of Rheumatology and Coalition of

State Rheumatology Organizations, and also plan to engage with the Rheumatology Nurses Society and the National Organization of Rheumatology Managers. To streamline the process of coordinating outreach efforts, we would encourage CMS meet with the arthritis patient and provider organizations collectively and we would welcome the opportunity to assist in this effort. Like many therapeutic areas, our population is uniquely impacted by Part D out-of-pocket costs, in addition to the frequency and manner in which they seek care, and we welcome the opportunity to discuss in further detail the ways in which communicating about MPPP might be most effective for our patients.

We also affirm that pharmacists will play a vital role in educating beneficiaries, as they also have consistent touchpoints with a wide breadth of patients. We recognize that like many providers, pharmacists are experiencing challenges with workforce shortages and burnout, and they may have limited capacity to add new workstreams to their responsibilities. We understand how difficult it is to ensure each and every patient that could be affected by a particular program or policy receives the associated education or training, and that whether it is enrolling in MPPP or educating patients about other programs and benefits, this is one of many areas pharmacists must track. We encourage CMS to work closely with the pharmacist community to ensure adequate resources and the capacity to reach as wide a set of beneficiaries as possible at the pharmacy counter.

We will begin development of our educational materials in earnest this spring and will begin developing and executing our outreach campaign in the summer. The coalition comment letters we signed urge CMS to begin beneficiary outreach a few months before open enrollment begins, and should CMS undertake this recommendation the timing would align for you to begin your outreach in the summer months as well.

We are thrilled that beneficiaries will have the opportunity to enroll in the MPPP program in the next plan year and cannot emphasize enough how important it will be for all stakeholders who communicate with current and prospective beneficiaries to prioritize educating them about whether this program is right for them. We look forward to working with you and thank you for your consideration of our request to coordinate our messaging and outreach efforts with you as well. Should you have any questions, please contact me at [ahyde@arthritis.org](mailto:ahyde@arthritis.org) any time.

Sincerely,



Anna Hyde  
Vice President of Advocacy and Access  
Arthritis Foundation



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March 16, 2024

Chiquita Brooks-LaSure

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

200 Independence Ave SW

Washington, DC 20001

Submitted Electronically to PartDPaymentPolicy@cms.hhs.gov

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

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Medicare Prescription Payment Plan Draft Part Two Guidance that was released on February 15, 2024.

ASCO is a national organization representing nearly 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

\* \* \* \* \*

The Medicare Prescription Payment Plan (MPPP) is a new program required under the Inflation Reduction Act under which Part D sponsors must provide enrollees the option to pay out-of-pocket prescription drug costs in the form of monthly payments over the course of the plan year, instead of all at once at the pharmacy, beginning in 2025. The Part D sponsor would then bill these program participants monthly for any cost-sharing they incur while in the program.

Several studies have illustrated the profound financial impact that comes with the breadth of problems posed by a cancer diagnosis.<sup>1,2</sup> Even for insured

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<sup>1</sup> Ward E, Halpern M, Schrag N, et al: Association of insurance with cancer care utilization and outcomes. CA Cancer J Clin 58:9-31, 2008

<sup>2</sup> Banthin JS, Bernard DM: Changes in financial burdens for health care. JAMA 296:2712-2719, 2006



patients, the cost of cancer diagnosis and treatment can present a barrier to obtaining high-quality care. For patients with insurance, out-of-pocket expenses associated with cancer treatment may still be substantial and lead to delay in treatment, noncompliance, exhaustion of savings, and personal bankruptcy. A 2019 study found that cancer patients taking specialty tier Part D drugs have higher out-of-pocket costs than patients with other diagnoses. According to the same analysis, expected annual out-of-pocket costs in 2019 for the 14 covered specialty tier Part D cancer drugs included in the analysis range from \$8,181 to \$16,551.<sup>3</sup> For additional information on the cost of cancer care, please see our affiliate's, *The Society of Clinical Oncology's Guidance Statement: The Cost of Cancer Care*.<sup>4</sup>

ASCO is committed to supporting policies that reduce cost while preserving quality of cancer care, and it is important that these policies are developed and implemented in a way that does not undermine patient access to cancer therapies. ASCO supports the intent of the MPPP to assist Medicare Part D beneficiaries who have high cost-sharing distribute their Part D prescription payments throughout the year. High cost-sharing requirements such as upfront deductibles and monthly coinsurance can prevent patients from filling prescriptions, which can result in patients deciding to forego medication. If a patient does forego care, this decision will lead to poorer health outcomes and higher overall costs to the health care system.

We offer our comments on certain sections of the proposed guidance below.

#### *Section 30.2.3 Communications with Contracted Providers and Pharmacies*

ASCO commends CMS for recognizing that oncologists and other oncology professionals play a key role in cost-of-care conversations with patients, including discussions about potential prescription drug costs. Individuals with cancer often face enormous financial burdens and will approach their physicians for information about patient resources to assist with these burdens. Additionally, patients rely heavily on their care team to explain what their out of pockets costs will be for treatment; providers will need communication materials that will outline, in very simple language, what the program is and what a patient's monthly payment will be.

ASCO supports CMS' efforts to develop and provide educational materials for Part D enrollees and providers on the Medicare.gov website and through other communication channels, and we strongly urge CMS to develop and implement a real-time calculator for patients to have an accurate estimate of how the program could potentially ease some financial burden. Patients and physicians would benefit from access to real-time information about the cost of treatment at the point of care.

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<sup>3</sup> <https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-findings/>

<sup>4</sup> Meropol, N. J., Schrag, D., Smith, T. J., Mulvey, T. M., Langdon Jr, R. M., Blum, D., ... & Schnipper, L. E. (2009). American Society of Clinical Oncology guidance statement: the cost of cancer care. *Journal of Clinical Oncology*, 27(23), 3868-3874.



### *30.4 General Part D Enrollee Outreach Requirements*

ASCO supports CMS' requirement that outreach materials and communications be provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds. In addition, for markets with a significant population of persons with limited English proficiency, the requirements finalized in the CY 2024 MA and Part D Final Rule (CMS–4201–F) apply to all MPPP educational and communications materials. These requirements stipulate that Part D sponsors must provide translated materials to Part D enrollees on a standing basis in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area.

We agree with CMS that outreach and education of people with Medicare Part D and their caregivers is one of the most critical elements of this program. To support all Medicare beneficiaries and to improve health equity, ASCO supports CMS' clarifications that communication materials should be culturally appropriate and address the specific communication assistance and language needs of all beneficiaries enrolled in a Part D plan.

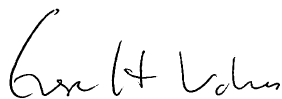
### *50.2 Pharmacy POS Notifications Late in the Plan Year*

Medicare beneficiaries need accurate information about this program to decide whether enrollment is beneficial. Patients should understand how monthly financial obligations will change depending on when in the plan year they enroll in the program, including awareness that earlier enrollment in the plan year may be more beneficial. CMS should provide clear, easy to understand examples of how the timing of enrollment during plan year can drastically affect out of pocket costs; deployment of a real-time calculator would be an extremely effective tool for beneficiaries to understand the real-life implications of enrolling in the program.

\* \* \* \* \*

We appreciate the opportunity to comment on the Medicare Prescription Payment Plan Draft Part Two Guidance. Please contact Gina Hoxie ([gina.hoxie@asco.org](mailto:gina.hoxie@asco.org)) with any questions or for further information.

Sincerely,



Everett Vokes, MD, FASCO  
Chair of the Board  
Association for Clinical Oncology

March 16, 2024

Chiquita Brooks-LaSure  
Administrator  
Centers of Medicare & Medicaid Services  
Department of Health & Human Services

Submitted electronically: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

RE: Medicare Prescription Payment Plan Guidance (Part 2)

Dear Administrator Brooks-LaSure:

The Association for Community Affiliated Plans (ACAP) respectfully submits comments in response to the request for comment from CMS on the *Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, Solicitation of Comments*. ACAP is an association of 79 not-for-profit, community-based, Safety Net Health Plans (SNHPs). Our member plans provide coverage to more than 25 million individuals enrolled in Medicaid, the Children's Health Insurance Program (CHIP), and Medicare Advantage Dually Eligible Special Needs Plans (D-SNPs), including Fully Integrated D-SNPs (FIDE SNPs), Highly Integrated D-SNPs (HIDE SNPs), and Applicable Integrated Plans (AIPs).

ACAP has chosen to respond to this draft guidance in support of the Medicare Prescription Payment Plan's overarching goals and suggested approaches; but with several requests to ensure that this program will be appropriately targeted to those who would benefit the most. Additionally, we also want to share our suggestions for how CMS can best monitor and refine the success of the program.

### **Summary of Comments**

- *Concerns about Impacts on the LIS/Duals Population*
  - *CMS has explicitly excluded PACE and Medicare-Medicaid Plan (MMP) enrollees from the requirements for billing and program promotion. This decision was based on the determination that for these individuals the MPPP would have "no practical application". We ask that CMS also apply this standard of "no practical application" to D-SNPs.*
  - *ACAP reiterates our request that the MPPP program not apply if the cost-sharing for a particular drug is de minimus.*
- *Model Materials:*
  - *ACAP appreciates the flexibilities plans are allowed on model materials.*
  - *ACAP urges CMS to work to finalize these model materials before plans must submit their own documents for CMS approval.*
- *Web-based Applications:*

- *As CMS notes, inaccurate, or missing information is a concern for the application process and may delay the time it takes to enroll beneficiaries. One solution to reducing application errors is to have the electronic MPPP application on a plan's member portal.*
  - *To support member portal application innovations, we ask that CMS allow plans to host their electronic applications for the MPPP on their member portals.*
- **Member ID Care Mailings:**
  - *For LIS beneficiaries, we are concerned that including the application with the Member ID will lead many to apply inaccurately believing this application is part of obtaining benefits.*
- **Requirements for Identifying Enrollees Likely to Benefit Prior to the Plan Year:**
  - *We ask that CMS allow for plans to exclude current LIS-enrolled beneficiaries from those "likely to benefit" if the OOP costs were incurred prior to the beneficiaries' LIS enrollment.*
- **Quality Measures:**
  - *ACAP remains concerned with potential Star Ratings implications that may result from the MPPP program.*
  - *In instances where Star Ratings may be affected as a result of the MPPP, we ask CMS to develop mechanisms to hold plans harmless.*
  - *We support CMS' consideration of creating a new CTM category for MPPP-related complaints.*
  - *We also ask CMS to investigate whether MPPP enrollment has any impact on Part D CAHPS measures.*
- **Program Monitoring:**
  - *ACAP encourages CMS to prepare for evaluation of the MPPP by putting in place proactive monitoring mechanisms.*
  - *First, we ask that CMS monitor the portion of MPPP enrollees that are benefiting from the program.*
  - *Second, we ask that CMS put in place mechanisms to collect and report the amount of uncollected MPPP billed amounts over time.*
  - *Lastly, we also ask that CMS monitor enrollment changes among those beneficiaries who have unpaid MPPP balances.*
- **Operational Flexibility:**
  - *We urge CMS to provide implementation flexibility where possible and to provide alternative, less administratively burdensome options if they will not be a meaningful detriment to member experience.*

### **Expanded Comments**

ACAP's comments are expanded below, with additional background.

### ***Concerns about impacts on the LIS/Duals Population***

ACAP plans primarily enroll dual-eligible Medicare beneficiaries in D-SNPs. As CMS noted in its guidance, almost all these individuals are LIS-eligible and thus have very little Part D cost-sharing. We are concerned that these beneficiaries could experience the negative impact of having higher cost-sharing in later months than they would outside of the MPPP program, if their nominal cost-sharing in early months is shifted to later months.

We understand CMS' concern that the statute does not allow for different treatment of LIS versus non-LIS beneficiaries. Nonetheless, **we note that CMS has explicitly excluded PACE and Medicare-Medicaid Plan (MMP) enrollees from the requirements for billing and program promotion. This decision was based on the determination that for these individuals the MPPP would have “no practical application”.** We ask that CMS also apply this standard of “no practical application” to D-SNPs.

**We also reiterate our request that the MPPP program not apply if the cost-sharing for a particular drug is *de minimus* (e.g., less than the cost-sharing associated with drugs in the LIS program).** In such an instance, no separate payment processing and monthly billing would be required for LIS beneficiaries and thus could alleviate the administrative costs for those LIS beneficiaries who elect to participate in the MPPP without a likely benefit.

### ***Model Materials***

ACAP appreciates the creation of model materials for the MPPP; having these materials will ease the program implementation for plans. As CMS continues to provide guidance and other materials for the implementation of this program, **we appreciate the flexibilities plans are allowed on model materials.** In particular, we appreciate the ability to tailor some of the program language to the needs of our member population—at least in the early years of the program. We think that this will provide for a better and less confusing member experience until beneficiaries become familiar with the program.

Nonetheless, many plans will utilize the standard model materials and **we urge CMS to work to finalize these model materials before plans must submit their own documents for CMS approval.** If these materials cannot be finalized before plans are required to submit them, we ask that CMS allow plans to use the draft model materials.

We also seek additional clarifications on what materials and processes should be made available or apply to enrollees in MMPs. CMS notes that there is no practical application for beneficiaries in MMPs; however, additional clarification on what specific requirements can be waived would be operationally helpful, and if those same flexibilities apply to other plans without Part D cost sharing.

### ***Web-Based Applications***

We note that CMS requires that plans support multiple means by which beneficiaries can apply for the MPPP. As CMS notes, inaccurate, or missing information is a concern for the application process and may delay the time it takes to enroll beneficiaries. **One solution to reducing application errors is to have the electronic MPPP application on a plan's member portal.** If the application is on the portal, validated information could be auto populated and confirmed.

**To support member portal application innovations, we ask that CMS allow plans to host their electronic applications for the MPPP on their member portals.** Because many other application means

will also be supported, we do not see this as creating any unnecessary burden for beneficiaries, and, in fact, will lead to more successful and more expedient application processing.

### ***Member ID Card Mailings***

ACAP continues to believe that the MPPP will create a great deal of confusion for LIS beneficiaries. While CMS believes that differentiated outreach is not permitted, CMS is creating an outreach process for those beneficiaries most likely to benefit from the MPPP. We believe that the Member ID card mailing should be tied to potential member benefit. **For LIS beneficiaries, we are concerned that including the application with the Member ID will lead many to apply inaccurately believing that this application is part of obtaining benefits.**

### ***Requirements for Identifying Enrollees Likely to Benefit Prior to the Plan Year***

ACAP supports CMS' decision to use a \$2,000 threshold in previous years' OOP costs as a threshold to identify those likely to benefit prior to the plan year. However, we note that some beneficiaries who incurred high cost-sharing in the beginning of the year may have applied for the LIS program in subsequent months. For this reason, **we ask that CMS allow for plans to exclude current LIS-enrolled beneficiaries from those "likely to benefit" if the OOP costs were incurred prior to the beneficiaries' LIS enrollment.**

### ***Quality Measures***

ACAP remains concerned with potential Star Ratings implications that may result from the MPPP program. This effect is most concerning for the CTM, but there may also be potential CAHPS survey implications. Because this is a new program, we are not sure whether the effects on measures will be similar across all MAPDs, or whether some types of plans will be affected differently. Therefore, **in instances where Star Ratings may be affected as a result of the MPPP (like the CTM), we ask CMS to develop mechanisms to hold plans harmless.**

**We support CMS' consideration of creating a new CTM category for MPPP-related complaints.** We believe a separate category would be essential for CMS to analyze the effects of these complaints separately to understand if their inclusion creates anomalies in Star Ratings.

**We also ask CMS to investigate whether MPPP enrollment has any impact on Part D CAHPS measures.** As CAHPS measures are currently adjusted based on beneficiary demographics there is a potential that either scores or adjustments could result in Star Ratings that are not aligned with actual plan performance. For this reason, we ask CMS to conduct analyses on Part D CAHPS measures and determine if a hold-harmless provision is appropriate for the 2026 Star Ratings.

### ***Program Monitoring***

**ACAP encourages CMS to prepare for evaluation of the MPPP by putting in place proactive monitoring mechanisms.** Being prepared to collect the necessary information from the beginning will ensure that CMS can make timely adaptations to the program. ACAP has several suggestions for what we see are necessary program monitoring elements.

**First, we ask that CMS monitor the portion of MPPP enrollees that are benefiting from the program.** If CMS finds that a substantial portion of MPPP participants are not benefiting from the program, then it could take action to better target outreach or identify those most likely to benefit from the program. **Second, we ask that CMS put in place mechanisms to collect and report the amount of uncollected MPPP billed amounts over time.** We would like this information reported by contract and plan type (e.g. D-SNPs versus Standard MA-PDs), as well as plan profit status.

**Lastly, we also ask that CMS monitor enrollment changes among those beneficiaries who have unpaid MPPP balances.** We believe CMS would want to understand if unpaid balances are associated with beneficiary plan switching, and if so, does that switching occur more for some plan types than others. ACAP would be especially concerned if small unpaid MPPP balances are causing dually eligible beneficiaries to disenroll from their integrated D-SNPs, thus creating unnecessary disruptions to their access to care and care plans.

### ***Operational Flexibility***

In its Final Part 1 Guidance, CMS notes that in many instances, the operational challenges and costs will be disproportionately higher for smaller, community-based health plans (e.g., hiring additional weekend staffing to accommodate faster enrollment). We understand the beneficiary perspective on ensuring easy access to this program—especially when affordability may determine whether a needed prescription is filled or not. Nonetheless, we note that disproportionate administrative burdens, in aggregate, make it harder for community-based safety-net health plans to compete. Therefore, **we urge CMS to provide implementation flexibility where possible and to provide alternative, less administratively burdensome options if they will not be a meaningful detriment to member experience.** Additionally, with any new program, unanticipated issues and questions will arise during implementation. We ask CMS to allow for good faith compliance efforts by plans as we aim to partner with CMS to refine the program and maximize value to beneficiaries.

\*\*\*\*

ACAP thanks CMS for its willingness to consider the aforementioned issues. If you have any additional questions or comments, please do not hesitate to contact Christine Aguiar Lynch (202-204-7519 or [clynch@communityplans.net](mailto:clynch@communityplans.net)).

Sincerely,

/s/

Margaret A. Murray  
Chief Executive Officer

Via Electronic Submission: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

March 16, 2024

Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director of the Center for Medicare  
Centers for Medicare & Medicaid Services  
U.S. Department of Health & Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Dr. Seshamani:

AstraZeneca appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Draft Part Two Guidance (the “Draft Guidance”) on the “Maximum Monthly Cap on Cost-Sharing Payments Program” (the “Medicare Prescription Payment Plan” or the “Program”).

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology, Cardiovascular, Renal & Metabolism, and Respiratory. Our mission is to deliver life-changing medicines that improve the health and quality of life of millions of people worldwide.

Alexion is the group within AstraZeneca focused on rare diseases. Our mission is to transform the lives of people affected by rare diseases through the development and delivery of innovative medicines, as well as supportive technologies and health care services. For 30 years, patients and their caregivers have been at the center of everything we do, and our mission is driven by understanding who they are as unique individuals, not just their disease. Every day, we are inspired to think differently and follow the science to create better outcomes for them and their families.

We welcome the proposed implementation of the Medicare Prescription Payment Plan, as established by section 11202 of the Inflation Reduction Act (IRA).<sup>1</sup> The Program will improve access to critical therapies for Medicare beneficiaries by ameliorating enrollee cashflow concerns that could negatively impact their ability to afford their medications. We are committed to collaborating with all stakeholders to ensure a successful implementation of this critical program. To this end, we urge CMS to use this first year of implementation as a learning opportunity, and to incorporate these learnings into guidance for the Program for future plan years.

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<sup>1</sup> Pub. L. No. 117-169.



As we discussed in our comments on the Draft Part One Guidance, it is vital CMS promote the use of consistent, standardized communications regarding the Program to ensure all stakeholders are informed of the Program's nuances and benefits, as well as each stakeholder's role in ensuring successful implementation. As such, we are concerned that in the context of certain communication channels, such as websites and provider/pharmacy communications, CMS is granting Part D plan sponsors too much discretion in the format and content of the materials, and that this will result in excessive variation and inconsistent information that will only serve to undermine the objectives of the Program.

To that end, we offer the following additional comments on this Draft Guidance:

**I. Section 30.1.5 – Part D Sponsor Websites**

- a. CMS should require Part D sponsors to use standardized content for Program information posted on their websites.

AstraZeneca appreciates that CMS will require Part D sponsors to include information on the Program on their websites, in addition to the required content under § 423.128(d)(2) and the election request mechanism that Part D enrollees can use to opt into the Program. However, we are concerned that CMS is only “encouraging” Part D sponsors to use language from the CMS-developed educational product on the Program and other CMS-provided resources to meet these requirements.

In addition to the Program's novelty, its components and requirements can be quite complex, and the benefit that can accrue to enrollees from opting into the Program can be significant. AstraZeneca thus believes that ensuring enrollees are informed of and understand the new Program is of the highest priority and should outweigh any Part D sponsor interest in flexibility in this context. As such, CMS should instead require Part D sponsors to use standardized materials developed by the agency to meet the relevant requirements with respect to Part D sponsor website information on the Program.

**II. Section 30.2.2 – Identifying Part D Enrollees Likely to Benefit During the Plan Year**

AstraZeneca supports a “likely to benefit” concept, recognizing the Program will be valuable for some, but not all patients. We are further supportive of a requirement on Part D sponsors to assess current Part D enrollees' prescription drug costs from the current year and to conduct outreach to Part D enrollees who incurred \$2,000 in OOP costs for covered drugs through September of that year. During the plan year, we are similarly aligned on the \$600 POS threshold that was established in the Part One Guidance.

To broaden education to both enrollees and plans, CMS should require Part D sponsors to include on their websites and other relevant educational materials: (1) a list of all on-formulary drugs that fall on and above the single prescription drug cost POS threshold of \$600; and (2) a list of all on-formulary drugs that would result in an enrollee exceeding the \$2,000 in OOP costs during the plan year. Such education will be useful to enrollees, prescribers, and dispensers in determining enrollees likely to benefit from the Program.



### **III. Section 30.2.3 – Communications with Contracted Providers and Pharmacists**

- a. CMS should require Part D sponsors to share CMS-developed standardized educational materials with their contracted providers and network pharmacies regarding the Program.

AstraZeneca agrees with CMS that health care providers and pharmacists play a key role in cost-of-care conversation with their patients. For this reason, we are disappointed that CMS is proposing to only “encourage” Part D sponsors to include Program information in their communications with contracted providers and network pharmacies. Successful implementation of the Program necessitates a thorough understanding of how the Program works and how it can benefit enrollees by all stakeholders involved, including providers and pharmacies. Part D sponsors are in the best position to ensure that providers and pharmacies are properly educated on the Program’s nuances. As such, we believe CMS should require Part D sponsors to provide educational materials to contracted providers and network pharmacies. Moreover, as discussed above, standardization of these materials is necessary to ensure all stakeholders are receiving adequate and correct information on the Program. We thus also believe CMS should require Part D sponsors to use CMS-developed standardized material in their communications with contracted providers and network pharmacies. This will mitigate against the risk of excessive variation and confusion in communication content and ensure that providers and pharmacies are properly informed of their role in successful implementation of the Program.

### **IV. Section 30.3 – Communications with Program Participants and Model Materials Requirements for Part D Sponsors**

- a. CMS should ensure Model Materials are broadly accessible to a wide range of enrollees and contain sufficient protections to ensure enrollees are properly informed before being enrolled or disenrolled from the Program.

AstraZeneca supports CMS’ commitment to developing Model Materials for use by Part D sponsors to ensure accuracy in communication about this critical program for patients. Clear, concise, customized (when possible), and easily understood communication will be essential to ensure that all enrollees, regardless of literacy level or socioeconomic background, are fully informed and made aware of the choices before them. This will be particularly critical for enrollees who may qualify for LIS; as CMS notes in the Draft Guidance, “for those who qualify [for LIS], is likely to be more advantageous than participation in the [Program].” Consistent with our previous comments, AstraZeneca believes that Part D sponsors should be required to utilize CMS Model Materials.

As CMS develops this Model Materials, AstraZeneca encourages the agency to keep accessibility in mind, including for enrollees with varying levels of health literacy. For example, many enrollees may be unaware of the difference between a Part B and Part D drug, and thus not understand that they may still be expected to pay out-of-pocket for their Part B prescriptions. Given that opting into the Program at various points in the plan year will have different impacts on Program payments, CMS should take extra steps to offer additional tools and resources, such as decisions aids or monthly cost calculators, to ensure enrollees are making the best decision for them and their families.

Lastly, AstraZeneca asks that CMS include provisions for a review or appeal process before disenrollment/involuntary termination from the program. The agency should also work to inform impacted enrollees on the availability of support services for financial difficulties, including information on the LIS program. Given that the individuals most likely to benefit from the program are also likely to be disproportionately low-income, it will be crucial to establish a process that is accessible and accommodates a broad range of enrollees in various circumstances.

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We appreciate your consideration of our comments and for CMS' continued dialogue with AstraZeneca as the agency continues to implement the Medicare Prescription Payment Plan and other relevant policies in the Inflation Reduction Act. Please contact us at [sarah.arbes@astrazeneca.com](mailto:sarah.arbes@astrazeneca.com) or [lisa.feng@alexion.com](mailto:lisa.feng@alexion.com) should you have any additional questions about our comments.

Sincerely,



Sarah C. Arbes  
Head of Federal Affairs and Policy  
AstraZeneca



Lisa Feng  
Senior Director, Health Policy  
Alexion AstraZeneca Rare Disease

March 15, 2024

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, MD 21244-8016

Submitted via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

**Re: Medicare Prescription Payment Plan: Draft Part Two Guidance**

Dear CMS Desk Officers:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) draft Part II guidance on the Medicare Prescription Payment Plan (MPPP) issued on February 15, 2024.

BCBSA is a national federation of independent, community-based and locally operated BCBS companies (Plans) that collectively cover, serve, and support 1 in 3 Americans in every ZIP code across all 50 states and Puerto Rico. BCBS Plans contract with 96% of hospitals and 95% of doctors across the country and serve those who are covered through Medicare, Medicaid, an employer, or purchase coverage on their own.

BCBSA appreciates CMS publishing the final Part I guidance and is eager to work with CMS on final standards and pricing guidelines for the MPPP for CY 2025. We recognize success for this program is dependent on the partnership between CMS, health plans, pharmacies, beneficiaries and caregivers, and we look forward to supporting this program launch. Below are general themes and recommendations as the agency moves forward with MPPP implementation:

- **Expedite release of final guidance.** BCBSA urges CMS to release the final Part II guidance, PDE reporting instructions and the Bid Pricing Tool as soon as possible. Given the variety and volume of plan documents (ANOCs, EOC, EOBs, etc.), model language needs to be finalized by April to give plans time to coordinate with business partners, review, operationalize, translate, allow for state review (for Dual Eligible Special Needs Plans), and produce in time for the fall AEP for CY 2025. BCBS Plans are building internal capabilities and contracting with vendors to stand up this new program in compliance with these sub-regulatory requirements. Early access to final CMS guidance will support this development and an ultimately successful launch of the program.

- **Provide bidding support.** BCBS Plans are concerned about pricing for the MPPP program and, specifically, unsettled balances from enrollees in CY 2025 bids. We urge the Office of the Actuary (OACT) to release assumptions and modeling support for Part D plans' pricing of this benefit to address the actuarial uncertainty facing plans.
- **Consistent accounting for medical loss ratio (MLR) calculation.** BCBSA is concerned with CMS' interpretation that unsettled balances should be considered administrative costs for purposes of the MLR calculation. Since unsettled monthly payment amounts constitute revenue paid by the plan for patient care, BCBSA recommends that such amounts should be treated as claims and therefore be included in the numerator.
- **Focus member communication requirements on high-value touches.** BCBS Plans have observed that overcommunication on a topic causes enrollee fatigue. This leads to enrollees being less likely to pay attention to high-value communications (e.g., notice of MPPP when enrollee has a script for a high-cost drug) if they have had to process low-value ones (e.g., notice of MPPP with every explanation of benefit). We support high-value communication with enrollees while avoiding oversaturation.
- **Provide a good faith safe harbor:** BCBSA supports CMS withholding enforcement action with respect to a Part D sponsor that is acting in good faith and using reasonable interpretation of CMS guidance to implement the MPPP. We believe a good faith safe harbor is necessary and appropriate for CY 2025 given the need to make operational adjustments in response to additional CMS guidance in 2024 and to respond to unforeseen challenges in the first year of implementation.

We thank CMS for consideration of BCBSA's comments, and we look forward to future collaboration on IRA implementation. We have summarized our detailed comments below.

## **Detailed Recommendations on the Medicare Prescription Payment Plan Draft Guidance (Part II)**

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

- *Overarching comments on model materials.* BCBSA appreciates CMS' efforts to date to draft guidance and identify areas where member communication is needed to support education and outreach. To support Part D plans, BCBSA recommends CMS:

- Issue final Part D redesign program instructions as soon as possible which will drive content for plan materials (e.g., definition of TrOOP). In the past, CMS has issued model language early in the year and then issued corrections later in the year, which can disrupt the document development and production activities and increase administrative challenges to changing multiple essential beneficiary-facing documents. CMS should provide plans with maximum flexibility in these situations.
- If model materials are delayed beyond the end of Q2 2024, provide flexibility for Part D plans to program notices based on draft model forms and modify language without additional CMS review. CMS should provide flexibility for Part D plans to have ample places in model documents to include non-standardized language without the need for additional CMS review. We recommend CMS not require plan sponsors to issue “erratas” for any change CMS makes to the model materials as this results in increased member confusion and places an unnecessary burden on plan sponsors who are focusing on the beneficiary experience.
- Issue model language for Summary of Benefits or allow plans to use EOC model language for the Summary of Benefits.
- Issue model language for formulary materials.
- In all notices and model materials, include language on individuals *unlikely* to benefit.
- In all notices and model materials, specify the MPPP applies only to pharmacy benefit drugs and that Part B drugs are excluded.
- *30.1.1 Required Mailings with Membership ID Card Issuance.* BCBSA requests CMS allow Part D plans to include the MPPP notice in the membership ID mailing or send in separate communication when an individual signs up for a plan. Sending the MPPP notice with the member ID presents challenges, as some plans’ enrollment systems would not be able to include the MPPP notice in all member ID mailings. An alternative to a requirement to include the notice in the ID mailing is to set a date by when a plan must send the notice. This grants plans flexibility to share the MPPP notice with other communications, such as the confirmation of enrollment letter, which is distributed prior to sending the ID card.
- *30.1.4 Explanation of Benefits (EOB).* We understand CMS is proposing including information in the EOB explaining how enrollees who participate in the MPPP will receive a separate monthly billing statement and that costs included in the EOB might differ from what an MPPP participant paid at POS. BCBSA recommends against including language on the MPPP language in all EOBs as it will drive beneficiary confusion about whether or not an enrollee has elected coverage. BCBS Plans note that overcommunication on a topic, like inclusion on every EOB, causes enrollee fatigue and

enrollees are less likely to pay attention to high-value communications if they have had to process low-value ones.

Also, including an MPPP statement in all EOBs does not target messaging to enrollees who are likely to benefit, and repeated messages in EOBs, especially those EOBs sent later in the calendar year, will result in enrollees electing coverage who will not benefit and/or will experience unexpected, high monthly payments. We recommend adding language to the MPPP approval letter notification that clarifies the EOB will not reflect participation in the program.

- *30.2 Targeted Outreach and Education Requirements for Part D Sponsors.* BCBSA seeks clarification on the number of times a Part D plan must notify an enrollee that they are likely to benefit from the program throughout the year. We ask CMS to state when plans may discontinue sending notifications after enrollees reject election to MPPP.
- *30.2.2.1 Identifying Part D Enrollees Likely to Benefit Prior to the Plan Year.* BCBSA understands that Part D sponsors are required to conduct outreach to enrollees during the plan year if they become aware in advance of a new high-cost prescription drug that would trigger the pharmacy POS notification process. In the draft guidance, CMS notes that an MPPP notice must be sent in the timeframes for a prior authorization (PA) or other utilization management (UM) request: 24 hours after receiving the request for expedited cases, or no later than 72 hours after receiving the request for standard cases.

BCBSA recommends CMS:

- Use as a threshold for identifying current enrollees to benefit from the MPPP calculation of True Out of Pocket (TrOOP) costs rather than out-of-pocket costs (OOPC). This suggestion is based on the assumption that the MPPP should be targeted to those likely to hit their maximum out-of-pocket costs.
- Clarify that MPPP notification should only be sent should the Part D plan *approve the PA or UM request*. As written, the MPPP notification must be sent within the appropriate timeframe within receiving the request, *regardless of whether the request was approved or not*. This clarification is needed to avoid enrollee confusion about receiving an MPPP notice for a drug meeting the POS notification trigger when the drug is not approved for coverage. Under our recommendation, the 24-hour or 72-hour timeframe would be triggered with the PA or UM request *approval*.
- Extend the 24-hour timeframe to review both the coverage determination via a PA or UM request and notification for MPPP. Requiring a 24-hour turnaround is not optimal given it drastically changes the way plans manage coverage determination requests internally.

- Provide additional guidance and examples noting how the MPPP intersects with accumulated TrOOP under an enhanced alternative plan related to identifying enrollees likely to benefit.
- *30.2.2.3 Requirements for Identifying Part D Enrollees Likely to Benefit at POS.* BCBSA recommends CMS consider a “Medicare Prescription Payment Plan Likely to Benefit Notice” that is standard for use by all Part D plans. We believe it a practical approach to have the notice be generic and not specific to the enrollee and enrollee’s Part D plan so pharmacies could stock a supply of the notices and provide them when enrollees incur OOP costs that exceed the threshold in the MPPP Part I guidance. The standard notice can direct enrollees to consult their member IDs for more information on election with their Part D plan.
- *30.3.1 Overview of Election Requirements.* BCBSA asks that CMS reconsider adding the option for enrollees to elect into the MPPP program during the time of enrollment into the plan. This will create widespread confusion for enrollees. We anticipate enrollees misunderstanding the MPPP program with how enrollees elect to have their plan premium billed.

Additionally, we ask CMS to provide additional guidance on if:

- A member must have their enrollment confirmed by CMS prior to the member opting into MPPP?
  - A potential member is able to enroll in an MAPD plan at the same time as opting into MPPP (i.e., can a plan process both at the same time?).
  - The MAPD application will be updated to include the opt-in to MPPP and, if so, will there be wording to inform the member that SSA withholding is not available for MPPP and that MPPP enrollees will be getting separately invoiced?
  - The open enrollment center will be updated to include an opt-in to MPPP?
- *30.3.1.3 Telephonic Election Requests.* BCBSA recommends CMS add that for enrollee calls that occur after normal business hours (e.g., received via voicemail) that the election request date be the following business day.
- *30.3.2 Notice of Acceptance of Election.* We urge CMS to eliminate the requirement to notify enrollees via telephone and retain the requirement for written notification based on the enrollee’s preferred communication method. BCBSA believes it is redundant for the Part D sponsor to deliver the notice of acceptance of election both via telephone and written notice. We also recommend CMS modify the communication timeframe to three *business* days versus *calendar* days for written notice of acceptance of election to the program.

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

- BCBSA supports CMS leadership in providing messaging that communicates information that beneficiaries should consider when electing MPPP. All stakeholders

need to speak with one voice to educate enrollees about the program and how it *may or may not* benefit individual enrollees. We appreciate CMS' collaborating with interested parties in provide communication materials and other support to align messaging prior to the launch of this new program.

## Section 50. Pharmacy Processes

- *50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount.* BCBSA recommends inclusion in the Notice that individuals with supplemental coverage “may be unlikely to benefit” from the program. Stakeholders supporting enrollees, including Part D plans, should send coordinated, initial signals to enrollees highlighting the potential benefits and risks of election to the program depending on each individual's situation, including access to supplemental coverage.

In general, Part D plans should have clear parameters to target enrollees likely to benefit from the program prior to POS and at POS to establish common standards across the industry. It is important that guardrails are put in place for consistency across Part D plans, across all enrollees and for each plan to demonstrate compliance. It also will provide common assumptions for bid calculations.

- *50.2 Pharmacy POS Notifications Late in the Plan Year.* BCBSA supports CMS directing plans to cease sending the “MPPP Likely to Benefit Notice” to enrollees, based on the OOP cost threshold finalized in the Part I guidance, at some point in Q4 in the calendar year. While we understand CMS direction to Part D plans' customer service representative receiving inquiries about the program late in the year, we believe a clear end date to sending these notices is a better approach. This will reduce the number of enrollees electing into MPPP where the benefit is minimal and the financial risk to the enrollee is high.
- *50.3.1 Long-Term Care Pharmacies.* BCBSA agrees with CMS' proposal to allow Part D plans to require the long-term care (LTC) pharmacy to provide the notice to the enrollee at the time of its typical billing process. As noted in BCBSA's comments to the Part I guidance, “post-consumption” billing commonly occurs in LTC pharmacies and allows for accurate billing for drugs consumed by the patient, thereby reducing waste and overall costs. The bill cycle can be 90 days post consumption and determining if the enrollee is likely to benefit would be difficult.
- *50.3.2 Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacies.* BCBSA supports the CMS proposal to not require a Part D sponsor to return the pharmacy notification indicating the enrollee is likely to benefit from the program, if there is a higher-cost drug claim, since these pharmacies provide no-cost prescription drugs to eligible IHS enrollees.



- *50.4 Readjudication of Prescription Drug Claims for New Program Participants.* As most pharmacy claims are adjudicated in real time, this proposal would apply to pending claims that have not yet been paid by the Part D plan. However, the burden to plans readjudicating pending claims after enrollee election in the MPPP would be considerable. When Part D sponsors reprocess claims, the member is moved around in the benefit (i.e., accumulation to the TrOOP), which could result in checks/invoices for accuracy. We recommend that election into MPPP be prospective, and if readjudication is necessary, have the plan only reprocess the pending claim closest to the date of election (e.g., the claim that triggered the POS notification). We also ask CMS to clarify that Part D plans should not reprocess or reverse paid claims.

## Section 60. Part D Sponsor Operational Requirements

- *60.1 Part D Bidding Guidance for CY 2025.* BCBSA Plans are concerned about pricing for the MPPP program and unsettled balances from enrollees in CY 2025 bids. BCBSA supports a field in the bid pricing tool (BPT), which will inform CMS on the magnitude of unsettled balances. We request CMS update and post the Part D BPT to reflect projected losses associated with MPPP by the end of April to support plan bid development. In addition, we urge the Office of the Actuary (OACT) to release assumptions and modeling support for Part D plans' pricing of this benefit to address the actuarial uncertainty facing plans.
- *60.2 Medical Loss Ratio (MLR) Instructions.* BCBSA opposes CMS' interpretation of unsettled balances to be considered administrative costs for purposes of the MLR calculation. All monthly payment amounts represent payments for prescription drugs that were dispensed to patients. Therefore, all unsettled monthly payment amounts constitute revenue paid by the plan for patient care and should be categorized as such in the MLR calculation. While the IRA requires, in relation to Part D plan bids, that such amounts be treated as plan losses and that the Secretary is not liable for such balances outside of losses estimated in bids, it does not dictate that unsettled balances should be treated as administrative expenses for purposes of MLR reporting. BCBSA recommends that such amounts should be treated as claims and therefore be included in the numerator.
- *60.3 Monitoring and Compliance.* We support exclusions of MPPP complaints in CY 2025 as plan sponsors work to implement this complex new program. CMS should apply a hold harmless policy where MPPP-related complaints do not negatively impact the performance of plans, specifically for Star Ratings. BCBSA companies are concerned about the volume of complaints that may be submitted due to factors outside of a Part D plan's control, and a hold harmless approach would insulate plans during the first implementation year. In addition, BCBSA urges CMS to create a new CTM category for MPPP complaints, with subcategories for complaints associated with a pharmacy interaction and for complaints against an MA-PD or PDP.

- *60.4 Audits.* BCBSA recommends CMS forego audits of Part D sponsors' implementation of MPPP programs in CY 2025 except in cases of material deficiencies in compliance. Providing a year hiatus for audits will allow plan sponsors to continue refining internal process and procedures, member communication, vendor support and other implementation strategies without the threat these innovative strategies will be analyzed via a CMS audit.

We appreciate your consideration of our comments. If you have any questions or want additional information, please contact Paul Eiting at [paul.eiting@bcbsa.com](mailto:paul.eiting@bcbsa.com).

Sincerely,

A handwritten signature in black ink, appearing to read "K. Haltmeyer", with a stylized flourish at the end.

Kris Haltmeyer  
Vice President, Policy Analysis  
Office of Policy & Advocacy



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March 16, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: Medicare Prescription Payment Plan Guidance– Part Two  
Baltimore, MD 21244–1810

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

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS's/the Agency's) 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.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO's member companies work to discover transformative therapies that provide a significant, durable benefit and value for patient health outcomes, delivery of care, and overall health care spending. These novel, disruptive therapies are aimed at serious and rare diseases where patients often have limited treatment options. Taken together, our companies offer hope for cures and treatments where there was none, help reduce health care costs, and ensure a better quality of life.

**General Comments**

BIO thanks CMS for its continued efforts to implement the Medicare Prescription Payment Plan (MPPP) through this Draft Part 2 Guidance, the recently released Final Part 1 Guidance, and the recent ICR opportunity on the draft MPPP model materials. As we have stated in previous comments, BIO strongly supports the development of the MPPP which will make healthcare expenses more manageable for enrollees and reduce the immediate financial strain of significant out-of-pocket (OOP) costs. The timely implementation of the MPPP is essential as patients continue to struggle with substantial cost-sharing, which may lead them to delay or

forego necessary care. Many enrollees will benefit from the flexibility of spreading out payments over time, making it easier for them to manage their financial situation and access the care they need.

As CMS develops ways to facilitate education and outreach of the MPPP to enrollees, we encourage CMS to minimize the potential for enrollee confusion and develop model tools and resources necessary for enrollees to benefit from the program. Even though Part D sponsors play an important role in coordinating the MPPP, solely leaving many aspects of the MPPP up to plan discretion may create challenges and confusion for enrollees. Accordingly, CMS should ensure that plan-developed materials are clear, consistent, simple to understand, and easily accessible to enrollees. In addition, while we appreciate CMS' release of the draft MPPP model documents, we also request that CMS prioritize the development of a calculator-tool and other educational materials that will help enrollees understand their monthly cost-sharing obligations. As CMS develops its upcoming educational materials, the Agency should again allow for stakeholder input so that patients and other parties can be involved in the development of outreach and education materials and ensure that the materials are patient-centered and user-friendly. Our more detailed comments on the guidance are below.

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

CMS proposes that Part D sponsors will educate enrollees about the MPPP using membership ID cards, Evidence of Coverage (EOC), Annual Notice of Change (ANOC), Explanation of Benefits (EOB), and their Part D sponsor website.

BIO thanks CMS for its guidance and willingness to prioritize MPPP outreach and education. We are supportive of widespread educational efforts on the MPPP and applaud CMS for its efforts in making the MPP available for all Part D enrollees in 2025. Educational materials on the MPPP not only will help encourage participation into the program but can also be used as an educational tool for beneficiaries to improve their health literacy. We greatly appreciate CMS' willingness to continue to actively work with stakeholders to develop easy-to-use educational tools that will minimize potential enrollee confusion regarding participation in the MPPP. However, we remain concerned that the level of discretion granted to Part D sponsors to operationalize the program may create further confusion and complexity for many enrollees.

For instance, while Part D sponsors are "encouraged" to provide enrollees with information on their estimated monthly payments before they enroll, they are not required to do so. Therefore, if the Part D sponsor chooses to not provide that level of specificity in their enrollment materials, a beneficiary may not understand how the MPPP could change their monthly payment obligations. As CMS confirms in the draft ICR draft model materials, "your payments might change every month, so you might not know what your exact bill will be ahead of time." This lack of information is particularly problematic for Medicare beneficiaries on fixed incomes who need to budget in advance so they can allocate funds for their prescriptions. Due to the high stakes of beneficiaries delaying prescription refills or abandoning them at the pharmacy, it is critical that Part D sponsors provide beneficiaries with estimated monthly payments under the MPPP. Both current and prospective enrollees need to be able to view their estimated monthly prescription OOP costs under the program so they can make informed decisions to assist with financial planning and make timely payments to prevent lapses in coverage.

BIO appreciates that CMS has included EOB within the required outreach and communication documents. As BIO has previously commented, enrollees will need to receive routine communication throughout the plan year regarding their cost sharing obligations under the MPPP; accordingly, the EOB will be an essential part of this reoccurring communication. As CMS develops the final EOB for CY 2025, we encourage CMS to include model language on how plans may provide beneficiaries with a projection of their cost sharing obligations, both with and without participation into the MPPP, to help beneficiaries determine whether they should opt-into the program.

As Part D sponsors send outreach and communication documents to Medicare beneficiaries, BIO also recommends that CMS consider taking the opportunity to remind beneficiaries about other important cost sharing support. For example, many Medicare beneficiaries are unaware that the IRA eliminated enrollee cost-sharing for recommended vaccines under Medicare Part D. CMS should also include explanations on the \$35 monthly cap on covered insulin products, restructuring of Part D benefit, and the expansion of eligibility for Extra Help (the Medicare Part D Low-Income Subsidy Program). Reminding beneficiaries within the outreach and communication documents would ensure that beneficiaries are informed of these important benefits and also encourage the uptake of important vaccines. Likewise, as Part D Sponsors are also required to provide materials to pharmacies to distribute at POS, CMS should also require these POS materials to be updated with information on the IRA vaccine cost-sharing benefit. Ensuring that beneficiaries are informed at pharmacy POS is critical as many beneficiaries receive vaccines on site at retail pharmacies. We encourage CMS to remind plans that they are required to cover all commercially viable vaccines under the IRA without utilization management and to adequately inform beneficiaries of these critical benefits.

BIO recognizes that the need for widespread beneficiary outreach should be balanced by the need for tailored and scenario-based tools that are adapted to the unique needs of enrollees. As CMS develops its educational products, we encourage the Agency to include a way for patients to receive tailored information on their monthly cost-share obligations, such as developing a scenario-planning calculator tool mentioned in the draft Part One guidance. A calculator tool is essential for beneficiaries to be well-informed about their specific cost-sharing obligations and how the MPPP may impact their final pay amount. The calculator tool should be developed with beneficiary feedback to ensure that it clearly and effectively explains the MPPP in a way that resonates with beneficiaries. CMS should develop this calculator tool as soon as feasible, with sufficient time for enrollees to use and comprehend the tool ahead of the Annual Election Period.

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

CMS proposes a standardized framework for the “Likely to Benefit Notice” based on their analysis of historic Prescription Drug Event (PDE) records.

BIO supports requiring Part D sponsors to use the targeted outreach and education requirements for enrollees who are identified as likely to benefit, prior to and during the plan year. We also applaud CMS for requiring Part D sponsors to report information related to the MPPP through PDE records and submit beneficiary and contract Plan Benefit Package (PBP) level data related to program participation. As CMS monitors and collects data around MPPP participation, we request that CMS provide greater transparency around how the Agency will review MPPP information and report participation data so that stakeholders may be able to collaborate on offering a comprehensive support system to benefit enrollees. The ongoing

monitoring and assessment of MPPP implementation should be a collaborative and patient-centered approach so all parties can identify areas for improvement and enhance the effectiveness of the program. Outreach and education materials related to the MPPP should not create further beneficiary confusion but rather empower patients to understand their personal prescription drug costs.

As BIO has previously commented, beneficiaries may have very different OOP situations and each beneficiary's ability to benefit from the program may not be captured by a single prescription POS threshold. BIO is concerned with CMS' decision to finalize a \$600 single prescription POS threshold to identify enrollees likely to benefit, as this will likely exclude a large group of beneficiaries who could have otherwise benefited from the program. For instance, the threshold may exclude beneficiaries who take multiple prescription medications where each prescription falls under the \$600 threshold but the cumulative cost-sharing would be burdensome for the beneficiary. It is critical that this threshold does not overshadow a broader necessity of ensuring that the entire spectrum of Medicare enrollees receive choice and access to information about the MPPP. CMS should not only emphasize outreach and education materials for those beneficiaries who fit the "likely to benefit" criteria, but instead provide widespread outreach to the wider Medicare population so that all beneficiaries are able to make an informed decision on whether they would like to participate.

BIO supports the POS notification requirement which will allow for proactive and timely notification to beneficiaries. Similarly, BIO supports notification requirement that the Part D sponsor must provide the "Likely to Benefit Notice" if there are prior authorization or other utilization management edits that would result in OOP costs above the pharmacy POS notification threshold. As this is a minimum requirement, BIO recommends that this can be further strengthened by requiring additional identification criteria as CMS continues to assess and monitor MPPP participation. While we appreciate the requirement that additional identification criteria be uniformly applied to all enrollees, future guidance would be helpful to clarify and respond to beneficiary needs as the program is implemented, particularly for those beneficiaries that may not trigger the pharmacy POS notification threshold but may nonetheless benefit from the program.

In order to facilitate understanding between Part D sponsors, contracted providers, and network pharmacies on MPPP requirements, BIO requests that CMS provide educational materials on the MPPP as a part of CMS' existing provider communications. CMS could also explore additional materials to contracted pharmacies and providers to identify eligible patients in real-time and assist in the POS notification process.

### **30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors**

BIO appreciates CMS' release of the MPPP Model Documents and the opportunity to provide further comments through the ICR. While BIO will be providing more detailed comments on the model documents through the ICR process, in the meantime, we urge CMS to provide additional guidance to effectively operationalize some of the procedures outlined in the model materials. For instance, to supplement the "Notification of Termination of Participation," we urge CMS to develop a uniform process and timeline around reinstatements. Importantly, beneficiaries who experience temporary financial challenges should be given the opportunity to be reinstated into the MPPP after paying overdue amounts. While we greatly appreciate CMS' provisions in Final Part 1 Guidance that requires Part D sponsors to reinstate individuals who

demonstrate good cause for failure to pay and pays all overdue amounts billed, the Final Part 1 guidance gives Part D sponsors full discretion to reinstate those individuals within a “reasonable timeframe.” BIO remains concerned about the lack of a concrete timeline given that beneficiaries in vulnerable financial situations may need timely reinstatement in the MPPP option. A delayed reinstatement could cause beneficiaries to accrue significant OOP costs later in the calendar year where they may no longer have an option to distribute OOP costs within that calendar year. Accordingly, it is evident that CMS should clarify the definition of “reasonable timeframe” and provide additional guidance to protect beneficiaries’ rights to reinstatement into the MPPP.

BIO also requests that CMS develop further guidance and clarify how beneficiaries will be notified throughout the good cause and reinstatement process. As it currently stands, a beneficiary who demonstrates good cause and pay all overdue amounts may not receive any communication from the Part D sponsor regarding their eligibility for reinstatement in the subsequent plan year after they pay all overdue amounts. Absent any requirement for Part D sponsors to notify beneficiaries, beneficiaries may not understand or be aware of their two-month grace period, the opportunity to demonstrate good cause, their rights to be reinstated into the MPPP, and their need to proactively opt-in again if interested in the subsequent year. It is clear that CMS should actively ensure that Part D sponsors notify beneficiaries of the good cause determination opportunity and reinstatement rights, as well as develop a uniform process to clarify the role and responsibilities of Part D sponsors, beneficiaries, and any other parties around reinstatement. CMS should also ensure that beneficiaries are informed of their rights to appeal a Part D sponsor’s rejection of the good cause determination.

In addition, BIO urges CMS to develop greater protections for beneficiaries who fall into situations not specifically listed under the good cause criteria in the Final Part 1 Guidance. BIO remains concerned by the level of discretion given to Part D sponsors to reinstate those beneficiaries in the absence of clear and uniform procedures to assess a beneficiary’s unique circumstances that may have caused beneficiaries to miss payments in the past. Given the diverse medical needs and financial situations of Medicare beneficiaries, it is important that all beneficiaries be protected from unjust terminations and be given the opportunity to participate again after paying overdue amounts. BIO strongly believes that missed payments should not exclude beneficiaries from future participation in the MPPP, particularly after they have paid back overdue amounts. BIO urges CMS to develop protections for beneficiaries who may be inadvertently disenrolled after missed payments and provide opportunities for these beneficiaries to be reinstated if they so choose.

As BIO has previously commented, we continue to request that CMS explicitly require Part D sponsors to publicly report information on enrollees who are terminated from the MPPP and denied reentry into the MPPP in subsequent years. Part D sponsors could report this data through their existing obligation to report data elements related to the MPPP through the MARx System and HPMS, as expressed in the Final Part 1 Guidance. Information around terminations will greatly enhance accountability and transparency to ensure that enrollees are not unjustly terminated or prevented from participating.

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

CMS proposes to develop an educational product for Part D enrollees on the Medicare.gov website and through other communication channels. CMS states that it will make appropriate

modifications to CMS-provided Medicare Part D documents, which may include the Medicare & You Handbook, Medicare.gov, and Medicare Plan Finder, among others.

BIO appreciates CMS' willingness to develop comprehensive educational resources on the MPPP in light of the inherent need to raise awareness of this important payment option. Ensuring the timely release of these educational resources ahead of the Annual Election Period will be critical to empower beneficiaries to participate in the MPPP and provide an opportunity for various stakeholders to collaborate on widespread outreach of the program. As CMS continues to develop and update these educational materials, additional clarity would be appreciated to help stakeholders understand their roles and responsibilities in assisting beneficiaries to make informed healthcare decisions. CMS should actively involve stakeholders in the drafting and development of these educational materials and ensure that such materials are patient-centered and provide clear, actionable, and accessible information to all parties.

## **Conclusion**

BIO appreciates CMS' efforts to implement this payment option and looks forward to partnering with CMS to finalize operational details and drive patient access into the MPPP. Should you have any questions, please contact us at 202-962-9200.

Sincerely,

/s/

Crystal Kuntz  
Vice President  
Healthcare Policy and Research

/s/

Melody Calkins  
Senior Manager  
Healthcare Policy





Submitted via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

March 15, 2024

Meena Seshamani, M.D., Ph.D.  
Deputy Administrator  
Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

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

Dear Deputy Administrator Seshamani,

As an organization representing cancer patients, survivors, and caregivers, the Cancer Support Community (CSC), would like to thank you for the opportunity to provide feedback and recommendations on the Centers for Medicare & Medicaid Services' (CMS) draft part two guidance on proposing policies and mechanism for implementing the Medicare Prescription Payment Plan (MP3) program under Section 11202 of the Inflation Reduction Act (Social Security Act Section 1860D-2(b)(2)(E)(the Program).

CSC is an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones. As the largest provider of social and emotional support services for people impacted by cancer, CSC has a unique understanding of the cancer patient experience. In addition to our direct services, our Research and Training Institute and Cancer Policy Institute are industry leaders in advancing the evidence base and promoting patient-centered public policies.

The successful implementation of the MP3 program is crucial. For many beneficiaries, the new flexibility will be among the most directly "felt" impacts of the *Inflation Reduction Act* (IRA). With successful implementation, cost smoothing, along with the new annual out-of-pocket (OOP) cap, will protect beneficiaries from high upfront costs while reducing the OOP burden of prescription drug costs. As such, we appreciate the measures taken by CMS to balance timely outreach and participation election for beneficiaries and manageable implementation of this new

program for Part D plans and sponsors. However, to realize the full potential of MP3, a multistakeholder approach that is proactive, comprehensive, and coordinated is key to maximize Medicare beneficiaries' understanding of this program to encourage enrollment.

We are pleased to share our comments and recommendations that focus on enhancements that align with real-life experiences of cancer patients and the Program's intended goal of ensuring all Medicare beneficiaries and caregivers can base treatment decisions on their needs rather than their financial constraints. Consistent with our mission to uplift the voices of people impacted by cancer in policymaking, CSC developed [patient-centered principles](#) to guide and inform engagement with CMS and other policymakers throughout implementation of the Medicare Drug Price Negotiation program and other policies.

We look forward to working with CMS to ensure that all Medicare beneficiaries likely to benefit from the Program and their caregivers have the information they need to make enrollment decisions.

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

CSC appreciates that CMS' requirements around Part D education and outreach materials include an emphasis on clear and uniform messaging through multiple channels, as we agree that CMS-created model notices, forms, and beneficiary communications will be critical to effective outreach. We urge CMS to publish these resources in draft form to allow for stakeholder feedback to maximize patient understanding.

We also support the requirement of plans to provide enrollees with Program information on their website in addition to within current requirements of Part D materials such as the mailings of Membership ID cards and "Likely to Benefit" notices. We strongly recommend CMS require plans to highlight important information about Program availability and opt-in requirements by including prominent language on the envelope and the first page of all documents. This measure is essential to ensure that enrollees do not overlook vital information due to the routine nature of these mailings.

In addition, we urge CMS to require plans to include a clear explanation of opt-in mechanisms by mail, telephone, or online, with step-by-step instructions, as well as information regarding the timeline for receipt, processing, and confirmation of their request. Finally, we recommend that CMS expands outreach of Program information and educational materials by including such documents on the plan finder tool that beneficiaries, families, and caregivers are accustomed to using when selecting their Part D plan as well as in the "Medicare & You" handbook with a phone number and website for beneficiaries to learn more about the Program.

While CSC recognizes that Medicare beneficiaries will have multiple opportunities to learn about MP3 in various settings, we recommend that CMS also develop Program information resources and tools for physicians and other prescribers and pharmacies to provide as many touch points as possible for Medicare beneficiaries to learn about the program, its benefits, and how to enroll. Additionally, we recommend CMS consider broadcasting Program Public Service Announcements, similar to those used to inform individuals about Affordable Care Act coverage and enrollment deadlines.

### *Targeted Outreach*

CSC agrees that increased outreach and education efforts targeted towards individuals that are likely to benefit from the Program is essential for its success, particularly in the early years of implementation, and we appreciate CMS' efforts to provide such individuals with multiple meaningful opportunities to review materials and opt-in. We strongly support the requirement for plans to investigate past prescription expenditures of Part D enrollees and target outreach to those with a history of high OOP costs, both prior to and during the plan year. Similarly, we support targeted outreach during the plan year to individuals based on prior authorization requests for costly treatments but are concerned that mail delays will inhibit individuals from understanding their alternative payment options before their prescription pickup. While there are options to pay at the pharmacy and request a refund based on retroactive participation in the Program, many patients will not have the financial resources to do so. Findings from [Cancer Support Community's Cancer Experience Registry \(CER\)](#) examining financial toxicity among people with metastatic cancer, with 95% confidence intervals, found that patients experiencing financial toxicity are 5.05 times more likely to have suboptimal medication adherence. Additionally, [CER data from 273 rural cancer patients](#) found that "having health care team conversations about treatment costs and distress-related care reduced the negative impact of financial toxicity on depressive symptoms and social function". Because of this, we strongly urge CMS to require plans to use a notification mechanism such as telephone contact to provide Program information and enable a real-time opt-in mechanism to avoid financial barriers that result in treatment delays.

Lastly, we urge CMS to require plans to identify those likely to benefit beyond the costs of one singular prescription. It is very common for cancer patients to fill multiple prescriptions each month in order to treat their cancer, manage side effects, and more, making it likely that cancer patients will reach the OOP maximum during the first quarter without incurring any singularly high cost prescriptions. To combat this issue, we recommend the requirement of plans to calculate the sum of prescriptions filled in a single day towards the part one guidance's single fill threshold of \$600.

## **Pharmacy Processes**

CSC strongly recommends that CMS reconsiders its decision to delay implementation of a pharmacy counter point of service (POS) election mechanism, and at a minimum, enable real-time 2025 plan year elections, ensuring that elections made take immediate effect. It is extremely important that patients impacted by cancer have timely access to prescribed medicines because far too many patients face financial barriers that limit access to treatments that best suit their needs. Financial toxicity is a pressing issue for patients impacted by cancer that is worsened by delays and uncertainty in the Program opt-in process. For these patients, the ability to spread OOP costs over the year can be the difference between confidently starting and maintaining their prescribed course of treatment and having to choose between paying for life-saving prescriptions and affording basic life necessities. To increase confidence in the Program and its benefits, CMS must take action to reduce such delays and enrollment uncertainties.

CSC appreciates CMS' decision to decline feedback to delay or limit the Program, which the IRA requires plans to make available to all enrollees. We understand that plans may require time to process requests and update their systems, but this should not impact patients' ability to receive smoothing benefits. There is no basis to decline an enrollee's opt in request in the 2025 plan year, since nonpayment of the prior year's monthly payment obligations is not relevant in the first year of implementation. With this, we encourage CMS to establish a straightforward mechanism for beneficiaries to present their member ID and program election confirmation number at the pharmacy POS, streamlining processes and ensuring timely access to medication without burdensome ministerial delays.

We similarly believe that offering a POS opt-in option will ensure that patients facing prohibitive costs when picking up their prescriptions can immediately elect to participate and receive the benefits without delays due to financial burdens. Part One Guidance processes allow plans to determine whether a prescription is "urgent," creating additional burdens to providers and therefore barriers to care for patients. Patients impacted by cancer urgently need all their prescriptions, pressing the need for an efficient election process that takes immediate effect, alleviating the burdens on providers and plans to determine whether a treatment is "urgent" for each patient's circumstance.

Lastly, we recommend the POS election option to streamline elections for future years. Many beneficiaries may assume that their plan enrollment and participation in the Program will continue year to year, though this is not the case. With a POS election option, the pharmacist filling a prescription in the last quarter of the plan year can prompt the patient whether they intend to opt-in to the Program the following year and offer real time election processes, the option to terminate participation, or general information for those undecided. This would streamline processes and increase participation for those who benefit for future years.

## **Conclusion**

CSC appreciates the opportunity to comment on CMS' part two guidance outlining CMS' intended implementation of the Medicare Prescription Payment Plan. We look forward to continuing to work with CMS to help ensure that all Medicare beneficiaries, including patients impacted by cancer, can receive the treatments they need without the financial barriers associated with high out-of-pocket costs. If you have any questions or need additional information, please contact me at [dsekoni@cancersupportcommunity.org](mailto:dsekoni@cancersupportcommunity.org) or (202) 659-9707.

Sincerely,

A handwritten signature in blue ink that reads "Daneen G. Sekoni". The signature is fluid and cursive, with the first name "Daneen" and last name "Sekoni" clearly legible.

Daneen G. Sekoni, MHSA  
Vice President, Policy & Advocacy



**David Schwartz**  
Vice President  
Public Policy & Federal Affairs

**CareFirst BlueCross BlueShield**  
840 First Street, NE  
Washington, DC 20065  
Tel. 202-680-7433

March 15, 2024

Centers for Medicare & Medicaid Services  
United States Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

*Submitted electronically via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)*

RE: Medicare Prescription Payment Plan Guidance – Part Two

Dear CMS Desk Officers:

On behalf of CareFirst BlueCross BlueShield (CareFirst), we appreciate the opportunity to provide feedback on the Medicare Prescription Payment Plan (MPPP) Part Two draft guidance. CareFirst strongly supports your pledge to make healthcare more affordable, equitable, and accessible for beneficiaries who rely on Medicare Part D prescription drug coverage. We believe provisions in the Inflation Reduction Act of 2022 (IRA) to help lower the cost of prescription drugs for Medicare beneficiaries are critical and we continue to advocate for expanding the applicability of these provisions to the commercial market to ensure maximum impact. We are committed to partnering with you as you work to implement the MPPP as required under the IRA.

CareFirst is the largest health insurer in the Mid-Atlantic region, serving approximately 3.5 million members. We believe it is important to utilize evidence-based practices to pioneer new ways to better meet the needs of our members and communities we serve. As a regional, not-for-profit carrier with an individual Medicare Advantage prescription drug (MAPD) plan, dual eligible special needs plan (D-SNP), and employer group waiver plan (EGWP), we have a unique perspective on how to operationalize the MPPP. As the Centers for Medicare & Medicaid Services (CMS) finalizes guidance to implement the MPPP for the 2025 plan year, our comments below underscore the need for timely guidance, additional clarity, and flexibility to ensure the program works as intended.

### **General Comments**

CareFirst generally supports the concept of the MPPP and appreciates CMS soliciting feedback but reiterates concerns regarding the outlined guidance release timeline. We strongly recommend the agency finalize Part Two guidance well in advance of the June 3, 2024 bid submission deadline. This will provide plan sponsors the time needed to more accurately and appropriately estimate related expenses and potential losses, as well as to account for other bid-related information included in the Part Two guidance. Releasing the final Part Two guidance sooner ensures plans have time to consider these provisions in conjunction with the 2025 Rate Announcement, Final 2025 Medicare Advantage and Part D Technical Rule, and Final Part D Redesign Instructions, which also must be reflected in plan bid submissions.

CareFirst also encourages CMS to issue sub-regulatory guidance on certain provisions finalized in the Part One guidance where additional clarity is needed by Part D sponsors. While acknowledging CMS's intention for Part D sponsors to have flexibility in debt collection procedures so long as they adhere to applicable law and regulations, additional guidance would be welcome to ensure there are clear expectations and

uniformity in how Part D sponsors treat unpaid balances. More specifically, we request guidance on the potential recovery process for members that fail to pay their outstanding balance after the grace period, including those that switch plans mid-year. Further guidance is also needed regarding appropriate recourse to collect payments from participants who change payment mechanisms, which will further exacerbate the difficulty of recovering any amounts owed.

### **Section 30 – Outreach, Education, And Communications Requirements for Part D Sponsors**

CareFirst strongly supports CMS providing model materials to help Part D sponsors satisfy requirements to provide educational materials to prospective program participants and other required notices. Model materials will promote consistency in messaging to beneficiaries across the country and help ensure a level playing field and robust competition between larger and smaller plans. We also support requirements for Part D sponsors to provide the “MPPP Likely to Benefit Notice” both in advance of the plan year and during the plan year. However, we encourage CMS to consider the role of pharmacies in having to provide this notice at the point of sale (POS) to beneficiaries who are likely to benefit from the MPPP. In addition to navigating their current, demanding operational obligations, providing consistent, accurate and complete notice to certain beneficiaries might be challenging even for retail chain pharmacies with larger networks and resources. Moreover, independent, community pharmacies will struggle. They may simply not have the systems and necessary resources to readily receive and understand notification from Part D sponsors or their affiliates and to relay this in a timely, compliant manner to enrollees. The widely reported pharmacy closures and challenges with clinically trained personnel in 2023 only increase these risks.

Given these concerns, we urge CMS to reconsider requiring Part D sponsors notify pharmacies at the POS of individuals likely to benefit, at least for the 2025 plan year. We believe those most likely to benefit will be best served by other forms of multi-faceted exposure and outreach including the educational information and an election request form with their membership ID card mailing. Not requiring pharmacies to provide this notice will reduce confusion for Part D enrollees, especially given CMS reiterated in the Final Part One guidance a POS election option for MPPP will not be mandated for the 2025 plan year due to operational complexity. Requiring pharmacies to provide the notice at the POS might unintentionally create an expectation that Part D enrollees may opt into MPPP at the POS, creating frustration for pharmacies unable to fulfill this request and ultimately for the enrollees.

Rather than requiring Part D sponsors to notify pharmacies at the POS of all beneficiaries likely to benefit and requiring pharmacy to provide the “MPPP Likely to Benefit Notice,” we encourage CMS to only require Part D sponsors to provide the notice to those that meet the \$600 single prescription threshold as finalized in the Part I guidance within a reasonable timeframe (e.g., within three business days). Having Part D sponsors be the sole entity providing this notice is the most appropriate alternative given Part D enrollees will only be able to enroll directly with the Part D sponsor either online, over the phone, or through the mail. This ensures the Part D enrollee receiving the notice is able to elect to participate in MPPP by following the instructions included on the back of the notice.

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

CareFirst strongly supports CMS developing educational materials on MPPP and updating existing Part D resources detailing the prescription drug benefit. Given the ability of Part D sponsors to leverage CMS’s educational product to satisfy certain requirements, we encourage CMS to finalize this product as soon as possible. This educational product should reference participants’ obligations to timely repay Part D sponsors monthly despite not incurring any costs at the POS. We also encourage CMS to ensure pharmacies have sufficient support and materials to educate patients on MPPP. This is particularly important if CMS opts to finalize a requirement for pharmacies to provide the “MPPP Likely to Benefit Notice” at the POS.

### **Section 50 – Pharmacy Processes**

CareFirst appreciates CMS acknowledging pharmacies will play a critical role in operationalizing MPPP. Given the operational complexity and shortened timeframe to implement the program effective January 1,

2025, CareFirst strongly encourages CMS to consider enforcement discretion for good faith efforts to comply with this guidance. Part D sponsors will have to work with pharmacies, delegated pharmacy benefit managers, and other contracted vendors to ensure the necessary processes are in place to properly administer the program. The IRA is the most comprehensive reform to the Part D benefit since its inception in 2006. To support the momentous initial Part D implementation, CMS provided extensive sub-regulatory guidance, along with additional flexibility through a several month transition period which greatly assisted plan sponsors in meeting new obligations without historical trends or data to guide the effort. We implore CMS to adopt a similar approach with implementation of the MPPP to ensure Part D sponsors are temporarily held harmless for good faith efforts to ensure Part D enrollees are able to realize the benefits of the MPPP.

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

CareFirst encourages CMS to provide more detailed guidance in developing assumptions for bid calculations. Given the Secretary will not be liable for any unsettled balances, except those assumed as losses in plan bids, it is critical to have a clear understanding of how plan sponsors should account for this in their bids. CMS should also provide guidance on anticipated administrative impacts associated with the creation of the technology to operationalize the MPPP and other required notices and mailings. There will be an increase in outbound communications, as well as incoming member calls, and additional complexities that must be factored into current PBM arrangements as well as new vendor needs. There might also be an increase in member complaints as plan sponsors work through implementation in the first year, which further underscores the need for enforcement discretion. Additionally, we recommend CMS issue guidance on how to account for enrollees that can leverage a special enrollment period to change plans mid-year (e.g., DSNP enrollee switching plans or an enrollee choosing to enroll in a 5-star plan) and how these impacts should be calculated. This is particularly important for participants that switch plans mid-year with unsettled balances. Treatment of these complexities will have a direct impact on plan premiums, which are ultimately borne by Part D enrollees. Therefore, we urge CMS to finalize a modified Part D bid pricing tool and for the Office of the Actuary to release bid assumptions and modeling support as soon as possible, ideally by the end of April.

With respect to the medical loss ratio (MLR) instructions, CareFirst encourages CMS to reconsider its position of unsettled balances being considered administrative costs for the purposes of MLR calculations. The IRA did not address how unsettled balances should be treated for the purposes of MLR reporting and only required these amounts to be treated as plan losses. Given all monthly payment amounts contribute towards payments for dispensed Part D drugs, they should be properly accounted for in the MLR. CareFirst recommends CMS modify its MLR instructions to ensure all monthly payment amounts, including those unpaid by the enrollee, are recognized as revenue for patient care and should be treated as such in MLR calculations.

Thank you again for the opportunity to provide our input. We look forward to future collaboration on IRA implementation.

Sincerely,

A handwritten signature in blue ink, appearing to read "David Schwartz".

David Schwartz



Section/Title	Commentor	Functional Area	Comment(s)
10. Introduction	Membership Medicare Operations (MMO) <i>Formerly Membership Compliance Oversight (MCO)</i> (Email: mmco_comp_oversight@healthnet.com)	EMB (Enrollment, Membership & Billing)	<p><b>Context:</b> This provision applies to all Part D sponsors,1,2 including both stand-alone Medicare prescription drug plans (PDPs) and Medicare Advantage (MA) plans with prescription drug coverage (MA-PDs), as well as Employer Group Waiver Plans (EGWPs), cost plans, and demonstration plans.</p> <p><b>Question:</b> Does this program apply to both Medicare Advantage (MA) and Medicare Advantage Prescription Drug (MAPD) plans?</p>
20. Overview of the Medicare Prescription Payment Plan	Membership Medicare Operations (MMO) <i>Formerly Membership Compliance Oversight (MCO)</i> (Email: mmco_comp_oversight@healthnet.com)	EMB (Enrollment, Membership & Billing)	<p><b>Context:</b> In the draft part one guidance, CMS explained how Part D sponsors can satisfy statutory requirements for the Medicare Prescription Payment Plan, including how they must: provide all Part D enrollees with the option to elect into the Medicare Prescription Payment Plan prior to, and during, the plan year; determine a maximum monthly cap for each month's amount; bill the program participant for an amount that must not exceed the applicable monthly cap; and have in place a mechanism to notify a pharmacy during the plan year when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from the program.</p> <p><b>Question:</b> Does the "Opt-In" mechanism need to be on the enrollment form?</p>
30.1 General Outreach and Education 30.1.5 Part D Sponsor Websites	Membership Medicare Operations (MMO) <i>Formerly Membership Compliance Oversight (MCO)</i> (Email: mmco_comp_oversight@healthnet.com)	EMB (Enrollment, Membership & Billing)	<p><b>Context:</b> • General information about the Low-Income Subsidy (LIS) program, including information on recent the LIS expansion of eligibility, and how to apply and enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs), noting that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.</p> <p><b>Question:</b> Will need TRC Codes be released if the member elects the Medicare Prescription Payment over the LIS program? Confirmation is needed on if TRC Codes will be released for members opting-in to the program and if the plan terminates the member from the program for nonpayment.</p>



## CCA RESPONSE TO MEDICARE PRESCRIPTION PAYMENT PLAN DRAFT PART TWO GUIDANCE

March 16, 2024

Meena Seshamani, MD, Ph.D.  
Deputy Administrator and Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244  
Submitted via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

RE: Medicare Prescription Payment Plan Guidance – Part Two

Deputy Administrator Seshamani,

On behalf of Commonwealth Care Alliance (CCA), we appreciate this opportunity to comment on the Medicare Prescription Payment Plan Draft Part Two Guidance issued February 15, 2024.

Headquartered in Boston, Massachusetts, CCA is a multi-state integrated care system delivering innovative models of complex care to individuals with the most significant needs. CCA's model is consistently recognized for its ability to manage whole-person care across the continuum, including full integration of primary and acute care, behavioral health, long-term services and supports (LTSS), and services that address social needs. We advocate for equitable and cost-effective policies that lead to high-quality health care for individuals who need it most.

CCA was a founding plan in the 2004 launch of Senior Care Options (SCO), the first dual eligible demonstration in Massachusetts and the fourth dual eligible demonstration in the nation approved by the Centers for Medicare and Medicaid Services (CMS). Now operating under permanent authority as a Fully Integrated Dual Eligible Special Needs Plan (FIDE SNP), CCA serves more than 15,000 SCO enrollees. For the past four years, our SCO program has received a 4-Star rating or better from the CMS Quality Rating System for excellence in quality health care.

CCA was a thought leader in the development and implementation of One Care, the first Medicare-Medicaid Plan (MMP) program implemented through the Financial Alignment Initiative (FAI) demonstration and the only such program in the nation exclusively serving dual eligible enrollees aged 21 to 64 at the time of enrollment. Today, CCA's One Care program serves nearly 30,000 enrollees.

In 2021, CCA began a multi-year, mission-aligned geographic diversification growth strategy to extend our proven care model throughout the United States. In 2022 we launched MA plans in Massachusetts and Rhode Island and in 2023 added MA plans in Michigan and California through acquisition. Including D-SNPs in Rhode Island and Michigan, CCA now serves more than 100,000 individuals, including more than 45,000 dually eligible individuals.

Beginning January 1, 2025, the Medicare Prescription Payment Plan (MPPP) will provide Part D enrollees the option to pay their out-of-pocket (OOP) Part D drug costs through monthly payments over the course of the plan year instead of as upfront payments at the pharmacy point of sale (POS). This program may be immensely beneficial to Medicare beneficiaries who are unable to afford high OOP costs for covered Part D drugs at POS, and CCA supports policy changes which improve prescription drug access and adherence. However, as CMS develops the processes and materials for educating and outreaching Part D enrollees, we urge careful consideration regarding when and how the MPPP might apply to individuals in plans that cover most or all of their members' OOP drug costs.

MPPP is a very complex program to explain. For example, members will need to understand the financial implications of participating in the MPPP, including whether and why they are likely or unlikely to benefit from participating in the program. We have significant concerns about beneficiary confusion, particularly for vulnerable individuals navigating complex medical conditions and/or health related social needs. Part D sponsors and CMS have a responsibility to help individuals with high OOP costs navigate the program. However, CCA continues to believe that individuals for whom MPPP will either have no practical applicability, or are least likely to benefit, are at greatest risk of confusion and should not be targeted for outreach. To that end, we appreciate CMS clarifying that MPPP has no practical application to MMPs that have no Part D cost-share. We urge CMS to (1) confirm that plans are not required to send targeted or general outreach to populations to whom the MPPP has no practical applicability and (2) clarify that MPPP also has no applicability to D-SNPs, such as those available through [SCO](#) in Massachusetts, when all medically necessary services, including prescription drugs, are provided without application of deductibles, copayments, coinsurance, or other cost-sharing that would otherwise apply under Medicare or Medicaid.

CMS further states in the draft Part Two Guidance that Part D sponsors should “provide support tailored to the potential participant’s unique situation and clearly communicate to enrollees when it appears that they are less likely to benefit from the program,” such as enrollees with low-to-moderate recurring OOP drug costs. CCA is concerned that providing a request form and educational materials to low-income beneficiaries whose coverage type limits their exposure to high OOP costs will lead to significant confusion. For example, for beneficiaries in the low-income subsidy program (LIS), prescription drug [cost-share](#) is extremely limited, ranging from \$0 to \$11.20 in 2024 with no deductible. These individuals would not benefit from spreading such low costs over the plan year. To prevent unnecessary confusion, we urge CMS not to require the provision of an MPPP request form and/or educational materials to beneficiaries whose cost-sharing will never exceed the maximum LIS cost share amount (i.e., \$11.20 in 2024). If CMS continues to include these beneficiaries, we request CMS, at a minimum, delay general outreach to these members until more tailored standardized and model communications



are available. Such materials should clarify why MPPP is unlikely to benefit them as well as provide a link to an easy-to understand online calculator showing exactly when MPPP is likely/unlikely to benefit these beneficiaries. We think that this will provide for a better and less confusing member experience.

CCA is deeply committed to serving the most vulnerable beneficiaries. With more than 92 percent of our members enrolled in either fully subsidized duals plans with no Part D cost sharing or receiving assistance through LIS, we are particularly interested in ensuring the MPPP meets the unique needs of these individuals.

We thank you for your consideration of our responses and look forward to continuing to work with CMS on these matters.

Sincerely,

A handwritten signature in black ink, appearing to read 'Elizabeth Cahn Goodman', followed by a long, horizontal flourish.

Elizabeth Cahn Goodman  
Chief Legal and Public Affairs Officer  
Commonwealth Care Alliance

Hello, I am following from our question discussed on the 3/13/2024 CMS Part CD User Call regarding the model documents. Again, we appreciate receiving the models early in the program.

Our question is, we would ask CMS if other models will be provided or can be provided for purposes of standardization across the industry and uniform language for enrollees as well as Plan Sponsors.

Those models would be:

1. Request For Information (incomplete election request)
2. Billing Invoice/Statement or Template (although the requirements are listed)
3. Notice of Reinstatement (good cause)
4. Notice of Denial

Thank you in advance for review and consideration.

**Paula Rubendall**

Medicare D Program Manager, Regulatory Affairs, CVS Caremark

p 480-922-7007 | c 480-240-8083

**CVS Health** | 9501 E. Shea Blvd. MC 16 Scottsdale, AZ 85260

Sent via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)  
Subject line "Medicare Prescription Payment Plan Guidance – Part Two."

March 15, 2024

The Honorable Xavier Becerra  
Secretary, Department of Health, and Human Services

The Honorable Chiquita Brooks-LaSure  
Administrator, Centers for Medicare & Medicaid Services

Meena Seshamani, MD, Ph.D.  
Director, Center for Medicare  
U.S. Department of Health and Human Services  
Attention: CMS-2024-0006  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Secretary Becerra, Administrator Brooks-LaSure, and Director Seshamani:

Thank you for the opportunity to provide comments on the Draft Part Two Guidance on the Medicare Prescription Payment Plan ("the Program"), released on February 15, 2024.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. Aetna, a CVS Health company offers Medicare Advantage Prescription Drug (MA-PD) plans in 46 states and D.C. Aetna also offers robust standalone prescription drug plans (PDPs) to individuals in all 50 states and D.C. Our unique healthcare model gives us an unparalleled insight into how health systems may be improved to help consumers navigate the healthcare system—as well as their personal healthcare—by eliminating disparities, improving access, lowering costs, and being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

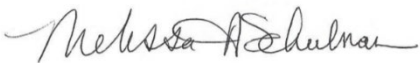
As a leading healthcare solution company, we are committed to working with the Department of Health and Human Services (HHS) to implement the Medicare Prescription Payment Plan ("the Program") smoothly, and in a manner that serves the best interests of Medicare beneficiaries. We strongly support CMS developing and providing educational materials about the Program and the changes in the Part D benefit more generally in 2025 as a result of the Inflation Reduction Act of 2022 (IRA). Since the monthly amounts billed under the Program are based on the new Part D benefit, it is important that CMS' include in its own IRA outreach and education information about Part D redesign and the Program. We believe beneficiaries will benefit most if communications are clear, concise and easy-to-understand, build on existing processes with which enrollees are already familiar, and Part D sponsors and pharmacies are allowed to communicate about the Program through an enrollee's preferred contact method.

Part D sponsors should also be allowed the flexibility to adopt processes designed to reduce beneficiary abrasion, consistent with the statutory requirements for the Program. This includes not reaching out when beneficiaries are less likely to benefit, such as in the last quarter, and avoiding duplicative or multiple communications, especially where this is likely to cause delay. Finally, we reiterate our concerns regarding the requirement to account for projected Program losses in Part D bids for CY 2025, given that not only the Program will be new in 2025, but the entire Part D benefit will be changing. Plans will have no experience on which to base projections on numerous issues that will affect Program costs, including beneficiary plan choices, Program enrollment and delinquencies. We ask that CMS consider ways to keep Part D sponsors whole from Program losses, at least for CY 2025, so that Part D sponsors have the resources to invest in the many system and other changes needed to make the Program a success.

We have included a more detailed discussion of the Program recommendations in the attached Appendix I.

Thank you for considering our comments. We welcome any follow-up questions you may have.

Sincerely,

A handwritten signature in black ink, reading "Melissa A. Schulman".

Melissa Schulman  
Senior Vice President, Government & Public Affairs  
CVS Health

## Appendix I

### 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

#### 30.1 General Outreach and Education

Because the Program applies only to Part D medications, we are concerned that participants whose coverage includes non-Part D medications, such as those enrolled in some Employer Group Waiver Plans (EGWPs) or individual enhanced alternative plans, or those with Medicare Part B coverage, may be confused and dissatisfied when they are required to pay cost sharing at the point of sale (POS) for non-Part D medications.

While we understand that the statute limits the Program to Part D, CVS Health strongly recommends that CMS include language in model communications and other educational materials that explains the Program applies only to Medicare Part D drugs so that enrollees are fully aware that the Program does not apply to non-Part D and Medicare Part B medications. CVS Health also recommends including this language in the model Annual Notice of Change (ANOC), the Evidence of Coverage (EOC), the Likely to Benefit Notice, and other educational materials under development.

#### Recommendation:

- **CMS should include language in the following plan communications and materials to educate enrollees that the Program applies only to Medicare Part D drugs: the ANOC, the EOC, the Likely to Benefit Notice, Part D Sponsor websites and in educational materials under CMS development.**

#### 30.1.1 Required Mailings with Membership ID Card Issuance

For CY 2025, when a beneficiary signs up for a plan, Part D sponsors will be required to include with the membership ID card hard copy mailing information about the Program and an election request form. CVS Health requests the flexibility to include in the mailing a website address where the beneficiary may electronically complete the election request form.

#### Recommendation:

- **CMS should allow Part D sponsors the flexibility to include a reference to a website address where enrollees may complete an electronic election request form in plan materials such as the ANOC, EOC, Likely to Benefit Notice and other materials discussing the Program.**

#### 30.1.5 Part D Sponsor Websites

CMS states that Part D sponsors should include easy-to-understand explanations of the Program. We agree the success of the Program will depend on it being as simple and easy-to-understand as possible for enrollees. To that end, we ask that CMS make every effort to leave existing processes with which enrollees are already familiar unchanged. An example of this is the process for handling retroactive LICS refunds. This is a well-established process whereby Part D sponsors issue retroactive LIS refunds within 45 days. While we understand these amounts must be considered in Program calculations, we urge CMS to allow Part D sponsors to continue administering this process as they do today, and not have to make enrollees choose whether to incorporate these refunds into the Program, as suggested in the Final Part One Guidance. Not only would this require Part D sponsors to create an entirely new and separate process for retroactive LIS refunds depending on the enrollee's status as a Program participant (which new process could impact the 45-day turnaround



time), but more importantly, it adds yet another layer of complexity, explanation, and decision-making for enrollees.

**Recommendation:**

- **CMS should make every effort to keep the Program as simple and easy-to-understand as possible by not changing or impacting existing processes that work well and are familiar to enrollees, such as the retroactive LIS refunds process.**

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

CMS states that it is developing a standardized notice, the Medicare Prescription Payment Plan Likely to Benefit Notice (Likely to Benefit Notice) for Part D sponsors to use to satisfy their obligation to perform targeted outreach to Part D enrollees who are identified as likely to benefit prior to and during the plan year, including those identified through the pharmacy notification process. We appreciate CMS developing a standardized notice for this purpose and ask CMS to make every effort to keep this notice as simple, clear, and concise as possible, and not more than one page in length.

We also ask that CMS confirm that the requirement contained in the 2024 Part D Final Rule (CMS-4201F) that Part D sponsors send enrollees an annual written notification stating they may opt out of plan business notifications at any time also applies to Program materials, including the Likely to Benefit Notice.

**Recommendations:**

- **We support the development of a standardized Likely to Benefit Notice, and ask that it be simple, clear, and no more than one page in length.**
- **CMS should confirm that the requirement to allow enrollees to opt-out of plan business notifications also applies to Program-related materials, including the Likely to Benefit Notice.**

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

CMS states that during the fourth quarter of the year, Part D sponsors must review their claims history from the first three quarters of the year to identify Part D enrollees who are likely to benefit in the upcoming year. Specifically, for CY 2025, Part D sponsors must assess claims for covered Part D drugs with dates of services from January through September 2024 and treat those enrollees who incur \$2,000.00 in out-of-pocket (OOP) costs by the end of September 2024 as “likely to benefit” from the Program in 2025.

CVS Health is concerned about notifying enrollees who have \$2,000 in OOP costs based on 2024 data. While this analysis may work for future years where the Part D benefit, and the calculation of TrOOP and OOP costs in particular, remains largely unchanged from one year to the next, this is not the case for 2024 and 2025. We are concerned using 2024 data to project OOP costs for 2025 will result in incorrectly identifying enrollees who would not be likely to benefit from the Program in 2025, especially enrollees in enhanced alternative plans. Notifying these enrollees that they are likely to benefit from the Program will not only result in potentially misinforming these enrollees but may also cause enrollee confusion around the plan benefit.

Since TROOP includes payments by supplemental payers in CY 2025, enrollees in enhanced alternative plans will reach their TrOOP threshold much sooner in 2025 than in 2024. Based on our analysis, this means many enrollees in enhanced alternative plans would not pay \$2,000 in OOP costs before they reach the TrOOP threshold. As a result, there will be a significantly smaller population of

enhanced benefit plan enrollees in 2025 who are likely to reach \$2,000 in OOP costs compared to the 2024 population. To avoid having Part D sponsors reach out to enhanced alternative plan enrollees who are not likely to benefit in 2025, we recommend that CMS not use the 2024 data of enhanced alternative plan enrollees to identify those likely to benefit.

CMS states that a Part D enrollee is less likely to benefit from opting into the Program during the last quarter of a year and, therefore, a Part D enrollee should not be notified that they are likely to benefit in the last month of the plan year. We agree that enrollees are less likely to benefit from opting in during the last quarter of the plan year. As such, we recommend that plans not be required to send out Likely to Benefit Notices in the entire last quarter, not only the last month, of a plan year. This will not only avoid enrollee confusion but will allow Part D sponsors to focus on patient education for the following plan year during the annual enrollment period.

**Recommendations:**

- **Given the impact of the Part D redesign on OOP costs of enhanced alternative enrollees in 2025, CMS should not require Part D sponsors to include 2024 data of enhanced alternative plan enrollees to identify those likely to benefit from the Program in 2025. These enrollees' 2024 OOP costs will not be comparable to those for 2025, and few of these enrollees are likely to benefit from the Program in 2025.**
- **Part D sponsors should not be required to send out Likely to Benefit Notices in the last quarter of the plan year since, as CMS notes, few are likely to benefit that late in the plan year. This will also allow plans to focus on patient education about the Program during the annual enrollment period for the following plan year.**

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

CMS states the Part D sponsor must ensure compliance with the language access and accessibility requirements outlined in section 30.4 in the delivery of the Likely to Benefit Notice. We ask CMS to confirm these requirements apply only to communications made by Part D sponsors, and not to those made by pharmacies. This is consistent with CMS' approach with other materials provided by pharmacies, such as the Medicare Prescription Drug Coverage and Your Rights form (CMS Form #10147) and recognizes that pharmacies are not in a position to meet these plan-specific requirements at POS for the many different Part D plans they support.

CMS states the requirement to provide the Likely to Benefit Notice in no way obligates the pharmacy to provide additional Program counseling or consultation to the Part D enrollee, or to provide Program educational material at the time they provide an enrollee with the notice. We appreciate CMS providing this clarification, since pharmacies generally do not have the resources to support these activities and doing so will necessarily take away from the time and resources devoted to patient care.

CVS Health also recommends that the likely to benefit POS notice be limited to a single page for ease of understanding. Many members will not read beyond the first page. If a multi-page notice is absolutely necessary, this is even more reason to allow pharmacies to deliver the notice via the member's preferred method of communication. This may include SMS text message that provides a link to the standardized notice.

**Recommendations:**

- **CMS should clarify that the MLI, translation and accessibility requirements in 42 CFR 423.2267 do not apply to Likely to Benefit Notice provided by the pharmacy.**

- **We support CMS making clear that pharmacies are only required to provide the standardized POS Likely to Benefit Notice, and that education about the Program should be the responsibility of Part D sponsors and CMS.**
- **The POS Likely to Benefit POS notice should be limited to a single page for ease of understanding.**
- **Pharmacies should be allowed to deliver the Likely to Benefit Notice using the enrollee's preferred method of communicating with the pharmacy, which may include a SMS text message with a link to the standardized notice.**

### **30.3.1.1 Request to Participate in the Medicare Prescription Payment Plan**

CMS states the election request form, along with information on the Program, must be sent with the membership ID card issuance materials that are provided to new Part D enrollees upon enrollment in the Part D Plan. We would like to confirm, consistent with this requirement (i.e., to send the election request form after the enrollee is enrolled in a Part D plan), CMS will not provide an option to enroll in the Program on the plan enrollment form.

CVS Health is concerned that including a Program enrollment option on a plan enrollment form would present significant processing, coordination, and timing issues to manage acceptance into the plan, prior to submitting the request to opt into the Program to CMS. Additionally, including the necessary payment options for the Program on the plan enrollment form would lead to beneficiary confusion. Finally, the new Sexual Orientation and Gender Identity (SOGI) demographic data fields required for CY 2025, although optional to complete, will make the plan enrollment form even longer and more complex for beneficiaries to complete. The most streamlined and beneficiary-friendly approach would be to allow enrollment through a separate election request form.

Program materials should also explain to new enrollees that they must complete the Program election form in order to enroll in the Program, and that this form will be provided to them by the plan after the plan receives notice from CMS that their plan enrollment has been accepted transaction.

#### **Recommendations:**

- **CMS should not include an election to opt-in to the Program on the Part D plan enrollment form.**
- **Program materials should explain to new enrollees they must complete the election request form in order to opt-in to the Program, and the new plan will provide this form to them once it receives confirmation from CMS that they are enrolled.**

### **30.3.2 Notice of Acceptance of Election**

CMS states that for existing enrollees, Part D sponsors must deliver a notice of acceptance within 24 hours, first by telephone and then in writing within 3 calendar days of delivering the telephone message. As currently written, it does not appear the transaction acceptance processing time is accounted for in the 24-hour turnaround time for Program enrollment.

We ask that CMS clarify what actions Part D sponsors are required to take in the event an acceptance transaction is received from CMS more than 24 hours after a submission. Part D sponsors often receive responses from submitted transactions three to four days after the submission date since the Daily Transaction Response Reply (DTRR) is not executed on Mondays as well as other days, such as during CMS system maintenance periods.

CVS Health requests CMS to allow Part D sponsors the flexibility to omit telephone outreach for existing enrollee under the following circumstances:

- when a “request for additional information” must be made or other circumstances lengthen the timeline for acceptance;
- when a CMS acceptance transaction is not received within 24 hours; and
- if an enrollee submits a complete request verbally and the Part D sponsor is able to opt the enrollee into the Program during the call and provide the confirmation number.

We also CMS to confirm Part D sponsors may leave voicemails to satisfy the telephonic outreach requirements and/or use other automated methods, such as email, if that is the enrollee’s preferred communication method. Program educational materials should clearly explain to new enrollees that pharmacy reversals could happen after the monthly billing that included those scripts, and thus could impact the monthly amount billed.

CVS Heath also requests that CMS include guidance for Program participants on how the Program will affect their prescription records used for tax purpose. This is important because the POS payments will differ from the monthly amounts billed and paid, and patients frequently request and rely on prescription claims reports generated by pharmacy systems for tax reporting purposes. The patient OOP costs will reflect \$0 on these reports. This is a gap caused by the use of the COB claims methodology rather than a POS debit card.

#### **Recommendations:**

- **For existing enrollees opting in during the year, CMS should count the 24-hour timeframe from the date the plan receives the acceptance of Program opt-in from CMS via the DTRR.**
- **Part D sponsors should be allowed flexibility to omit telephonic outreach when circumstances delay the acceptance timeline and to use other automated technologies such as voicemail and email (if this is the enrollee’s preferred communication method) in lieu of telephonic outreach.**
- **Program educational materials should clearly explain to new enrollees that pharmacy reversals could happen after the monthly billing that included those scripts, and thus could impact the monthly amount billed.**
- **CMS should include guidance to enrollees on the impact of the Program on pharmacy records traditionally used for tax purposes.**

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

We support CMS’ intention to develop and provide an educational product for enrollees on the Medicare.gov website and through other communication channels. And we understand that by utilizing these products in the cited ways and places, Part D sponsors will fulfill the requirement to provide information on the Program.

#### **Recommendation:**

- **CMS should include language that instructs enrollees who do not want to participate in the Program they may contact their plan to indicate they do not want to participate and would no longer receive likely to benefit information.**

## 50. Pharmacy Processes

We agree with CMS that pharmacies will play an important role in operationalizing the Program. In light of this, it is critical that steps be taken to standardize and streamline their role in providing the Likely to Benefit Notice as much as possible.

One important step that would support pharmacies in this regard is for CMS to clarify that Part D sponsors must use the NCPDP Approved Message Code (AMC) field 548-6F to communicate the enrollee's Program election status (i.e., Likely to Benefit, Participating, Not/No Longer Participating). The final guidance could also refer to the NCPDP External Code List and associated guidance to facilitate standardization of POS messaging. The specific Approved Message Code (548-6F) value returned will allow pharmacies to operationalize next steps, for example:

- Likely to Benefit → provide required notice to beneficiary
- Beneficiary Participating → submit COB transaction to the beneficiary's Medicare Prescription Payment Plan
- Beneficiary Not/No Longer Participating → update patient insurance profile.

The final guidance should also allow all pharmacy service types (Retail, Mail, LTC, etc.) to provide the Likely to Benefit Notice to participants based on their preferred method of communication with the pharmacy. Requiring pharmacies (specifically retail) to print and provide a hard copy notification creates inconsistencies in the process, especially for patients who may use different types of pharmacies or retail prescription delivery services. Pharmacy customers who select electronic communication as their preferred method do so for a reason, often because paper copies may be disregarded or lost.

CMS should make available to pharmacies a Program participation status and claim billing identifier data resource in addition to the claim level POS Part D claim response. Including this information within the CMS Medicare E1 process will be a critical tool for poly-pharmacy and transition of care patients (Retail, Specialty, Mail, LTC). Since each pharmacy system may have a different solution to identify the participation status and claim billing details, pharmacies need a way to obtain the Program information at the patient level, versus just the claim level. The lack of information at the patient level will result in inconsistencies in applying all claims for the patient to the Program monthly billing process.

We ask CMS to explicitly explain what it expects from Part D sponsors when it states, "Except as otherwise required in this guidance or under other applicable requirements" all Program requirements are the same for every pharmacy type" Sections 50 and 50.3 of the Draft Guidance are unclear with respect to pharmacy requirements, based on the pharmacy type/care setting.

### Recommendations:

- **CMS should clarify in the final guidance that pharmacy notifications must be communicated) within the NCPDP Approved Message Code (AMC) field 548-6F, and that the guidance refer Part D sponsors to the NCPDP External Code List and associated guidance to facilitate standardization of POS messaging**
- **CMS should allow all pharmacy service types (Retail, Mail, LTC, etc.) to provide the Likely to Benefit Notice to participants based on their preferred method of communication with the pharmacy.**
- **CMS should make available to pharmacies a Program participation status and claim billing identifier data resource in addition to the claim level point of service Medicare Part D claim response.**

- **CMS should explicitly explain what it expects from Part D sponsors when it states the requirements are the same for all pharmacy settings except as “otherwise required in this guidance or under other applicable requirements.”**

### **50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount**

Under Part 1 final guidance, CMS states that COB issues are out of scope. We are concerned, however, that without CMS guidance Part D sponsors and pharmacies will take inconsistent approaches when a supplemental payer has a higher copay than the Medicare Part D plan, and this will affect Program participants as these inconsistent approaches flow through to the amount the pharmacy seeks to collect from the participant at POS. For example, assume the following:

Medicare Part D patient pay = \$215.35

The supplemental plan returns a patient pay = \$275.00

The pharmacy submits the COB claim to the Program plan, reporting first the \$215.35 patient pay, then the \$275 patient pay from the last payer.

Based on established NCPDP COB pricing formulas and guidance, it is the patient pay from the last payer billed (\$275) that is used in the Other Payer Patient Responsibility Amount financial calculation.

To avoid inconsistent approaches and allow participants the greatest flexibility, we recommend that in the above scenario the Program use the lower Medicare Part patient, but also return the difference between the two amounts (\$59.65 in the above example) as an amount due from the patient. This would alert the pharmacy and the enrollee to this situation, giving the enrollee the opportunity to choose whether they still want to use their supplemental coverage. Given the complexities and different scenarios that could arise with supplemental coverage, enrollees should be directed in Program materials to discuss these issues with their plans, rather than seek advice from pharmacies.

#### **Recommendations:**

- **CMS should clarify how a Part D sponsor Program should handle a situation where a participant’s supplemental coverage returns a higher cost sharing than the Medicare Part D plan to ensure consistency between Part D sponsors.**
- **CMS Program material should direct enrollees with supplemental coverage to seek information from their Part D plan on how their participation in the Program will be impacted by such coverage.**

### **50.2 Pharmacy POS Notifications Late in the Plan Year**

CMS notes that because the pharmacy POS threshold amount is a static amount, there may be scenarios late in the plan year in which a Part D enrollee receives a Likely to Benefit Notice but is then required to pay the full OOP amount as part of their first month’s bill. CMS states Part D sponsors should ensure that customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election. To reduce the likelihood of this type of scenario occurring and limit enrollee confusion, we recommend Likely to Benefit Notices not be required in the last quarter.

#### **Recommendation:**

- **To avoid enrollee confusion and frustration, CMS should not require that Likely to Benefit Notices be sent in the last quarter of the plan year.**



### 50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies

CMS notes that regardless of the setting, if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the pharmacy must provide the Likely to Benefit Notice to the beneficiary. While we understand hard copies may seem like a preferable method to deliver information in a timely way, we believe it is neither the most efficient nor enrollee-friendly approach. Requiring the notice be provided to beneficiaries who choose not to obtain the medication, is not feasible in situations where the pharmacy and participant are not face-to-face.

#### Recommendations:

- **CMS should remove the requirement that pharmacies provide hard copies of the Likely to Benefit Notice when the enrollee chooses to not pick up their prescription.**
- **Pharmacies and Part D sponsors should have the flexibility to provide the Likely to Benefit Notice using the enrollee's preferred method of communication in all scenarios.**

#### 50.3.3 Other Pharmacy Types

We appreciate CMS' flexibility to allow preferred contact methods for certain pharmacy types. As noted above, we ask CMS to allow all pharmacy types to leverage this option. We also ask CMS to accommodate variations in electronic communication methods. Pharmacy software and digital communication methods generally support SMS Text messages, with embedded links/QR codes as needed. We ask that CMS confirm that these forms of electronic communication are acceptable. We also ask CMS to clarify the expected content for telephonic methods of communication.

#### Recommendations:

- **CMS should allow the use of SMS text messages that include website links or QR codes to access the Likely to Benefit Notice.**
- **CMS should allow a hyperlink to the Likely to Benefit Notice when the preferred contact method has character limits.**
- **CMS should allow a shorter message for telephone communication, such as advising enrollees to contact their plan for information about the Program.**

### 50.4 Re-adjudication of Prescription Drug Claims for New Program Participants

CMS states that when an enrollee returns to a pharmacy to pick up their prescription(s) after successfully opting into the Program, all claims for covered Part D drugs, from prior dates of service, that have been dispensed but not yet paid for and picked up **must** be re-adjudicated to allow for appropriate processing by the plan and/or its PBM. We ask CMS to clarify that pharmacies should **attempt** to reverse and reprocess these claims, rather than mandating this, since there are several scenarios where this may not be feasible for the pharmacy. For example, while CMS does not appear to expect pharmacies other than the pharmacy sending the Likely to Benefit Notice to an enrollee to reprocess prior prescriptions, it would not be feasible for other pharmacies to do so unless they are all connected to a single pharmacy practice system. As a result, if a specialty pharmacy sent the Likely to Benefit Notice, there is no way for a retail (or any other unrelated) pharmacy to know it must reprocess any prescriptions filled but not yet picked up. There are also significant barriers to reprocessing all prescriptions for the pharmacy that provided the Likely to Benefit Notice to the enrollee. The claim reprocessing step is time consuming, requires the complete pharmacy workflow process to be redone, and may result in claim rejections that did not occur with the original claim.

Reprocessing claims to apply the Program benefit also leads to conflicts in dates of service and the effective date of an enrollee's election. This will result in POS rejects and confusion. It is our understanding that CMS expects pharmacies to change the date of service for all previously filled, but not picked up prescriptions, to the date of reprocessing. Changing the date of service may impact coverage rules, where the specific drug incurred a formulary change, or plan limit change, changes in benefits from the supplemental payer. Resolving these rejects, which may require prescriber outreach, will delay patient access to care. Changing the date of service also requires full pharmacy workflow processes, including pharmacist verification and clinical oversight. Resubmitting the claim, especially with a change in the date of service, starts the entire process over again. It is not just the submission of the additional transaction to the benefit.

Mandating all prescriptions filled but not yet picked up to be reversed and reprocessed to include the Program transaction further compromises the pharmacy workflow, as not all prescriptions may be covered under the Part D benefit. Some prescriptions may have been paid under the plan's enhanced or Part C benefit, resulting in a reject when attempting to submit the transaction. This could result in pharmacies reversing claims paid under the Part B or co-administered benefit, and resubmitting to only see the same results with added transaction fees, unnecessary pharmacy labor and patient access to care delays.

**Recommendations:**

- **The final guidance should not mandate pharmacies reprocess claims for prescriptions the participant returns to a pharmacy to pick up after calling their plan. The guidance should instead state that pharmacies "should attempt to re-adjudicate impacted claims."**
- **CMS should clarify that for pharmacies that ship drugs before receipt of payment and before participation in the Program is effective, the pharmacies are not expected to re-adjudicate claims once the medication has been shipped.**

**50.5.2 I/T/U Pharmacies**

We ask that CMS clarify that an "eligible" IHS enrollee is any Part D enrollee that fills a prescription at a IHS pharmacy. Accordingly, the final guidance should make clear that if a Part D sponsor receives any claim from an I/T/U pharmacy that was submitted to the Program-specific BIN/PCN, it must be rejected

**Recommendation:**

- **The final guidance should clarify that any enrollee who fills a prescription at an IHS pharmacy is "IHS-eligible" and, therefore, IHS pharmacies must reject any claim from an I/T/U pharmacy submitted to the Program-specific BIN/PCN.**

**60.3 Monitoring and Compliance**

CMS has not shared specific changes related to the Program Indicator outside of the August 21, 2023 memo titled, "Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments," in which it states it will create a one position field.

We recommend using the value "Y" when an enrollee participates in the Program but would recommend not using the "Y" indicator when CMS analyzes coordination of benefits (COB) claims data and confirms a paid claim was received on the Program COB Plan. There may be processing and timing issues in searching claims history for a COB paid claim and situations when a claim may



not be submitted at all to the Program, therefore setting the value to “Y” after an enrollee is participating would be the ideal approach.

**Recommendation:**

- **CMS should use the value “Y” when an enrollee participates in the Program.**

**60.4 Audits**

CMS states that it and/or its contractors may conduct specific audits of Part D sponsors’ implementation of the Program and may initiate audit activity that requires additional data collection or site visits. In order for Part D sponsors and their contractors to plan for and budget the necessary resource for such audits, we request that CMS provide additional information on the nature and timing of planned audits. For example, it would be helpful to know whether compliance with the Program will be audited as part of the one-third financial audits conducted annually by CMS or whether CMS will establish a separate audit schedule for the Program and, if so, when it proposes to start such audits and their cadence.

**Recommendation:**

- **We ask CMS to provide information on the nature, timing, and frequency of pricing payment plan audits so that Part D sponsors and their contractors can appropriately budget and plan for these audits. This will help ensure Part D sponsors have in place the resources to manage audits in an efficient manner.**

The Inflation Reduction Act has introduced a critical provision that addresses a significant financial hurdle for Medicare Part D participants: the burden of out-of-pocket prescription drug costs. For many seniors living on a fixed income, the reality of having to pay large lump sums for medications is daunting and, in some cases, prohibitive. The Medicare Prescription Payment Plan is a thoughtful response to this issue, offering a much-needed alternative by allowing beneficiaries to spread these costs over the course of a year with manageable monthly payments. Thus, Doctors for America (DFA) is in strong support of the implementation of this program.

A report by the Kaiser Family Foundation highlighted that one in four people taking prescription drugs reported difficulty affording their medication.<sup>1</sup> In fact, 29% of adults stated not taking their medicines as prescribed due to cost, and 30% of those individuals reported a worsening of their condition as a result.<sup>1</sup> Research has consistently shown that high upfront costs can lead to medication non-adherence, which is linked to poorer health outcomes, increased risk of hospitalization among disabled persons and seniors, and increased healthcare costs.<sup>2,3</sup>

By enabling beneficiaries to plan for and manage their healthcare expenses more effectively, the Medicare Prescription Payment Plan can help reduce these risks. The plan's potential to improve medication adherence and health outcomes cannot be overstated. This initiative is not just a matter of financial convenience; it is a matter of health equity and access.

As CMS moves forward with this program, it is crucial that the process is made as seamless as possible for beneficiaries. The complexity of healthcare programs often acts as a deterrent, and simplifying the enrollment process will be central to ensuring high uptake. Clear communication, straightforward enrollment procedures, and robust support systems will be key to ensuring that seniors can take full advantage of the plan's benefits. CMS must use its platform and budget to promote the program extensively, including mandating Part D plans to contribute to marketing efforts. Furthermore, collaborations with healthcare organizations, advocacy groups, community organizations, and senior centers can facilitate targeted outreach to Medicare beneficiaries.

The Medicare Prescription Payment Plan represents a significant step forward in making healthcare more affordable and accessible for seniors. As the program is rolled out, it will be important to monitor its effectiveness and make adjustments as needed to maximize its impact. With thoughtful implementation and widespread adoption, DFA believes that this plan has the potential to greatly alleviate the financial strain of prescription drug costs for Medicare beneficiaries, ultimately leading to better health outcomes and a higher quality of life for our senior population.

## References

1. Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult To Afford Their Medicines, Including Larger Shares Among Those With Health Issues, With Low Incomes and Nearing Medicare Age. KFF Newsroom. March 1, 2019.  
<https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/#:~:text=In%20addition%20to%20difficulty%20affording%20prescriptions%2C%20about%20three%20in%20ten%20%2829%25%29%20of%20all%20adults%20report%20not%20taking%20their%20medicines%20as%20prescribed%20at%20some%20point%20in%20the%20past%20year%20because%20of%20the%20cost.>
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3. Heisler M, Choi H, Rosen AB, et al. Hospitalizations and deaths among adults with cardiovascular disease who underuse medications because of cost: a longitudinal analysis. *Med Care*. 2010;48(2):87-94. doi:10.1097/MLR.0b013e3181c12e53



March 16, 2024

VIA ELECTRONIC SUBMISSION – [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

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

Dear Dr. Seshamani,

Eli Lilly and Company (Lilly) is pleased to respond to the Medicare Prescription Payment Plan (MPPP) Draft Part Two Guidance. Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives. Lilly thanks CMS for its guidance and willingness to prioritize MPPP outreach and education. We are supportive of widespread educational efforts on the MPPP and applaud CMS for its efforts in making the MPPP available for all Part D enrollees in 2025.

As a member of both the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) and the Biotechnology Industry Organization (BIO), Lilly largely joins those groups in their comments on the MPPP Guidance and encourages CMS to carefully consider the input of those organizations. That said, Lilly would like to offer the following comments to highlight matters of concern and company-specific positions.

**I. CMS Should Implement a Comprehensive Outreach and Education Plan for All Beneficiaries on All 2025 Part D Plan Benefit Changes**

Lilly applauds CMS dedication to outreach and education to patients on the MPPP program. This education should also encompass the \$2,000 maximum OOP and the removal of the coverage gap in the Part D design. CMS leading the charge on ensuring that patients understand the major provisions of the Part D redesign resulting from the IRA will go a long way in guaranteeing a smooth transition for all interested parties.

Per CMS' guidance, the Part D redesign will assist patients with access and affordability of prescription medications by changing stakeholder financial responsibilities resulting in maximum patient OOPs and the removal of the coverage gap. The MPPP, a component of the redesign, aims to assist patients in handling monthly expenses. Certain elements of the program might pose challenges, particularly due to intricate calculations and enrollment choices. Considering the complexity of the program, effective educational efforts by CMS, along with other stakeholders, are crucial for preparing patients for program changes and successfully enrolling Part D beneficiaries into the MPPP. Exclusively relying on plans for patient communication may exacerbate communication gaps and foster confusion, as evidenced during the early days of ACA enrollment

when many consumers struggled to decipher new provider directories and understand Qualified Health Plan (QHP) terminology.<sup>1</sup>

To that end, Lilly recommends CMS develop and launch a campaign for all Medicare beneficiaries and other significant stakeholders (e.g., caregivers, pharmacists, prescribers, and counselors educating beneficiaries) inclusive of important plan benefit design changes in their entirety. This effort should be independent of the traditional annual beneficiary education and outreach activities related to open enrollment season, to ensure that all patients are aware of the potential benefits available to them.

Information dissemination should utilize multiple touchpoints such as social media, traditional media outlets, community events, and educational workshops to reach a wide audience spectrum.<sup>2</sup> CMS should include Medicare.gov, the “Medicare and You” handbook, customer service representative engagement at 1-800-MEDICARE, and interactive tools on Plan Finder in their rollout. Additionally, CMS should employ multiple deliverers of the message, including CMS regional offices, experts and community leaders. Moreover, creating easy-to-read materials with clear language, visual aids, and simplified explanations ensures complex concepts are easily understood for all audiences.<sup>3</sup>

## **II. CMS Should Require Plans to Evaluate Beneficiaries who are Likely to Benefit Using a Full Year of Expenditure**

Lilly appreciates CMS’ requirement for plans to assess beneficiary costs based on the previous years out of pocket (OOP) spending, Lilly urges CMS to consider assessing a full year OOP costs data in identifying beneficiaries likely to benefit for MPPP. Without a full year assessment, beneficiaries who reach the \$2,000 threshold in the last quarter of the year would be excluded, even though they may still benefit from participating. A 2023 ADVI analysis found that 40% of non-low-income subsidy (LIS) Part D beneficiaries reached the \$2,000 threshold between September and December of their plan year.<sup>4</sup> Were plans to stop aggregating OOP expenditures in September, a significant number of beneficiaries likely to benefit from the program would not be notified proactively.

## **III. CMS Should Provide Transparency on MPPP Data and Dissemination**

As CMS monitors and collects data around MPPP participation, Lilly recommends CMS provide greater transparency around how the Agency will review MPPP information and report participation data via annual updates so that stakeholders can continue to refine and tailor processes for their constituencies. This engagement should be collaborative and patient-centered so all parties can identify areas for improvement and employ greater program effectiveness.

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<sup>1</sup> 2016 Report on PPACA and Enrollee Satisfaction: [GAO-16-761, PATIENT PROTECTION AND AFFORDABLE CARE ACT: Most Enrollees Reported Satisfaction with Their Health Plans, Although Some Concerns Exist](#)

<sup>2</sup> “Strategies for Effective Communication: A Handbook for Communicators,” World Health Organization, 2019.

<sup>3</sup> “Plain Language: Improving Communication from the Federal Government to the Public,” Center for Plain Language, 2020.

<sup>4</sup> “Evaluating the Impact of the Inflation Reduction Act (IRA) \$2,000 Out-of-Pocket Spending Cap on Medicare Part D Beneficiaries.” ADVI. Available: <https://www.advi.com/wp-content/uploads/2023/09/ADVI-AMCP-Nexus-2023-Poster.pdf>.

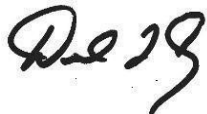
**IV. For 2025, CMS Should Create a Standardized Process for Estimating Losses Due to Unsettled Balances and a True Up Process to Reconcile Records and Accounts**

CMS is allowing sponsors to treat projected unsettled balances as plan losses in their plan bids, specifically as administrative costs. This allowance impacts the bidding process for 2025, where the applicable guidance has not been published, and the Medical Loss Ratio (MLR). As MPPP is a new program with no historical data upon which to base estimates, Lilly is concerned that without further guidance from CMS sponsors may be ill-equipped to accurately estimate their losses, which could have unintended consequences that could negatively impact other stakeholders within the healthcare system. Lilly recommends that CMS create a standard loss estimate per patient per month, or other standardized calculation, that could be applied consistently across all sponsors. Sponsors might be able to then use existing data to estimate how many patients may default on their payments to more accurately project losses. During the 2026 bidding process, CMS should issue guidance that allows sponsors to account for any true ups in their anticipated loss estimates based upon actuals from 2025 and program data. To accomplish this, the current data lag period would need to reduce from two years to one.

\*\*\*

Lilly is grateful for the opportunity to comment on the Medicare Prescription Payment Plan: Draft Part Two Guidance. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future to help ensure that patients have meaningful access to affordable health care benefits and prescription drug coverage. Please do not hesitate to contact Derek Asay at [Asay.Derek.L@Lilly.com](mailto:Asay.Derek.L@Lilly.com) with any questions.

Sincerely,



Derek L. Asay  
Senior Vice President,  
Government Strategy and Federal Accounts



Shawn O'Neil  
Senior Vice President,  
Global Government Affairs

Hello,

Below is a comment from Fallon Health (H9001) on part two of the Medicare Prescription Payment Plan guidance.

Comment for section: 30.2.2.2 Identifying Part D Enrollees Likely to Benefit During the Plan Year

The Coverage Determination (CD/prior authorization) process is a clinical review. The financial cost of a medication is not a typical component of the CD review. This section (30.2.2.2) would require IT work to incorporate pricing information into the CD process. Also, unless a drug has a quantity limit, the total daily dosing may not be known. If the drug is given prior authorization only at the strength-level, the authorization will allow any quantity. With lack of known, or potential increase in dosing, determining if the member may benefit from the Medicare Prescription Payment Plan may not be straight forward.

Our organization suggests that the notification “Medicare Prescription Payment Plan Likely to Benefit Notice” not be required within the turnaround time of the CD. This will allow time for reporting to be performed to identify the drug and attempt to calculate the potential cost to the member. Once that is known, the notification can be delivered to the member.

Thank you,

Keith Greiner | Medicare Compliance and Regulatory Affairs Associate

Fallon Health | 10 Chestnut Street | Worcester, MA 01608

Ph: 1-508-368-9722 | Fax: 1-508-368-9981



March 15, 2024

Dr. Meena Seshamani, M.D., PhD.  
Deputy Administrator and Director  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

**Subject: Comment Letter on Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025.**

Dear Dr., Seshamani,

Farmacia Isla Verde, a community pharmacy strategically located in the vibrant municipality of Carolina, Puerto Rico, is pleased to provide detailed insights and feedback on the Centers for Medicare & Medicaid Services (CMS) Part Two Guidance for the Medicare Prescription Drug Payment Model, as specified in the provisions of the Inflation Reduction Act of 2022. Our engagement in this process reflects our commitment to contributing constructively to the shaping of policies that impact healthcare affordability and access, particularly in the context of prescription medications under Medicare frameworks.

We appreciate the efforts of CMS to involve stakeholders in the continuous improvement of this critical healthcare initiative, and we are poised to provide comprehensive feedback that encapsulates the perspectives and needs of our community. Our pharmacy is deeply committed to improving access to affordable medications and healthcare services for all patients we serve, especially targeting the underrepresented communities within our municipality and its surrounding areas. This dedication stems from a comprehensive understanding of the distinct healthcare challenges encountered by these groups. We aim to make a significant contribution toward enhancing healthcare outcomes for these populations, embodying our commitment to making a positive impact on public health within our community. While we commend the CMS for implementing measures aimed at easing the financial burden on Medicare Part D enrollees through the Medicare Prescription Payment Plan, we must express our profound concern regarding the exclusion of Puerto Rico from the Low-Income Subsidy (LIS) under this program.





The LIS, also known as "Extra Help," assists eligible beneficiaries in paying for their Medicare Part D premiums, deductibles, and co-payments related to prescription drugs, offering significant financial relief to low-income individuals. To navigate these challenges and advocate for equitable access to prescription drug cost relief, we propose integrating strategies that leverage Puerto Rico's demonstrated success in healthcare initiatives, notably our high vaccination rates during the COVID-19 pandemic. This example of excellence highlights Puerto Rico's capacity to implement effective health care strategies and underscores the potential for similar successes in medication accessibility and affordability with the right support and inclusion in federal programs.

### **COVID-19: PUERTO RICO: PROPER FUNDING = PROVIDERS DELIVER**

Achieving one of the highest COVID-19 vaccination rates in the United States, Puerto Rico stands as a testament to the effectiveness of equitable resource allocation and proper funding in public health campaigns. This significant accomplishment underscores the importance of providing adequate financial resources to regions facing unique challenges, demonstrating that with the right support, highly effective health interventions can be implemented.

Puerto Rico's success in its vaccination campaign not only exemplifies the critical role of equitable resource distribution in addressing a global health crisis but also highlights how extraordinary public health outcomes are achievable when territories are given comparable financial support to that of the states. With the proper funding the Puerto Rico was able to:

1. **Allocate Resources:** The U.S. federal government's decision to allocate resources and funding to Puerto Rico on par with the states was pivotal. This equitable approach ensured that Puerto Rico had access to sufficient quantities of COVID-19 vaccines and the necessary funding to support the infrastructure required for a large-scale vaccination campaign.
2. **Expand Healthcare Infrastructure:** The island could invest in the necessary healthcare infrastructure to store, distribute, and administer vaccines efficiently. This included purchasing ultra-cold freezers for vaccines requiring low-temperature storage and setting up vaccination sites across the island.
3. **Leverage Local Pharmacies:** Equitable funding enabled the integration of local pharmacies into the vaccination strategy, expanding access to vaccines across Puerto Rico. Pharmacies were equipped and compensated to serve as vaccination sites, ensuring broad geographic coverage and convenience for residents.



4. **Educate the Public:** Adequate funding supported comprehensive public health campaigns to educate the population about the vaccine, address hesitancy, and encourage participation in the vaccination program. These efforts were crucial in achieving high vaccination rates.
5. **Innovate and Adapt:** Financial resources allowed Puerto Rico to innovate in response to challenges, such as deploying mobile vaccination units to reach remote communities and ensuring that vulnerable populations had access to vaccines.

### **Recommendations for Improving the Medicare Prescription Payment Plan**

The Medicare Prescription Payment Plan, as outlined in the Centers for Medicare & Medicaid Services (CMS) draft guidance, aims to significantly reform the way Part D enrollees manage their out-of-pocket (OOP) prescription drug costs starting in CY 2025. This reform is a direct consequence of the Inflation Reduction Act of 2022, targeting to make healthcare more accessible, equitable, and affordable, especially in terms of prescription drugs under Medicare. Key elements of the plan include providing Part D enrollees the option to spread their OOP prescription drug costs over monthly payments, instead of facing potentially high upfront costs at the point of sale (POS). This arrangement is designed to alleviate the financial burden on beneficiaries, particularly those who face high medication costs, by allowing for better budget management and potentially preventing the need for individuals to forgo necessary medications due to cost constraints.

However, individuals residing in Puerto Rico who are excluded from the Low-Income Subsidy (LIS) will likely face adverse effects under this new payment plan. The exclusion means that these beneficiaries will not benefit from the additional financial support intended to lower prescription drug costs for low-income individuals. Consequently, while the Medicare Prescription Payment Plan facilitates a more manageable payment structure for enrollees, those without LIS eligibility, including certain residents of Puerto Rico, may still find themselves challenged by high cumulative drug costs. This is particularly impactful in Puerto Rico, where the population might face unique economic and healthcare access challenges.

The CMS draft guidance outlines comprehensive requirements for Part D sponsors in terms of outreach, education, and communication to ensure enrollees are well-informed about this new option. It includes mandatory notification of the payment plan in various enrollee communications and the development of targeted outreach strategies to ensure those likely to



benefit from the plan are aware of it. These efforts are intended to support informed decision-making among Part D enrollees, including understanding the benefits of the payment plan and the process for opting in.

Yet, the effectiveness of these strategies in reaching and adequately supporting all segments of the Medicare enrollee population, particularly those in Puerto Rico excluded from the LIS, remains a critical concern. Without access to the additional support provided by the LIS, these enrollees may not achieve the full potential benefits of the payment plan, particularly in terms of reduced financial strain from prescription drug costs. This situation underscores the need for continued evaluation and potential adjustment of the plan's implementation and outreach efforts to ensure equitable access and support across all Medicare enrollees, irrespective of their geographic location or LIS eligibility status.

While the Medicare Prescription Payment Plan represents a significant step forward in reducing the financial burden of prescription drug costs for Medicare Part D enrollees, the exclusion of certain low-income beneficiaries, such as those in Puerto Rico from the LIS, may limit the plan's overall impact on alleviating medication cost challenges for all segments of the Medicare population. Addressing these disparities and ensuring equitable access to prescription drug cost support remains a crucial aspect of the plan's ongoing implementation and refinement.

We strongly advocate for the immediate inclusion of Puerto Rico in the LIS program. This action would provide much-needed financial relief to our low-income seniors and individuals with disabilities, enabling them to afford their medications without having to sacrifice other basic needs. The inclusion of Puerto Rico in the LIS program under Medicare is of paramount importance for several reasons, each directly impacting the economic well-being and healthcare outcomes of the American citizen residing in island, as outlined below:

#### **1. Economic Relief for Individuals and Families**

- **Direct Financial Support:** Many residents of Puerto Rico live below the poverty line and face significant economic challenges. The LIS would provide direct financial relief to these individuals, reducing the financial burden of prescription medications.
- **Increased Disposable Income:** By reducing out-of-pocket expenses for medications, individuals would have more disposable income available for other essential needs, such as food, housing, and utilities, contributing to overall economic stability.



## 2. Improved Healthcare Outcomes

- **Enhanced Medication Adherence:** Excessive costs are a major barrier to medication adherence. With the LIS, individuals are more likely to afford their prescribed treatments, leading to better management of chronic conditions and overall improved health outcomes.
- **Preventive Health Measures:** The LIS can also play a role in preventive health by making medications more affordable, potentially preventing the progression of diseases, and avoiding more costly medical interventions in the future.

## 3. Healthcare System Sustainability

- **Reduction in Healthcare Costs:** By improving medication adherence and managing chronic conditions more effectively, the LIS could lead to a reduction in emergency room visits and hospitalizations, thereby saving healthcare costs in the long term.
- **Support for Healthcare Providers:** With more patients able to afford medications, healthcare providers, including pharmacies, can better serve their communities without the financial strain of unpaid services or aiding patients who cannot afford their medications.

## 4. Social Equity and Inclusion

- **Reducing Health Disparities:** The inclusion of Puerto Rico in the LIS addresses a significant inequity in the Medicare program, ensuring that low-income individuals in Puerto Rico have the same access to affordable medications as those in the mainland U.S.
- **Promoting Social Inclusion:** Integrating Puerto Rico into the LIS program signals a commitment to the welfare of all U.S. citizens, regardless of where they live, fostering a sense of inclusion and equity.

## 5. Strengthening Local Economies

- **Support for Local Pharmacies:** By making medications more affordable, the demand for prescription drugs is likely to increase, supporting local pharmacies and the broader healthcare sector in Puerto Rico.
- **Economic Multiplier Effect:** Improved health outcomes and financial stability among residents can lead to increased productivity and spending, further stimulating the local economy.



## **Conclusion**

The inclusion of Puerto Rico in the LIS program is not just a matter of financial relief; it is a critical step towards improving public health, advancing social equity, and fostering economic stability within the island. It acknowledges the challenges faced by American citizens living in Puerto Rico and provides a tangible solution to alleviate the burden of prescription drug costs, ensuring that low-income individuals and families have access to the healthcare they need. By integrating Puerto Rico into the LIS, the U.S. can take a significant step forward in addressing healthcare disparities and supporting the well-being of all its citizens, reinforcing the principle of equity across all territories. We believe that by working together, we can overcome the challenges faced by our community and ensure that all individuals have access to the medications they need to live healthy and productive lives.

Sincerely,

Elliot Pacheco  
Chief Compliance Officer  
[elliott@farmaciaislaverde.com](mailto:elliott@farmaciaislaverde.com)

Hello,

Thank you again for providing an overview of the Medicare Prescription Payment Plan guidance on the Part C & D User Call on IRA implementation today. I appreciate the opportunity to send this question in for further review.

From the draft part two guidance, section 30.3.2 Notice of Acceptance of Election:

*For all requests, in addition to the written notification of acceptance of election and effectuation, Part D sponsors must provide the new program participant with the information required in section 70.3 of the draft part one guidance.*

From the draft part one guidance, section 70.3.3 Processing Election Request at the Time of Enrollment in a New Plan:

*When a request to participate in the Medicare Prescription Payment Plan is approved, the Part D sponsor must provide the participant with the following (CMS will provide more specific information, including model language in the next round of guidance):*

- *An overview of the program and participant rights, responsibilities, and protections, including information on procedures for involuntary termination, reinstatement, and resolution of grievances;*
- *Examples of calculations of the maximum monthly cap in the first month and subsequent months, including example calculations describing scenarios in which the program would not be beneficial to an individual; and*
- *General information about applying for the LIS program and how to enroll (as an additional or alternative avenue for addressing prescription drug costs), noting that LIS enrollment, for those who qualify, is more advantageous than participation in the Medicare Prescription Payment Plan alone; and*
- *The effective date of the individual's participation in the Medicare Prescription Payment Plan.*

However, when reviewing the final part one guidance, I was unable to find the same language from the draft part one guidance. It's possible I may have interpreted this

incorrectly but in the interest of meeting all requirements, could we get clarification on what information Part D sponsors must provide in addition to the notice of election approval and whether an additional CMS-developed product would satisfy the requirement in the draft part two guidance?

Thank you,

**Mike Kwan** | BEIC/GPPC Spec V Corporate Compliance

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March 15, 2024

VIA ELECTRONIC SUBMISSION — [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

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

Dear Dr. Seshamani,

We appreciate the opportunity to respond to CMS's Maximum Monthly Cap on Cost-Sharing Payments Program Draft Part Two Guidance.<sup>1</sup> Genentech is a leading biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening illnesses. We are committed to improving patients' lives through new innovations. To this end, in 2023 we, under the Roche umbrella, invested nearly \$15 billion globally in research and development. In the past ten years, we have delivered to patients 17 new medicines that treat devastating diseases like cancer, multiple sclerosis, and hemophilia. In addition to our over 40 approved medicines, we have over 80 potential new medicines in clinical or preclinical development and have been granted 39 FDA Breakthrough Therapy Designations for medicines with the potential to provide substantial improvement over currently available treatments.

Since the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), the Medicare Part D program has provided seniors with critical coverage for prescription

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<sup>1</sup> 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



medicines by creating a marketplace where Part D sponsors can offer a range of affordable coverage options and beneficiaries are empowered to select the Part D plan that best suits their needs. As noted in our June 5 and September 23 comments relating to the CY 2025 Medicare Part D Benefit Redesign and the Medicare Prescription Payment Plan (MPPP), we strongly support the patient out-of-pocket (OOP) spending cap and the OOP “smoothing” provision enacted under the Inflation Reduction Act (IRA), as both represent key elements to improving patient affordability. We appreciate CMS’s continued efforts in this Guidance to implement a robust and patient-friendly MPPP. In this response, we build upon our previous comments, specifically focusing on several key aspects of implementation where we believe further refinement from the agency is needed to fully realize the program’s potential: 1) beneficiary education materials and tools; 2) the identification of beneficiaries “likely to benefit” from the MPPP; and 3) data reporting to monitor program uptake.

### **Beneficiary Education Materials and Tools**

As we have emphasized, a robust, multi-modal educational campaign coordinated by CMS with involvement from Part D plan sponsors is critically important to ensure broad awareness and successful adoption of the MPPP. Comprehensive materials explaining the program’s benefits, terms and conditions, and enrollment process must be widely accessible to beneficiaries prior to the start of each plan year. This will enable participation upon plan enrollment and midyear, for those who expect to benefit.

We appreciate CMS’s efforts to develop standardized educational content to promote consistency across plan materials and minimize potential confusion among beneficiaries. However, we are concerned that CMS has only *encouraged* plans to use the CMS-developed content, as this could result in a lack of consistency in patient awareness, and potentially lower enrollment in the MPPP. We strongly recommend that CMS *require* all plan sponsors to use the CMS-developed content as the core material when communicating about the MPPP. CMS could allow plans to develop supplemental content, provided that CMS reviews and approves the content before dissemination. As part of the CMS-developed content to be used by plans, we recommend CMS include illustrative examples demonstrating how the MPPP monthly billing process and OOP cap work for beneficiaries under various scenarios (e.g., those remaining on consistent medication regimens throughout the year vs. those whose regimen changes, those enrolling mid-year, etc.). Such examples will improve comprehension among beneficiaries.

Beyond the standardized educational content that plans would be required to provide beneficiaries, we support CMS’s development of its own “educational product” for dissemination through Medicare.gov and other channels, to directly educate beneficiaries, their families, patient advocates, and others. This resource should explain, in easily understandable terms, not only the MPPP itself but how it interacts with other recent Part D benefit changes like the new annual OOP cap and expanded Extra Help eligibility. To further empower beneficiaries in assessing whether the MPPP is right for their circumstances, CMS should update the Medicare Plan Finder tool to include an interactive feature estimating a beneficiary’s monthly OOP costs if enrolled in the program. This tool should account for key variables like multiple prescription regimens, mid-year medication changes, and varying enrollment timing (at start of year vs. later). The tool should also provide clear disclaimers that actual OOP costs may vary from the estimates based on changes in the beneficiary’s medication regimen or other factors. Such a tool would be a meaningful addition, providing a new type of OOP cost transparency to beneficiaries. Combined with

clear, consistent educational materials, it would allow beneficiaries to make truly informed decisions about plan selection and MPPP enrollment.

Finally, because patients will not have the option to enroll in the MPPP at the point of sale in 2025, providers could play an outsized role in helping beneficiaries understand potential benefits of enrolling before arriving at the pharmacy counter. CMS should leverage existing outreach mechanisms like the Medicare Learning Network to fully equip providers with the information needed to educate patients, particularly those specialists more likely to prescribe drugs for which MPPP participation could significantly “smooth” a beneficiary’s OOP cost.

#### *Targeted Education for Non-LIS Beneficiaries*

While we agree with CMS that Low-Income Subsidy (LIS) enrollees are unlikely to see significant benefits from the MPPP given their already low OOP costs, there is a clear opportunity to inform non-LIS beneficiaries about their potential eligibility for the Extra Help program, especially considering the expanded income limits that took effect this year.

CMS should direct plan sponsors to include, in the educational content shared with beneficiaries, information about the Extra Help program including eligibility criteria and application instructions. This content should also clearly explain the differences in cost-sharing between the Extra Help program and the MPPP. This type of comprehensive, multi-program education will be critical to realizing the Inflation Reduction Act’s goal of maximizing affordability of prescription drugs for all Part D enrollees.

#### **Identification of Beneficiaries "Likely to Benefit"**

CMS’s Part One Final Guidance outlines the approach the agency will take to defining beneficiaries “likely to benefit” from the MPPP based on prior year OOP drug costs. We understand and agree with the overall concept of proactively educating beneficiaries with historically high OOP costs about the MPPP enrollment opportunity, as these individuals have the highest likelihood of benefiting from lower, predictable OOP costs up to the annual cap. We also appreciate CMS’s data-based approach to establishing the thresholds around which the “likely to benefit” notices are based. However, we are concerned that CMS’s proposed thresholds may significantly underestimate the number of beneficiaries who could benefit.

Specifically, when assessing before the plan year who may be likely to benefit from the program, we believe the \$2,000 OOP threshold—looking only at expenses from January through September of the prior year—could exclude many beneficiaries from the pre-plan year notification. Many beneficiaries may cross the \$2,000 OOP cap later in the year, perhaps starting a new high-cost treatment regimen mid-year or incurring substantial costs from an infrequently filled medication. At a minimum, CMS should establish the threshold for the pre-plan year notification at \$1,500 in OOP costs (representing \$2,000 in annual OOP costs, prorated over 9 months). However, given the varied timing and nature of beneficiaries’ prescriptions noted above, an even lower amount may be more appropriate to avoid undercounting beneficiaries “likely to benefit” from the program. In this vein, CMS should consider alternative

thresholds that would be more inclusive and predictive of those truly likely to benefit from the program. For example, beneficiaries who have incurred:

- \$500 or more in OOP drug costs in any single month
- \$250 or more in average monthly OOP drug costs across any 2-month period
- \$500 or more in OOP cost over the course of the 3rd quarter

In all of these examples, the specified OOP amount should represent the beneficiary's total costs across all prescriptions, rather than from a single drug claim. This will help capture more patients managing multiple medications who could benefit from the MPPP.

We similarly believe the proposed \$600 OOP drug cost threshold for point-of-sale (POS) notification, finalized in the Part One Guidance, is too high. While we appreciate CMS's efforts to reduce the number of patients that will receive the "likely to benefit" notice but will not actually benefit from enrolling, CMS's own data<sup>2</sup> show that more than 2.5 times as many patients could benefit from the program if the threshold was lowered to \$400. In establishing this lower threshold, plans could still communicate to beneficiaries with high confidence that 9 out of 10 beneficiaries could benefit from the program.

In addition to the substantive shortcomings of the pre-plan year and POS thresholds, we also believe the risk of "overexposing" beneficiaries to MPPP educational materials is very low considering that no beneficiary will be automatically enrolled, and that all MPPP enrollees may opt out of the program whenever they wish. The greater risk, in our view, is missing an opportunity to further educate, and facilitate enrollment for, individuals who absent the MPPP might not fill their prescriptions, jeopardizing their health and potentially adding cost to the system.

Finally, echoing a broader point from our earlier comments, we recommend that any "likely to benefit" notice should include clear language around next steps to enroll, program details and beneficiary rights, and potential financial impact based on historical and/or projected spending.

## **Reporting Data to Monitor Program Impact**

We support CMS's requirement that Part D sponsors report data elements related to their MPPP, both at the beneficiary-level and contract Plan Benefit Package levels. To further enhance the MPPP and ensure it is operating as intended, we encourage CMS to require plans to publicly report additional data elements beyond those currently specified in Section 100 of the Part 1 Final Guidance. These could include:

- Number/percentage of beneficiaries who enrolled in the MPPP and benefitted from the lower, more predictable monthly OOP
- Number/percentage who enrolled but did not actually benefit
- Number/percentage who did not enroll but would have benefitted had they done so
- Number/percentage who did not enroll and would not have benefitted

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<sup>2</sup> Table in Section 60.2.3 of the Medicare Prescription Payment Plan: Final Part One Guidance

Analyzing these metrics could help CMS calibrate the "likely to benefit" threshold, refine educational efforts, and improve other program elements for future years to strike the right balance between being inclusive in outreach efforts and limiting unnecessary exposure of MPPP materials to beneficiaries with little to gain.

\* \* \* \* \*

We appreciate CMS considering these recommendations as it continues the critical work of implementing the MPPP for 2025. Please do not hesitate to contact Dan Neves, Director of Federal Policy at [nevesd2@gene.com](mailto:nevesd2@gene.com) with any questions, or to discuss further.

Sincerely,

A handwritten signature in black ink, appearing to read "DB", with a stylized flourish extending from the end.

David Burt  
Executive Director, Federal Government Affairs  
Genentech, Inc.



March 16, 2023

VIA ELECTRONIC SUBMISSION — [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-8016

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

Dear Dr. Seshamani,

GSK and ViiV Healthcare (ViiV) appreciate the opportunity to comment on the *Medicare Prescription Payment Plan: Draft Part Two Guidance*.<sup>1</sup> GSK is a global biopharma leader with the ambition and purpose to unite science, technology, and talent to get ahead of disease together. Over the next ten years, it's our ambition to positively impact the health of more than 2.5 billion people. GSK supports policy solutions that transform our healthcare system to one that rewards innovation, improves patient outcomes, and achieves higher-value care.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment.

In addition to supporting both BIO and PhRMA's comments on this guidance, GSK and ViiV would like to offer the following comments for consideration.

The smoothing program, which CMS named the Medicare Prescription Payment Plan (MPPP), represents an opportunity to build on the success of the Part D program and enhance affordable beneficiary access to life-changing medicines. Successful implementation of the MPPP requires careful policy development and effective communication from health plans and pharmacies to

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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>

beneficiaries. GSK and ViiV support increasing predictability of out-of-pocket (OOP) costs for Medicare beneficiaries.

#### **Part D Enrollee Education and Outreach**

**Recommendation: In MPPP educational materials, CMS should require plans to alert beneficiaries of zero cost-sharing in Part D for Advisory Committee on Immunization Practices (ACIP)-recommended vaccines.**

GSK and ViiV applaud CMS for seeking input on the tools that will be most beneficial to Part D beneficiaries. CMS notes that for purposes of the MPPP, it will develop an “educational product” for beneficiaries on Medicare.gov and through other Medicare communication channels. While information on the MPPP may be a central focus for the educational product, it is equally important for beneficiaries to understand other recent affordability changes in the Part D program.

**CMS should require health plans/sponsors to specifically alert beneficiaries to zero cost-sharing for vaccines in educational materials.** Many Part D seniors may not be aware that they have access to new affordability measures under the law. CMS should require plans/sponsors to alert beneficiaries that they can receive vaccines at no cost in coverage statement materials and in educational/outreach materials. Aligned with CMS’s goal to increase uptake of preventative vaccines, CMS should also require pharmacies to alert patients of zero-dollar cost sharing for vaccines at the point-of-sale, as 42 million individuals currently receive at least one vaccine in a retail pharmacy setting.<sup>2</sup>

#### **Redesign Concerns | Access to Vaccines and HIV Therapies**

**Recommendation: CMS should issue an HPMS Memo to health plans enforcing the required coverage of vaccines and monitor access to HIV therapies.**

The MPPP is an affordability program to improve Part D beneficiaries’ access and adherence to critical medicines. With Part D redesign, there is concern that health plans will implement new utilization management (UM) practices to offset new plan liability. The MPPP program will not achieve its intended objectives if beneficiaries cannot gain access to treatments due to restrictive UM. To that end, along with effective implementation of the MPPP program, we urge CMS to give increased attention to the growing access barriers imposed by Part D plans such as formulary exclusions, prior authorization requirements, step edits, and formulary tiering.

Recently, some health plans have tried to enforce new UM practices for therapies that have Medicare coverage protections – including vaccines. However, the Part D Manual is clear that “all commercially available vaccines” are to be covered without health plans’ ability to implement UM practices.<sup>3</sup> While we have not yet seen this action by plans in the HIV therapeutic area, GSK and

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<sup>2</sup> CDC. [Influenza Vaccinations Administered in Pharmacies and Physician Medical Offices, Adults, United States](#). May 2023.

<sup>3</sup> Sec. 30.2.7 in CMS Manual for Part D: “CMS will review all Part D sponsors’ formularies to ensure they contain all commercially available vaccines (unless excluded due to available reimbursement under Part B, e.g., influenza or pneumococcal vaccines, or if a commercially available vaccine manufacturer does not participate in the coverage gap discount program). Sponsors will only be allowed to use drug utilization management tools to: 1) Assess the necessity of vaccines that are less commonly administered in the

ViiV encourage CMS to monitor plans' actions in the HIV category given the same access protections apply to HIV therapies.<sup>4, 5 6</sup> **GSK and ViiV recommend that CMS actively monitor health plans' UM practices that undermine coverage protections of vaccines and HIV therapies.** After Part D sponsors submit their formularies to CMS, the agency should rigorously review plans' coverage offerings. If CMS finds instances where plans are trying to issue UM for vaccines and HIV therapies, CMS should consider action through rulemaking in the 2026 Medicare Advantage and Part D Technical Proposed Rule.

Thank you for this opportunity to comment on CMS's MPPP: Draft Part 2 Guidance. If you have any questions or if GSK and ViiV can provide additional insight, please do not hesitate to contact Kristi Thompson at [kristi.g.thompson@gsk.com](mailto:kristi.g.thompson@gsk.com).

Respectfully submitted,



Harmeet S. Dhillon  
Head of Public Policy  
GSK



Carie Harter  
Senior Director, Government Relations  
ViiV Healthcare

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Medicare population, such as anthrax and yellow fever vaccines; 2) *Facilitate use of vaccines in line with Advisory Committee on Immunization Practices (ACIP) recommendations*; and 3) Evaluate potential reimbursement of those vaccines that could be covered under Part B when directly related to the treatment of an injury or direct exposure to a disease or condition (e.g., tetanus).

<sup>4</sup> Kaiser Family Foundation. Medicare and HIV. Oct 14, 2016. <https://www.kff.org/hiv/aids/fact-sheet/medicare-and-hiv/>. Accessed January 30, 2023.

<sup>5</sup> Polycymed.com. CMS Announces Medicare Part D Final Rule Maintaining Current Policy on Six Protected Classes – Policy & Medicine. Jun 3, 2019. <https://www.polycymed.com/2019/06/cms-announces-medicare-part-d-final-rule-maintaining-current-policy-on-six-protected-classes.html> -

~:text=Consequently%2C%20CMS%20identified%20six%20categories%20of%20drugs%2C%20commonly,are%3A%20anticonvulsants%2C%20antidepressants%2C%20antineoplastics%2C%20antipsychotics%2C%20antiretrovirals%20and%20immunosuppressants. Accessed January 30, 2023.

<sup>6</sup> See Chapter 6 (sec 30.2.7) of the Prescription Drug Benefit Manual: <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf>



[www.HaystackProject.org](http://www.HaystackProject.org)

By Electronic Transmission to: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

March 16, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS–1771–P  
P.O. Box 8013  
Baltimore, MD 21244–1850

Meena Seshamani, M.D., Ph.D.  
Deputy Administrator  
Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

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

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani:

Haystack Project is pleased to contribute feedback and recommendations on Part Two of the Centers for Medicare & Medicaid Services' (CMS') Guidance implementing the Medicare Prescription Payment Plan (MPPP).

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease advocacy organizations to highlight and address systemic access barriers to the therapies they desperately need. We strive to amplify the patient and caregiver voice in disease states where unmet need is high, and treatment delays and inadequacies can be catastrophic. Our core mission is to evolve health care payment and delivery systems, spurring innovation and quality in care toward effective, accessible treatment options for Americans living with rare or ultra-rare conditions. Haystack Project is committed to educating policymakers and other



stakeholders about the unique circumstances of extremely rare conditions with respect to product development and fair access to care.

For members of our patient communities relying on Medicare Part D to access medications, the MPPP offers tangible relief from the financial burdens associated with high or unexpected out-of-pocket costs. Medications for rare and ultra-rare conditions tend to be placed on the highest tiers of Part D plan formularies. Patients have frequently found that the cost of filling their prescriptions, particularly at the beginning of the plan year, is too high to be absorbed within a single month.

Our comments focus on ensuring that patients, especially those with rare and ultra-rare conditions, have access to the financial relief the MPPP was intended to convey. We look forward to supporting CMS however we can, including bringing together the 140+ groups that participate with Haystack to review materials or provide further input on Program implementation and communication strategies.

### **General Comments and Recommendations**

Haystack understands that CMS has had an extremely narrow timeline for implementing the prescription drug provisions of the Inflation Reduction Act (IRA). We agree that publishing and soliciting stakeholder comments on draft program instructions and guidance in a piecemeal manner has helped CMS ensure that it can move efficiently in implementing program changes. Unfortunately, in reviewing this Part Two guidance, we found that reference to the Part One draft guidance (which was only recently finalized) in the Part Two Guidance and reference to the draft Part Two Guidance in the finalized Part One Guidance creates uncertainties and gaps in our understanding of how the MPPP will work in the real world.

We strongly urge CMS to afford an opportunity for stakeholders to provide feedback on the two parts of the Guidance as a whole.

In addition, our comments to Part One of the MPPP Guidance included several aspects of the MPPP on which our patient communities expressed a need for greater clarity. As these issues were not discussed in the draft Part Two Guidance or the finalized Part One Guidance, we reiterate our request that CMS clarify the following:

- First, participants and plans need to understand how drug returns due to intolerable side effects or a lack of response to treatment would impact the calculation of monthly payment amounts. Since out-of-pocket costs for a single rare disease treatment could potentially reach the \$2,000 annual cap in a single month, this issue is particularly important to our communities. It is unclear whether participants would be issued refunds for returned products or be required to continue paying for doses they have not used. We expect that the same could be true for individuals receiving a 3-month mail

order fill and that the lack of CMS clarification could create variability among Part D sponsors and leave some beneficiaries with financial obligations they did not expect.

- Patients have also expressed concerns about whether plans can prevent individuals from opting into the payment plan for multiple subsequent years after a prior termination due to nonpayment.
  - We appreciate clarification that individuals would be eligible to participate if they pay amounts due from prior years or enroll in a different sponsor's plan.
  - We continue to believe that plans and participants would be well-served if CMS encourages plans to offer an opportunity distribute past-due amounts over the remaining plan months instead of requiring a single up-front payment. CMS could, for example, require (or encourage) plans to provide at least one opportunity per plan year for participants to catch up on missed payments with a recalculation that evenly spreads their monthly payments over the remaining months.
- Although there is detailed information on enrollment processes, timeframes for processing requests, and standards for urgent enrollment processing and retroactive applicability, we are unable to ascertain:
  - What information will plans require from enrollees requesting to opt into the MPPP that is not already within records maintained by plans and would, if missing, delay processing?
  - Are there any justifications for plans to decline an opt-in request in 2025?
  - Can plan participants who have received a confirmation number after opting into the MPPP (online or by telephone) present their member ID and the confirmation number to a pharmacy when filling a prescription with high out-of-pocket costs?

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

### ***General outreach***

Effective beneficiary outreach and education are crucial to facilitating the MPPP's success. We agree with CMS that model notices, forms, and beneficiary communications would significantly enhance consistency and predictability. We urge CMS to release these resources in draft form so that patients and advocacy organizations have an opportunity to offer feedback and input.

We appreciate that CMS will require plans to use existing Part D materials furnished to their enrollees and include information about the MPPP. We support CMS' proposed requirements that plans:

- Include MPPP information and an enrollment form when sending Part D enrollee membership ID cards.
- Utilize CMS' revised Explanation of Benefits (EOB) that includes MPPP information and explains that enrollees participating in the program will receive a separate monthly MPPP billing statement.
- Send the Annual Notice of Change (ANOC) with educational language describing the MPPP and instructing plan enrollees on how to opt into the program. This document must be sent to Part D enrollees by September 30 of each year.
- Include educational information on the MPPP within the Evidence of Coverage (EOC) document detailing covered benefits and enrollee cost-sharing responsibilities.
- Provide MPPP information on their websites, including election request mechanisms that enrollees can use to opt into the MPPP.

Haystack urges CMS to require that plans ensure that the required MPPP information is conspicuously displayed on the various documents so that enrollees do not overlook this important information due to its inclusion in documents routinely receive from their plans.

We also expect that the online election request mechanism will be particularly helpful to individuals wishing to have real-time confirmation that their opt-in request was received and appreciate that the Agency is encouraging plans to provide a confirmation number. We have previously urged CMS to create a calculator tool that could be included on plan websites so that individuals can see how the MPPP might benefit them based on their anticipated prescription drug needs. This would be more helpful to beneficiaries than the set of examples CMS would require plans to develop and include on their websites.

Similarly, Haystack believes that CMS' efforts to inform Medicare beneficiaries of this new program would be greatly enhanced with informational materials tailored for use by pharmacies to educate beneficiaries about the program. These materials should be distributed in advance of the 2025 plan year and offer clear instructions on how to opt into the program. In addition, active prompts at pharmacy counters could be used to augment targeted outreach and inform Part D enrollees about the program.

Finally, patient advocacy organizations like Haystack Project can play an important role in helping CMS ensure patients are not only aware of, but thoroughly understand the Program. CMS-developed FAQs and model PowerPoint presentations would be helpful to patient advocacy organizations wishing to inform their patient and provider communities on the Program, including how each patient can calculate whether they would benefit from opting in.

### ***Targeted outreach***

Haystack appreciates CMS' efforts to ensure that beneficiaries most likely to benefit from the MPPP have multiple opportunities to review and evaluate program information and opt-in if the program will likely benefit them. We agree that:

- Requiring plans to notify enrollees with high out-of-pocket costs in 2024 and previously years will reduce the number of Medicare beneficiaries delaying prescription fills due to the time required to opt-in and receive confirmation of MPPP participation.
- Targeted outreach during the plan year for enrollees with pending prior authorization requests for high-cost drugs would enhance other ongoing efforts to identify individuals likely to benefit from the MPPP. We believe that this mechanism would be more helpful if:
  - o Plans identifying these enrollees too late in the plan year to convey an MPPP participation benefit notified these individuals about the program and offered an opportunity to opt-in for the upcoming plan year.
  - o Plans used a notification mechanism (e.g., telephone contact or text messaging) more likely to provide a real opportunity for the individual to opt-in to the MPPP and benefit from the program. It is unlikely that mailing the notification the day after the prior authorization request is flagged would be provide MPPP information in time for opt-in election prior to prescription pick-up.
- Pharmacies are an important contact point for patients likely to benefit from the MPPP and plan notification to pharmacies of an individual likely to benefit from the program can enable pharmacies to convey that information to patients. We believe this targeted outreach will be most effective if it reduces the possibility that a Medicare beneficiary would decline to pick up their prescription due to high out-of-pocket costs. We recommend:
  - o The information on MPPP should be conveyed to the patient **before** the patient picks up their prescription.
  - o The patient should have an opportunity to opt-in by telephone or online and can pick up their prescription with \$0 cost at the pharmacy counter by providing their member ID and election confirmation number.

### ***Overview of Election Requirements***

Haystack believes the MPPP offers a tremendous opportunity to help beneficiaries afford their life saving prescriptions. The ability to spread out-of-pocket costs evenly over the course of a year can, for many Medicare beneficiaries, reduce the possibility that a patient will have to choose between receiving their medication and paying their housing, utility, and transportation bills. We are concerned that confusion or unnecessary complexity in the enrollment process will either dissuade beneficiaries from participating, add to their existing financial stressors, or deter participation in future years.

Because the IRA requires plans to make the Program available to all enrollees and does not provide for any denial mechanism other than involuntary termination in the previous year, enrollment in the first year of the Program should be a ministerial task, not a determination. While we understand plans may need some time to process requests, we urge CMS to enable a mechanism through which participants could present their opt-in confirmation number when picking up their prescription. We believe this would reduce the need for retroactive participation and ensure that individuals unable to pay at the pharmacy counter and wait for a “refund” do not walk away without necessary medication. This issue is

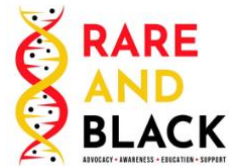
critically important to Haystack Project and its members. For many rare disease patients, every prescribed treatment that can reduce disease burden or progression should be viewed as urgent.

Finally, we strongly encourage CMS to mandate that plans maintain their enrollees' participation from one year to the next, adopting a procedure akin to the auto-enrollment protocols used in Medicare or Qualified Health Plans. Participants would be reminded that they have the option to opt out of participation at any time. This approach would streamline the process for Medicare beneficiaries who might otherwise assume that both their plan enrollment and program participation automatically continue from year to year.

## Conclusion

Haystack Project appreciates the opportunity to submit feedback on CMS' draft Part Two Guidance implementing the Medicare Prescription Payment Plan. We look forward to continuing to work with you in ensuring that all Medicare beneficiaries, including those with rare diseases, can receive the treatments they need without financial hardships associated with high out-of-pocket costs. If you have any questions, please contact me at [Kara.berasi@haystackproject.org](mailto:Kara.berasi@haystackproject.org) or our policy consultant, Kay Scanlan of Consilium Strategies at [mkayscanlan@consilstrat.com](mailto:mkayscanlan@consilstrat.com).







## HEALTHCARE LEADERSHIP COUNCIL

March 15, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

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

Dear Administrator Brooks-LaSure:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Prescription Payment Plan Draft Part Two Guidance.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC has long been committed to ensuring seniors have access to their choice of affordable, high-quality prescription drugs and was instrumental in the creation of the Part D program, which has been popular and successful since its inception. In a 2023 Morning Consult survey, 91 percent of seniors report being pleased with their Part D plan and 86 percent say it provides good value.<sup>1</sup>

We strongly support the objective of the new Medicare Prescription Payment Plan (MPPP) program to help beneficiaries who have high upfront prescription costs smooth payments out over the course of the plan year to better afford their medications. However, as we asserted in our response to the Draft Part One Guidance, we are worried that current operational barriers, if not addressed, will undermine the success of the program. Lack of clarity, unnecessarily cumbersome requirements, and inadequate time to operationalize the MPPP program will not only burden Part D sponsors and pharmacists but may adversely impact beneficiaries through delays in receiving medications and confusion for those unlikely to benefit from the program.

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<sup>1</sup> Medicare Today 2023 Senior Satisfaction Survey, Morning Consult (August 2023), [https://medicaretoday.org/wp-content/uploads/2023/08/2307070\\_HLC\\_Seniors-on-Medicare\\_Satisfaction-Memo-2.pdf](https://medicaretoday.org/wp-content/uploads/2023/08/2307070_HLC_Seniors-on-Medicare_Satisfaction-Memo-2.pdf).

Given the short timeframe to implement the MPPP program, it is critical CMS ensure necessary flexibilities and closely engage Part D sponsors, pharmacies, and other stakeholders as the agency continues to issue model materials and additional program notices.

In particular, we urge CMS to provide clarity and further explore the following areas:

**Ensure communication to beneficiaries is easy to understand and actionable.** The success of the MPPP program hinges on clear communication and a streamlined program election experience for beneficiaries. HLC appreciates CMS' efforts to ensure that beneficiaries who are most likely to benefit from the program – certain beneficiaries with high up-front costs early in the plan year – become aware of their options. We encourage CMS to explore ways to meet this goal by prioritizing a seamless experience for beneficiaries and minimizing confusion. It is important that beneficiaries who are not likely to benefit from the program, including those enrolled in the low-income subsidy (LIS) program, are not burdened with repeated communications about the MPPP program.

**Expedite comprehensive model materials.** We appreciate CMS' intent to provide model materials informed by stakeholder feedback through following an Information Collection Request (ICR) by the Office of Management and Budget; comprehensive model materials are very much needed. However, the current timeline to issue model documents in the summer of 2024 does not allow adequate time for Part D sponsors to operationalize the new models by the 2025 annual enrollment period. Model language would need to be finalized by April 2024 to allow time for Part D sponsors to review and translate documents, coordinate with business partners, and provide time for state Medicaid agencies to review as the program pertains to dual-eligible beneficiaries. Additionally, in its upcoming model language, we encourage CMS to provide clear program calculation examples for each plan type.

**Provide Part D sponsors and pharmacies with the necessary flexibility to operationalize the MPPP program.** The quick implementation of this program necessitates flexibility for Part D sponsors and other stakeholders. For example, CMS should allow Part D sponsors to rely on draft model documents prior to finalization, and if CMS issues corrections to draft model language during the plan year, flexibility must be afforded. CMS likewise should offer appropriate safe harbors that take timeline constraints into account in its enforcement of the program. It is important that Part D sponsors are not penalized for good faith compliance efforts.

**Fully consider digital-forward pharmacies to meet beneficiaries where they are.** CMS states that the MPPP program “requirements are the same for every pharmacy type”, however, this ignores the unique circumstances of digital-forward and home delivery pharmacies. A 2023 consumer survey showed 13 percent of Americans report their primary pharmacy as being online or mail-order.<sup>2</sup> MPPP program requirements should promote the most user-friendly experience possible for the growing number of beneficiaries who choose the convenience of filling their prescriptions virtually. Within the short subsection 50.3.3, CMS provides guidance for “other pharmacy types” and specifies that pharmacies without in-person interactions must contact beneficiaries by telephone or their preferred contact method; we suggest deletion of this requirement. Because digital-forward pharmacies currently allow beneficiaries to place prescriptions in their virtual cart and check out simultaneously, we are concerned that this requirement will result in delays for patients, despite the best efforts of pharmacists. This

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<sup>2</sup> Meeting changing consumer needs: The US retail pharmacy of the future, McKinsey & Company (March 2023), <https://www.mckinsey.com/industries/healthcare/our-insights/meeting-changing-consumer-needs-the-us-retail-pharmacy-of-the-future>.



operational and logistical reality is at odds with CMS' note in the draft guidance that indicates the contact requirement "should not, however, be interpreted as a requirement to delay dispensing the medication." Furthermore, such entities would benefit from clarification around expectations for the provision of a "Likely to Benefit" notice from a digital-forward pharmacy that does not include an in-person component. This would include confirmation on whether a digital alert, such as an email, pop-up, online acknowledgement at point of sale or push notification, would be sufficient notice to patients or whether an additional paper notification must be presented to the patient at a later time and prior to the dispense of the prescription that triggers the "Likely to Benefit" notice requirement.

In addition, the section covering the readjudication of prescription drug claims for new program participants (50.4) does not make clear how digital-forward pharmacies should address communications between the Part D sponsor, beneficiary, and themselves given how such transactions occur in near real-time. This is particularly concerning given the lack of clarity around process for digital-forward pharmacies (i.e. paper versus push/email notifications) and how they are expected to coordinate with a Part D sponsor to identify where the MPPP program notification would apply. Lack of real-time updates from Part D sponsors could result in digital-forward pharmacies not being able to sufficiently flag the "Likely to Benefit" notice prior to beneficiary checkout, resulting in the need for readjudication of the claim after check-out.

**Provide clarity on operational gaps identified by Part D sponsors, pharmacies, and other stakeholders.** The final guidance should address numerous ambiguous requirements that leave Part D sponsors, pharmacies, and other stakeholders unsure of how to comply and could result in inconsistencies and unnecessary burdens, disrupting the beneficiary experience.

**Consider how the MPPP program interacts with other changes to the Part D redesign regulatory landscape.** CMS should consider how the new MPPP program interacts with other significant design changes taking place in the Part D program as the Inflation Reduction Act is implemented as well as other recent regulatory developments. For example, Part D sponsors need information that will be included in the final Part D Plan Redesign Instructions (such as the True Out-of-Pocket Costs [TrOOP]) in order to draft materials for the MPPP program.

Thank you for the opportunity to provide feedback on the draft part two guidance of the Medicare Prescription Payment Plan Program which has the potential to build on the success of the Part D program to help Medicare beneficiaries better afford their medications. HLC looks forward to continuing to engage with CMS to help reduce implementation barriers and promote the success of this important program. If you have any questions, please do not hesitate to contact me at [kmahoney@hlc.org](mailto:kmahoney@hlc.org) or (202) 449-3442.

Sincerely,

A handwritten signature in cursive script that reads "Katie Mahoney".

Katie Mahoney,  
Executive Vice President and Chief Policy Officer



March 15, 2024

Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)**

**RE: Healthfirst Comments on Medicare Prescription Payment Plan: Draft Part Two Guidance**

Dear Sir or Madam,

Thank you for the opportunity to provide comments on the Medicare Prescription Payment Plan: Draft Part Two Guidance released via HPMS memo on February 15, 2024.

Our comments and recommendations are described in the following pages.

If you have questions regarding our comments and recommendations, please do not hesitate to contact me at 212-453-4457 or [mhusmann@healthfirst.org](mailto:mhusmann@healthfirst.org).

Thank you,

A handwritten signature in black ink that reads "Michael Husmann". The signature is written in a cursive, flowing style.

Michael Husmann  
AVP, Regulatory Affairs  
Healthfirst



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

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

#### **30.1.1 Required Mailings with Membership ID Card Issuance**

*Under § 423.2267(e)(32), the membership ID card is a model communications material that Part D plans must provide to Part D plan enrollees. It must be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment in the Part D plan or by the last day of the month prior to the plan effective date, whichever is later. The membership ID card must be provided in hard copy, and Part D plans may also provide a digital version, in accordance with § 423.2267(d).*

*For CY 2025, when an individual signs up for a plan, Part D sponsors will be required to include with the membership ID card hard copy mailing:*

- information regarding the Medicare Prescription Payment Plan; and*
- a Medicare Prescription Payment Plan election request form.*

#### **Healthfirst Comments:**

**Sending information on the Medicare Prescription Payment Plan to our D-SNP members that have no cost-sharing for Part D drugs (and therefore will not benefit from M3P) will be confusing for these beneficiaries. Additionally, if the enrollee signed up for M3P at the point of enrollment, it may be confusing to resend an election form/program information. We request that CMS only require the form for enrollees who have not yet elected to enroll into the M3P program.**

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

#### **30.1.2 Evidence of Coverage (EOC)**

#### **30.1.3 Annual Notice of Change (ANOC)**

*CMS is updating the model EOC to include educational information about the Medicare Prescription Payment Plan, given the program's relevance to Part D plans' descriptions of their covered benefits and related cost-sharing responsibilities.*

*The updated model EOC will be released in spring 2024 as part of the general issuance of CY 2025 Model Materials (CMS-10260; OMB 0938-1051).*

*As required under § 423.2267(e)(3), the ANOC is a standardized marketing material that must be provided by Part D sponsors to current Part D enrollees annually and outlines changes in plan costs, coverage, and benefits that take effect on January 1 of the next plan year to help Part D enrollees decide whether to remain in their plan or choose a different plan.<sup>8</sup> In general, the document must be sent to Part D enrollees by September 30 of each year, and posted on the Part D sponsor's website by October 15, prior to the plan year.*



*CMS has added educational language to the ANOC that describes the Medicare Prescription Payment Plan and provides instructions on how to opt into the program.*

*The updated model ANOC will be released in spring 2024 as part of the general issuance of CY 2025 Model Materials (CMS-10260; OMB 0938-1051).*

#### **Healthfirst Comments:**

**We appreciate the inclusion of education information for beneficiaries in the EOC model documents. CMS releasing model materials earlier in the spring allows Medicare Advantage Organizations more time to implement all changes.**

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

#### **30.1.5 Part D Sponsor Websites**

*In addition to offering an election request mechanism, Part D sponsors must provide on their websites:*

- *An overview of the program;*
- *Examples of how the program calculation works with easy-to-understand explanations. CMS encourages Part D sponsors to include a few examples of cost-sharing scenarios that demonstrate when the program would and would not benefit a Part D enrollee;*
- *A description of who is likely to benefit;*
- *The financial implications for the enrollee of participating in the program, including that the program is free to join, there are no fees or interest charged under the program, and the program does not reduce the amount of cost-sharing a participant owes for their Part D prescriptions. Part D sponsors are also encouraged to include information about the \$2,000 Medicare Part D OOP cap in 2025;*
- *The importance of paying monthly bills, including the implications of not paying monthly bills;*
- *A description of how to opt into and out of the program, including timing requirements around election effectuation;*
- *A description of the standards for urgent Medicare Prescription Payment Plan Election, as described in section 70.3.8 of the draft part one guidance;*
- *A description of how Part D enrollees can file complaints and grievances related to the program;*
- *Contact information that Part D enrollees can use to obtain further information; and*
- *General information about the Low-Income Subsidy (LIS) program, including information on recent the LIS expansion of eligibility, and how to apply and enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs), noting that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.*

*Part D sponsors are encouraged to use language from the CMS-developed educational product on the Medicare Prescription Payment Plan and other CMS-provided resources to meet these requirements. The CMS-developed educational product and other resources will be released at a later date and are discussed in more detail in section 40 below. Additionally, CMS encourages Part D sponsors to link to the CMS-developed educational products or CMS-developed resources, where applicable, to ensure the content is up to date.*

### **Healthfirst Comments:**

**Healthfirst appreciates CMS providing educational content to support member understanding of this program.**

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

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

*CMS is also requiring that Part D sponsors put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit during the plan year. At minimum, Part D sponsors must undertake targeted outreach to Part D enrollees if they become aware in advance of a new high-cost prescription for a Part D enrollee that would trigger the pharmacy POS notification process. Specifically, if Part D sponsors have prior authorization or other utilization management edits in place for a drug that, based on their benefit structure, would result in OOP costs above the pharmacy POS notification threshold, then the Part D sponsor must undertake outreach to the Part D enrollee, informing them of the Medicare Prescription Payment Plan and of the opportunity to opt into the program. (More details on this process are below.) A Part D enrollee is less likely to benefit from opting in during the last quarter of a year. For example, in December, the last month of the plan year, because OOP costs incurred in that month cannot be spread over more than one month. As such, a Part D enrollee should not be notified that they are likely to benefit in the last month of the plan year. Additionally, participants who have already opted into the Medicare Prescription Payment Plan should not be notified about opting into the program while their participation is in effect.*

*During the plan year, when a Part D sponsor identifies current Part D enrollees using the above methods, it is required to provide the "Medicare Prescription Payment Plan Likely to Benefit Notice" (as discussed above in section 30.2.1) to the identified Part D enrollee within the same timeframe that applies to the coverage determination for the associated utilization management requirement. For example, if the Part D sponsor receives a request for an expedited coverage determination for a covered Part D drug with OOP costs above the pharmacy POS notification threshold, they must provide the "Medicare Prescription Payment Plan Likely to Benefit Notice" to the Part D enrollee within 24 hours of receiving the request. This outreach must be performed in writing either by mail or electronically (based on the Part D enrollee's preferred and authorized communication methods). The outreach must also include additional information about the Medicare Prescription Payment Plan, and this additional information requirement may be fulfilled by including with the notice a CMS-developed educational product about the program. See section 40.1 for additional information about the product. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed educational products to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through HPMS, and use of marketing materials. Additionally, the initial notice may be provided via telephone, so long as the written "Medicare Prescription Payment Plan Likely to Benefit Notice" and additional information are sent within three calendar days of the telephone notification. Part D sponsors are encouraged to inform the Part D enrollee that they are likely to benefit when contacting the Part D enrollee for other reasons, such as while communicating a prior authorization coverage determination.*

### **Healthfirst Comments:**

While Healthfirst recognizes the importance of targeted outreach to Part D enrollees likely to benefit, we are concerned with the proposal to provide notification within the same timeframe that applies to coverage determination (24 or 72 hours). Generally, prior authorization evaluates clinical appropriateness of the requested Part D drug. It does not consider the out-of-pocket cost of the individual Part D enrollee based on their benefit structure. We recommend allowing additional time for Part D sponsors to identify Part D enrollees likely to benefit based on prescriptions with prior authorization or other utilization management edits.

Furthermore, while we agree with identification of members during the plan year in principle, standing up these capabilities for year one will be challenging for plans. Additional runway in year one would be helpful for smoother identification of likely to benefit members during subsequent plan years.

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

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

*CMS is requiring that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs that exceed a set threshold. The specific threshold amount will be published in the final part one guidance. To fulfill the requirement for pharmacies to then inform the Part D enrollee, the Part D sponsor must require the pharmacy to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” (discussed above in section 30.2.1) to the Part D enrollee. The Part D sponsor must ensure compliance with the language access and accessibility requirements outlined in section 30.4 in the delivery of the “Medicare Prescription Payment Plan Likely to Benefit Notice.” CMS encourages Part D sponsors to provide pharmacies with additional educational material on the Medicare Prescription Payment Plan, such as the CMS-developed educational product described in section 40.1, which could also be distributed to Part D enrollees along with the notice.*

*This requirement to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee. Pharmacies are encouraged, but not required, to provide educational material related to the Medicare Prescription Payment Plan at the time they provide an enrollee with the notice.*

*When a Part D enrollee opts into the Medicare Prescription Payment Plan after receiving the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, in addition to providing the notice of acceptance of election, as described in section 30.3.2 of this guidance, the Part D sponsor is responsible for clearly communicating additional necessary next steps to the Part D enrollee. Next steps may include, but are not limited to, how to proceed with filling any outstanding prescriptions.*

### **Healthfirst Comments:**

Healthfirst agrees with Part D sponsors having a mechanism to notify a pharmacy when a Part D enrollee incurs out-of-pocket cost for a Part D drug that makes the enrollee likely to benefit from participating in the program. However, besides amending pharmacy provider network agreements





and providing education and resources, Part D sponsors have limited means to ensure the pharmacy informs the enrollee they may benefit from the Medicare Prescription Payment Plan.

The health plan does not have visibility into member-pharmacist interactions and therefore cannot enforce specific pharmacist behaviors. 80% of Healthfirst pharmacy utilization occurs at local/independent pharmacies. These pharmacies have vastly different capability maturities than large chain pharmacies, and the plan does not always have direct insight into these capabilities. Therefore, it is difficult to mandate and enforce an approach for each pharmacy. This is particularly true given the burden M3P education will place on pharmacists and members who may have to make an M3P decision at the point of sale.

We encourage CMS to create and disseminate comprehensive guidelines for pharmacy provider requirements to drive aligned adherence.

## **50 Pharmacy Processes**

### **50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount**

*In the draft part one guidance for the Medicare Prescription Payment Plan, CMS stated that the likely to benefit notification required at the pharmacy POS will be based on the OOP costs incurred for a single prescription. Part D sponsors will be responsible for notifying the pharmacy when OOP prescription costs equal or exceed the determined threshold that will be finalized in the final part one guidance. This notification will be returned to the pharmacy on the primary Part D claim response from the Part D sponsor or pharmacy benefit manager (PBM). CMS is aware, however, that a small portion of Part D enrollees will have supplemental coverage, such as through a State Pharmaceutical Assistance Program (SPAP), charity, or other health insurance (OHI). In these cases, the final patient pay amount on a covered Part D prescription drug claim may then be reduced below the required notification threshold because of the contributions of a supplemental payer. CMS intends to provide language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” that recommends enrollees with supplemental coverage seek advice related to their specific situation prior to opting into the Medicare Prescription Payment Plan.*

*Part D sponsors should ensure that their customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election. When discussing a Part D enrollee’s prescription drug costs, customer service representatives may need to review records for Information Reporting (Nx) transactions, indicating supplemental coverage or OHI. As discussed in more detail in the draft part one guidance, all Part D enrollees are eligible for the Medicare Prescription Payment Plan, but those with low OOP costs are less likely to benefit.*

#### **Healthfirst Comments:**

**Healthfirst encourages CMS to factor in Extra Help cost-sharing and VBID Part D cost-sharing reductions in the OOP threshold calculation. From an education perspective, although customer service reps may be aware of the generalities of supplemental coverage, they typically do not have insight into the specifics of a member's situation. It may create confusion for members to expect**



education from reps who are not well versed in a particular member's supplemental coverage implications.

## **50.2 Pharmacy POS Notifications Late in the Plan Year**

*The number of months remaining in the plan year is an important component of the maximum monthly cap calculation.<sup>23</sup> As described in section 30.1 of the draft part one guidance, the maximum monthly cap in the first month of program participation is determined by calculating the annual OOP threshold minus any Part D costs the Part D enrollee incurred during the year before opting in, divided by the number of months remaining in the plan year. Given that the pharmacy POS threshold will be a static amount, this may result in scenarios late in the plan year in which Part D enrollees who receive the “Medicare Prescription Payment Plan Likely to Benefit Notice” at the pharmacy based on their OOP costs, but whose costs are below the maximum monthly cap, are then required to pay the full amount as part of their first month’s bill. For example, if a Part D enrollee has not yet opted into the Medicare Prescription Payment Plan and fills a new prescription with an OOP cost of \$650 in October 2025, their maximum monthly cap in the first month could be as high as \$666.67 (assuming \$0 in prior true out-of-pocket (TrOOP) accumulation). In this scenario, a Part D enrollee could receive the POS notification based on their OOP costs exceeding the threshold, but if they opted into the Medicare Prescription Payment Plan, because their OOP costs are below the maximum monthly cap, the Part D sponsor would bill them for the entire \$650 as part of their first month’s bill.<sup>24</sup> Part D sponsors should ensure that customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election.*

### **Healthfirst Comments:**

**Healthfirst is concerned that the beneficiary calculated payment amounts will be confusing to members, and even with our best efforts to educate and support members that the program may be more negatively than positively perceived by members and health plan ratings for CAHPS may be unfavorably impacted.**

**We also request clarification and/or an example calculation that outlines a scenario where the enrollee has limited out-of-pocket cost incurred for the majority of the year, opts into the Medicare Prescription Payment Plan towards the end of the year (October or November) and incurs a cost that exceed the maximum monthly cap.**

## **50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies**

### **50.3.3 Other Pharmacy Types**

*CMS notes that regardless of the setting, if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the Part D sponsor must ensure that the pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee. For example, if a Part D enrollee visits a retail pharmacy to pick up their prescription but then declines to complete the transaction because of the cost, the Part D sponsor must still ensure that the pharmacy provides the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” to that Part D enrollee.*





*Pharmacies may also choose to develop additional strategies to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to enrollees identified as likely to benefit. For example, pharmacies with disease management or medication management programs may choose to include Medicare Prescription Payment Plan information as a component of those processes. In addition to providing a hard copy, pharmacies may also choose to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in other modes of communication with enrollees identified as likely to benefit, such as through a patient portal or secure email.*

*For other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. This requirement should not, however, be interpreted as a requirement to delay dispensing the medication. Pharmacies are encouraged to utilize existing touchpoints with Part D enrollees, such as outreach to review medication instructions or collect a method of payment, to convey the content of the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to processing payment for the prescription that triggered the notice. CMS encourages Part D sponsors to work with pharmacies to establish and maintain reasonable procedures related to the timing and number of attempts for prompt notification of identified Part D enrollees.*

#### **Healthfirst Comments:**

**Besides amending pharmacy provider network agreements and providing education and resources, Part D sponsors have limited means to ensure the pharmacy informs the enrollee they may benefit from the Medicare Prescription Payment Plan. We encourage CMS to create and disseminate comprehensive guidelines for pharmacy provider requirements to drive aligned adherence. We also request that CMS provide clarification for expectations when a person picks up the prescription on behalf of the Part D enrollee.**

#### **50.4 Readjudication of Prescription Drug Claims for New Program Participants**

*Part D enrollees who opt into [M3P] will pay \$0 at the POS for a covered Part D drug instead of the OOP cost-sharing they would normally pay when filling a prescription. For claims to be processed appropriately using the [M3P] BIN/PCN methodology, the date of service on the primary Part D claim and the additional program-specific transaction must be on or after the date of program effectuation. When a Part D enrollee receives the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription. As such, when the Part D enrollee returns to the pharmacy to pick up their prescription(s) after successfully opting into the program, all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary must be readjudicated to allow for appropriate processing by the Part D sponsor and/or PBM. This includes unpaid claims for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification.*

*For example, a Part D enrollee is prescribed a new medication with an OOP cost that is above the POS notification threshold. The plan would notify the pharmacy that the enrollee is likely to benefit from the Medicare Prescription Payment Plan. The pharmacy would then provide [notice] to the Part D enrollee.*



*The enrollee decides to leave the pharmacy without paying for their high-cost prescription, so they can contact their plan and opt into the program. However, the pharmacy also has two other covered Part D prescriptions filled for the Part D enrollee from prior dates of service, for which the Part D enrollee also decided to leave the pharmacy without picking up and paying. When the Part D enrollee returns to the pharmacy after their election into [M3P] has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess all three claims, so the program participant pays \$0 at the pharmacy for all three drugs. Alternatively, the Part D enrollee could choose to pick up and pay for the two other covered Part D prescriptions at the initial pharmacy visit and only return for the high-cost prescription that triggered the notification once their election into [M3P] has been effectuated. The pharmacy must then reverse and reprocess only the claim for the high-cost prescription that is being billed under the program, so that the program participant pays \$0 at the pharmacy for that prescription. This same process applies when the Part D enrollee has prescriptions that have not yet been picked up and paid for at multiple pharmacies.*

*In the case of same-day program effectuation (when the Part D claim date of service is the same as the date of program effectuation), the pharmacy is not required to reverse and resubmit the Part D claim, provided that they otherwise obtain the necessary [M3P] BIN/PCN for the program-specific transaction.*

*CMS notes that, in general, plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for by the Part D enrollee. As noted in section 70.3.8 of the draft part one guidance, Part D sponsors must have processes in place to reimburse enrollee cost-sharing for urgent prescriptions when an enrollee has met the conditions for a retroactive election into the [M3P].*

#### **Healthfirst Comments:**

**Given the real-time nature of pharmacy claim adjudication, Part D sponsors do not have insight to know if a member has picked up and paid for a prescription. Besides amending pharmacy provider network agreements and providing education and resources, Part D sponsors have limited means to ensure the pharmacy informs the enrollee they may benefit from the Medicare Prescription Payment Plan and readjudicates Part D claims the enrollee decided to not pick up and pay for while enrolling in the Medicare Prescription Payment Plan. We encourage CMS to create and disseminate comprehensive guidelines for pharmacy provider requirements to drive aligned adherence.**

**Additionally, once an enrollee opts to join the Medicare Prescription Payment Plan, the enrollee may no longer have knowledge at point-of-sale of the cost they are incurring for the Part D drug, which could hinder the enrollee's ability to make cost-driven costs, such as use of generics or lower tier formulary alternatives. We encourage CMS to consider enrollee's awareness to incurred cost when developing education resources.**

Humana Inc.  
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**Humana**

March 16, 2024

Meena Seshamani, M.D., Ph. D.  
Deputy Administrator and Director of the Center for Medicare  
7500 Security Boulevard  
Baltimore, Maryland 21244

Re: Comments on Part Two of the Medicare Prescription Payment Plan Guidance

Dear Dr. Seshamani,

Humana appreciates the opportunity to offer feedback and recommendations to CMS on the Medicare Prescription Payment Plan established by the Inflation Reduction Act (IRA). We provide these comments in response to the CMS proposed guidance dated February 15, 2024, titled *“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.”* Humana currently services approximately 5.9 million beneficiaries enrolled in our Medicare Advantage (MA) plans and 2.9 million beneficiaries enrolled in our Medicare Part D Prescription Drug Plans (PDPs). As a long-time sponsor of Part D plans, we hope you find our feedback and recommendations constructive in developing a viable approach to enrollee cost-sharing flexibility in calendar year 2025 and beyond.

Humana supports the policy goal of establishing the Medicare Prescription Payment Plan (MPPP) as a mechanism to allow Part D enrollees to spread significant costs over time in lieu of a single larger expense. As CMS works to finalize the details of the payment plan, the agency should:

- **Develop robust communication tools about the payment plan that can be used by all stakeholders** to educate beneficiaries, with a focus on who the program will and will not benefit and prioritize the outreach to those beneficiaries who are most likely to benefit from the payment plan before the start of the coverage year. **However**, we caution CMS that requiring inclusion of MPPP model materials on certain existing communications to members may not be appropriate and could lead to member confusion.
- **Finalize the proposed model materials in advance of the 2025 Annual Enrollment Period (AEP).** Final OMB approval of this material in July 2024 would give Part D plan sponsors enough time to integrate the documents into member communications before the 2025 AEP. If, however, the model documents are not available until later in the summer it may be difficult for plan sponsors to employ them in the lead up to the AEP.
- **Balance the financial benefits of payment plan participation to enrollees with the potential for program abuse** by participants who may never fulfill their financial responsibilities under the payment plan. We believe that CMS must establish additional mechanisms under the program to encourage participants to adhere to their monthly payments whenever possible.

- **Afford Part D plan sponsors a degree of flexibility in the first year or two of the MPPP.** CMS is proposing a wide range of program requirements applicable to plan sponsors and reserving the right to conduct audits and other compliance activities related to MPPP. While we anticipate working with CMS to facilitate successful implementation of the payment plan, we also encourage CMS to use careful discretion in seeking to enforce the myriad program provisions.

We value this opportunity to provide recommendations related to the MPPP and are pleased to answer any questions you may have with respect to the comments below. As always, our feedback is aimed at ensuring that together we continue to advance our shared goals of improving the delivery of coverage and services in a sustainable, affordable manner to Medicare beneficiaries, and improving their total health care experience. We hope you find this feedback helpful.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Hoak", is positioned above the printed name and title.

Michael Hoak  
Vice President, Public Policy

CC:

Cheri Rice, Deputy Director, Center for Medicare

Jennifer Shapiro, Group Director, Medicare Plan Payment Group

Vanessa Duran, Acting Group Director, Medicare Drug Benefit and C & D Data Group

## **Section 20. Overview of the Medicare Prescription Payment Plan**

CMS provides a high-level summary of the anticipated MPPP program functionality and notes the focus of the part two guidance is on enrollee communications materials and expectations for Part D plan sponsors in providing such communication materials.

**Humana Comment:** We thank CMS for voluntarily soliciting comments on the proposed member and pharmacy communication requirements applicable to Part D plan sponsors. In the responses we offer below, we provide both recommendations for streamlining member communications on the MPPP and suggestions for establishing a viable framework for targeting those communications to individuals most likely to benefit from program participation. **We share the belief that payment plan participation benefits a relatively small portion of the larger Part D population and believe it is essential to identify those members prior to the start of the coverage year whenever possible to ensure timely elections into the payment plan.**

Simultaneously, we ask CMS to finalize this part two guidance no later than May 1 and expedite the approval of the proposed model materials to the greatest extent possible. Humana continues to believe that the operations related to the payment plan will be some of the most complex provisions from the IRA to implement, involving new enrollment, billing, and claims processing mechanisms. We believe all Part D sponsors stand to benefit from timely guidance from CMS in proactively preparing for the launch of the MPPP.

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

CMS proposes a range of enrollee communication requirements applicable to Part D plan sponsors. CMS requests public comment on the scope of included materials, including updated existing Part D materials and newly developed resources; their use, content, and distribution; ways to ensure all Part D enrollees receive information in an easy-to-understand manner, including at an appropriate literacy level and using language that allows all Part D enrollees, particularly those who may have language and accessibility barriers, to make an informed decision; and other potential materials that may be appropriate to modify or develop that are not currently included in this section.

### Section 30.1 General Outreach and Education

#### 30.1.1 Required Mailings with Membership ID Card Issuance

CMS proposes to require Part D plan sponsors to include information regarding the MPPP and an MPPP election request form when providing an enrollee with a hard copy of their plan membership ID card.

**Humana Comment:** As noted above, MPPP participation benefits a relatively small portion of the full Part D population, and it will be important to identify those enrollees most likely to benefit from enrollment in the program. Accordingly, we believe that providing an election request form to all members, most of whom will not benefit from the MPPP, along with the plan membership ID card could result in **member confusion** related to whether the MPPP participation election is required as part of their enrollment in their Part D plan. This would be a new communication included with new enrollment information and members may think that completing the form is a necessary part of their successful enrollment in the plan, which could lead to members who would not benefit from MPPP participation being enrolled.

Of note, Humana does not issue a new membership card to each enrollee every coverage year. Members who are continuing their membership in the same Medicare Advantage or Part D plan

often retain a valid membership ID card for multiple coverage years. The part two guidance indicates that Part D plan sponsors will be required to furnish individuals with information on the MPPP along with the hard copy mailing of the membership ID card. However, the guidance is unclear as to whether or how this information must be provided to an individual who will not receive a new membership ID card. We ask for clarification on this issue. If CMS intends for this hard copy information on MPPP to reach every member, Humana believes that it may be more appropriate to include the information in tandem with the confirmation of enrollment letter sent to members who affirm their enrollment in a specific plan providing Part D coverage.

Separately, Humana is concerned that the final part one guidance on the MPPP, released by CMS on February 29, 2024, includes references to many proposed part two requirements not yet finalized. For example, section 60.1 of the final part one guidance includes text indicating that Part D plan sponsors will be required to use existing Part D communications materials to convey information about the MPPP, including the “membership ID card mailing that plans must provide to new Part D enrollees.” We are concerned that CMS has seemingly assumed that some of its proposed requirements will be finalized even before considering stakeholder feedback received in response to the proposed part two guidance. We understand that CMS is voluntarily soliciting comments on this guidance without a formal requirement to do so, but we hope CMS will consider stakeholder feedback in earnest before finalizing this part two guidance.

#### 30.1.2 Evidence of Coverage (EOC)

CMS proposes to require Part D plan sponsors to include educational information about MPPP as part of the updated Evidence of Coverage (EOC) model document, which is expected to be released in spring 2024.

**Humana Comment:** Humana supports CMS’s proposal, and appreciates the timeframe suggested for the issuance of model materials, as this is consistent with the general schedule for updated EOC model documents.

#### 30.1.3 Annual Notice of Change (ANOC)

CMS proposes to require Part D plan sponsors to utilize an updated Annual Notice of Change (ANOC) model document including educational language on MPPP, which is expected to be released in spring 2024.

**Humana Comment:** Humana supports CMS’s proposal, and appreciates the timeframe suggested for issuance of the model materials, as this is consistent with the general schedule for updated ANOC model documents.

#### 30.1.4 Explanation of Benefits

CMS proposes to require Part D plan sponsors to utilize an updated Explanation of Benefits (EOB) document which includes information about the MPPP and explains that enrollees who participate in the MPPP will receive a separate monthly MPPP billing statement. The EOB also explains that costs included in the EOB might differ from what a MPPP participant paid at the point of sale. After considering comments received during the 30-day comment period, CMS expects to issue a final EOB for CY 2025 in spring 2024 as part of the general issuance of CY 2025 model materials.

**Humana Comment:** Humana has concerns about including information about the MPPP in the EOB document. EOBs are sent to enrollees multiple times throughout the coverage year, including late in the year, when MPPP enrollment would be less beneficial, even to a member likely to benefit had they enrolled in MPPP earlier in the year. This requirement would also

mean that members who are not likely to benefit from MPPP enrollment would receive this information on multiple occasions. We recommend that CMS modify this proposal to require the inclusion of high-level information about the MPPP in the EOB, and direct members to where they can learn more about MPPP if they are interested.

#### 30.1.5 Part D Sponsor Websites

CMS proposes to require Part D plan sponsors to include a wide range of information on the MPPP on their websites. This includes a program overview, enrollment information, examples of monthly payment calculations, and points of contact for additional program details, among other required information.

**Humana Comment:** Humana supports this proposal to require information on the MPPP to be included on our website.

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

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

CMS is developing a standardized notice for Part D enrollees identified as likely to benefit from the Medicare Prescription Payment Plan, the “Medicare Prescription Payment Plan Likely to Benefit Notice.” CMS proposes to require Part D plan sponsors use this notice to satisfy their obligation to perform targeted outreach to Part D enrollees who are identified as likely to benefit prior to and during the plan year, including those identified through the pharmacy notification process. The standardized notice is expected to be made available in summer 2024.

**Humana Comment:** We concur with CMS’s assertion that “(e)arly notification will streamline the election process and prevent drug dispensing delays.” We support development of the proposed “Medicare Prescription Payment Plan Likely to Benefit Notice” and encourage the use of standardized materials to communicate the details of the MPPP to Part D enrollees as part of a coordinated effort to limit enrollee confusion about the program. **We strongly urge CMS to expedite review and approval of the model materials.**

We appreciate the timely release of the proposed model documents on February 29, initiating the Paperwork Reduction Act (PRA) approval process. We have begun reviewing the proposed model materials and will provide any relevant comments on the materials through the PRA process. But we also caution that plan sponsors will need to access the finalized model materials **in advance of the CY 2025 AEP**. Final OMB approval of this material in July 2024 would give Part D plan sponsors enough time to integrate the documents into member communications before the 2025 AEP.

Additionally, we urge CMS to craft model documents in ways that satisfy Part D plan sponsors’ potential obligations under federal and state laws related to payment plans, credit reporting, and debt collection. In its final part one guidance, CMS specifically stated that sponsors are required to adhere to these laws. This position now potentially imposes certain obligations on plan sponsors regarding disclosures to consumers under those federal and state laws. In particular, the federal Truth in Lending Act (TILA), which as implemented by the Consumer Financial Protection Bureau’s (CFPB’s) Regulation Z, requires highly technical disclosures to be given to a consumer in connection with a consumer credit transaction that does not bear interest but is “payable by written agreement in more than four installments (not including a

down payment).”<sup>1</sup> To the extent such disclosures are required under the laws that CMS and the CFPB will require plan sponsors to follow, CMS’s own template materials should conform to the laws by including the needed disclosures. CMS including this language in the template materials would significantly lessen burden across the entire industry and ensure that this information is being provided to beneficiaries in a consistent manner. We believe using consistent language as much as possible will help improve beneficiary understanding and reduce confusion about this new program.

### 30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year

CMS proposes to require that Part D sponsors, prior to and during the plan year, identify Part D enrollees likely to benefit from the program and undertake targeted outreach to inform those Part D enrollees of the program. CMS recently finalized the “likely to benefit” standard proposed in the part one MPPP guidance.

**Humana Comment:** We agree with CMS that payment plan participation should be targeted towards individual enrollees who incur, or can be expected to incur, substantial OOP costs under Part D, as those are the beneficiaries who are most likely to benefit from the payment plan. We also agree that Part D enrollees who incur high OOP costs early in the coverage year have the highest likelihood to benefit from participation in the payment plan. We continue to believe that CMS should emphasize the importance of making payment plan elections during the AEP whenever possible. We thank CMS for finalizing the part one MPPP guidance to give Part D plan sponsors adequate time to develop operational protocols consistent with the “likely to benefit” standard adopted by CMS.

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

CMS proposes to require Part D plan sponsors to assess their current Part D enrollees’ prescription drug costs from the current year and conduct outreach to Part D enrollees who incurred \$2,000 in OOP costs for covered drugs through September of that year. CMS proposes a process in which plan sponsors must, during the fourth quarter of the year, review their Part D claims history from the first three quarters of the year to identify Part D enrollees likely to benefit in the upcoming year. CMS anticipates that plan sponsors would then use standardized materials to conduct outreach to identified beneficiaries by the end of the Medicare Annual Election Period.

**Humana Comment:** We appreciate the additional details on the “likely to benefit” standard provided by CMS in the part one guidance. We concur that MPPP outreach should be targeted to those individuals most likely to hit the annual maximum out-of-pocket (MOOP) cap established under the IRA. Based on an informal internal analysis, we suspect a small percentage of Part D enrollees can be expected to reach the MOOP annually.

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

CMS also proposes to require Part D plan sponsors to establish reasonable guidelines for ongoing identification of Part D enrollees likely to benefit *during* the plan year. At a minimum, Part D sponsors must undertake targeted outreach to Part D enrollees if they become aware in advance of a new high-cost prescription for a Part D enrollee that would trigger the pharmacy POS notification process.

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<sup>1</sup> See definition of “creditor” in Section 1026.2(a)(17)(i) of Regulation Z implementing TILA.



**Humana Comment:** We appreciate the additional transparency from CMS on the identification of Part D enrollees “likely to benefit” from MPPP participation. CMS states that Part D plan sponsors must undertake outreach to an enrollee if the plan has “prior authorization or other utilization management edits in place for a drug that, based on their benefit structure, would result in OOP costs above the pharmacy POS notification threshold.” It may be challenging to identify during the Coverage Determination process the ultimate costs the member will pay at point of sale as this is not part of the clinical review generally needed, particularly in the existing required timeframes of 24 or 72 hours. We ask that CMS update this guidance to clarify that this additional communication would apply to approved prior authorizations and allow plans flexibility in which members receive this communication. Including information related to MPPP in denials would cause additional confusion for members not eligible for Part D coverage of the medication based on the Utilization Management review.

Moreover, Humana interprets Section 30.2.2.2 as not requiring Part D sponsors to implement new high-cost edits or to modify any existing high-cost edits to mirror the “likely to benefit” threshold which CMS established in the final part one guidance. We ask that CMS clarify that it does not intend for Part D sponsors to implement or modify high-cost pharmacy edits to match the \$600 single-drug threshold.

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

Building on requirements proposed in part one of the MPPP guidance, CMS proposes to require that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs that exceed a set threshold finalized in the part one guidance. To fulfill the requirement for pharmacies to then inform the Part D enrollee, the Part D sponsor must require the pharmacy to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice.”

**Humana Comment:** In section 60.2.4 of the final part one guidance on the MPPP, CMS establishes use of a set dollar threshold of \$600 to trigger the requirement for a point-of-sale (POS) notification to a Part D enrollee who is “likely to benefit” from program participation. CMS previously conducted claims analysis suggesting that an enrollee having a single prescription fill associated with OOP costs in the range of \$400-\$700 is highly likely to benefit from MPPP participation and a dollar threshold in this range should thus be the trigger for a plan sponsor to notify a pharmacy of the potential benefit of MPPP participation for the enrollee. The pharmacy or pharmacist would then provide such an enrollee with the proposed “Medicare Prescription Payment Plan Likely to Benefit Notice” or some variation of that model material. **Humana agrees with CMS’s logic in this matter, including the use of a dollar threshold on the OOP cost for a single claim, and supports using a \$600 threshold for the first year of the program.**

Additionally, with regard to enrollee education requirements under the MPPP, CMS should take into account specific nuances that may arise when prescriptions are filled with mail-order pharmacies and other closed-door pharmacies. These specialized pharmacies should not be required to educate the member on the MPPP in advance of dispensing the product if it could result in a delay of the medication delivery. As such, these pharmacies should be allowed to include materials about the MPPP in the packaging when the member hits the threshold. CMS seems to recognize the need for specific considerations related to mail-order and long-term care pharmacies, which are reflected in section 50 of this guidance.

### 30.2.3 Communications with Contracted Providers and Pharmacies

CMS encourages, but does not require, Part D plan sponsors to furnish contracted providers and network pharmacies with education and resources related to the MPPP. CMS suggests such resources should target subgroups of providers based on provider specialty and likelihood of prescribing high-cost covered Part D drugs.

**Humana Comment:** Humana appreciates CMS's recognition that providers and pharmacies must necessarily play a key role in educating enrollees about the MPPP. We believe it will be vital for providers and pharmacies to work in tandem with Part D plan sponsors to assist the enrollee decision-making process and convey both the potential benefits and responsibilities associated with MPPP participation.

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

### 30.3.1 Overview of Election Requirements

CMS references statutory requirements and portions of the part one MPPP guidance to remind Part D plan sponsors of enrollee election requirements. Part D sponsors must allow Part D enrollees to opt into the MPPP during Part D plan annual enrollment periods, initial Part D enrollment periods, and special Part D enrollment periods. Further, as noted in section 70.3.1 of the final part one guidance, Part D sponsors must offer paper, telephone, and website program election options. CMS also reminds Part D plan sponsors that they must provide general information about applying for the LIS program and how to enroll when communicating with enrollees about the MPPP.

**Humana Comment:** Humana agrees that Part D enrollees should have access to multiple pathways for making MPPP participation elections. We believe that the process of communicating with enrollees about MPPP participation should be streamlined and consistent, and program elections should be as simple as possible. However, we believe CMS should strive to avoid enrollee confusion whenever possible. We have some concern that requiring information about LIS enrollment in tandem with information on MPPP could drive an increase in enrollee confusion. We look forward to working with CMS to limit enrollee uncertainties to the greatest extent possible.

#### 30.3.1.1 Request to Participate in the Medicare Prescription Payment Plan

CMS is developing a model "Medicare Prescription Payment Plan Participation Request Form" for Part D sponsors that Part D enrollees can use to initiate the request to opt into the program. Part D sponsors must accept election requests they receive regardless of the format of the request (e.g., a letter or email). When a Part D sponsor receives an election request in an alternate format and required information is missing, they must contact the Part D enrollee telephonically or electronically to collect all missing information.

**Humana Comment:** Humana appreciates the timely release of the proposed "Medicare Prescription Payment Plan Participation Request Form" on February 29. If we have additional feedback on this draft document, we will provide it through the PRA approval process.

#### 30.3.1.2 Paper Election Requests

CMS outlines requirements associated with paper election requests and submissions. This includes proposing the form of the paper election request form and establishing standards for election request dates linked to the delivery of the request form via multiple shipping services.

**Humana Comment:** Humana is supportive of the paper elections process detailed here by CMS.

#### 30.3.1.3 Telephonic Election Requests

CMS proposes requirements associated with telephonic election requests and submissions. CMS indicates that election request date is the date on which a verbal request is made with a plan customer service representative or the date on which a message is left on the Part D sponsor's voicemail system if the Part D sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

**Humana Comment:** Humana appreciates this clarity on the handling of MPPP elections requests received via telephone.

#### 30.3.1.4 Website Election Requests

CMS proposes requirements associated with web-based election requests and submissions. CMS indicates that election request date is the date on which the enrollee completes the request through the Part D plan sponsor's secure electronic portal. CMS expects Part D sponsors to complete the entirety of the Medicare Prescription Payment Plan election request process, including documenting the individual's agreement to the Part D sponsor's terms and conditions, in that single electronic election request.

**Humana Comment:** Humana appreciates this clarity related to website election requests and concurs with CMS's perspective. We request confirmation from CMS that the MPPP website election request form can be accessed via a plan's member portal, after the enrollee signs in. To deliver a best-in-class integrated experience, this option will allow Humana to validate that the member is enrolled in a plan with Part D coverage and that they are eligible for MPPP enrollment. Existing and new members will be able to log into their MyHumana account to opt-in, using a familiar touchpoint that is used by over two thirds of our current membership. For members who have chosen not to set up a MyHumana account, information on the general website will refer them to call our member line to enroll; both the paper election form and telephonic enrollment will remain options for MPPP election.

#### 30.3.2 Notice of Acceptance of Election

CMS proposes requirements for Part D plan sponsors following acceptance of an enrollee election request. Once the program election request is accepted by the Part D sponsor, the Part D sponsor must communicate that the request to participate in the Medicare Prescription Payment Plan has been accepted and effectuated via written notice. For requests received prior to the plan year, Part D sponsors are required to send a written notice of acceptance of election within the timeframes specified in the final part one guidance. For requests received during the plan year, the Part D sponsor must deliver the notice of acceptance of election within the specified timeframe first telephonically and then via a written notice. CMS indicates that it is developing a written model notice to assist plan sponsors.

**Humana Comment:** Humana supports the proposed approach to contacting Part D enrollees following acceptance of their election into the MPPP.

### 30.3.3 Notice of Failure to Pay

CMS references part one guidance which directs a Part D plan sponsor to send an enrollee who fails to pay a monthly billed amount an initial notice explaining that the individual has failed to pay the billed amount within 15 calendar days of the payment due date. CMS is developing a written model notice to assist plan sponsors.

**Humana Comment:** Humana appreciates the additional detail related to the required initial notice of failure to pay that must be provided to an MPPP participant when that participant has failed to pay a monthly billed amount under the program. We will be reviewing the recently released model document entitled “Part D Sponsor Notice for Failure to Make Payments under the Medicare Prescription Payment Plan” and will offer any comments on the proposed model through the PRA process.

Humana continues to encourage CMS to balance the financial benefits of payment plan participation to enrollees with the potential for program abuse by participants who may never fulfill their financial responsibilities under the payment plan. We believe that CMS must establish additional mechanisms under the program to encourage participants to adhere to their monthly payments whenever possible. As noted throughout our responses to the part one guidance, we recognize the payment plan is designed to ease financial pressures on participants, but caution that the program could result in plan sponsors carrying significant delinquent or unpaid balances. It will be essential for CMS to give plan sponsors the flexibility to take a range of actions to limit the accrual of unpaid amounts under the payment plan, including allowing plan sponsors the ability to determine the billing timeline for the payment plan and establish incentives to ensure participants pay the payment plan bills, as well as allowing plans to bill the member in full upon disenrollment or to establish a payment plan that is shorter in duration for disenrolled members.

### 30.3.4 Notice of Termination of Election Following End of Grace Period

CMS notes Part D sponsors must provide a notice of termination of participation to Part D enrollees who have failed to pay their outstanding balance within the required grace period. This notice must be sent within three calendar days after the end of the grace period. CMS is developing a written model notice to assist plan sponsors.

**Humana Comment:** Pursuant to section 80.2.2 of the final part one guidance on the MPPP, Part D plan sponsors must furnish a participant with a grace period of at least two months once that participant has failed to pay the billed amount by the payment due date. Consistent with statutory requirements, a plan sponsor must terminate the participation of an MPPP participant following the grace period. CMS proposes that the notice of termination be sent within three calendar days of the end of the grace period. Humana recommends that, within three days of the end of the grace period, the notice be considered mailed when it leaves the Part D sponsor’s possession (or delegated entity) vis-a-vis deposit into the courier drop box or external outgoing mail receptacle (e.g., U.S. Postal Service or FedEx bin). This is consistent with the requirements for Part D sponsors under Section 10.5.3 of the “Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.” Additionally, we request clarification on whether there are any requirements dictating the mode in which this information is delivered (i.e., electronically delivered if an enrollee has opted-in to electronic communications).

Further, Humana continues to have concerns about the length of the required grace period. The requirement for a minimum grace period of two months could result in plan sponsors holding the full balance of a participant's incurred costs for three months or even longer. We continue to encourage CMS to balance the ability of Part D enrollees to participate in the MPPP with sufficient safeguards designed to prevent program abuse.

#### 30.3.5 Notice of Voluntary Termination

Part D sponsors must have a process in place to allow Part D enrollees participating in the Medicare Prescription Payment Plan to voluntarily terminate their participation in the program. The plan sponsor must process the participant's voluntary termination request and send the individual a notification confirming the termination within 10 calendar days of receipt of the request. CMS is developing a written model notice to assist plan sponsors, which is expected to be released in summer 2024.

**Humana Comment:** Humana requests clarification on the claims process if the voluntary termination occurs and within the 10-day window, a person fills a prescription. We urge CMS to clarify whether that claim should be processed as part of the MPPP and how that claim should be adjudicated if it falls within the processing window.

#### Section 30.4 Language Access and Accessibility Requirements

CMS notes that communication materials under the MPPP must be provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds. A range of existing guidance and Part D requirements apply to these communications, including the requirement for plan sponsors to use a multi-language insert (MLI) when an enrollee is provided a CMS-required material such as those outlined here.

**Humana Comment:** CMS should clarify that existing requirements related to accessibility and translation apply and that the only new requirement for the MPPP program is to add new MPPP required communications to the existing Part D regulations at § 423.2267(e). This would require that Part D sponsors must provide MPPP materials to Part D enrollees on a standing basis in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area. Additionally, the MLI would be required in all of these materials. Required MPPP materials should include the Election Request Form, Notice of Election Approval, Notice of Failure to Pay, Notice of Involuntary termination, Notice of Voluntary termination, and the "Medicare Prescription Payment Program Likely to Benefit Notice."

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

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

CMS intends to develop and provide an educational product for Part D enrollees on the Medicare.gov website and through other communication channels. Additionally, interested parties, such as Part D sponsors, pharmacies, providers, beneficiary advocates, and others, are encouraged to use this product to educate Part D enrollees.

**Humana Comment:** Humana appreciates that CMS plans to update many of its existing resources to include information about the MPPP. We have continued to support a unified approach to MPPP communications and applaud any efforts to ensure that communication materials on the program are as uniform as possible.

In our responses to the part one guidance on the MPPP, Humana recommended that CMS develop an interactive and dynamic cost calculation tool for use by enrollees interested in MPPP participation. **We are disappointed that neither the final part one guidance nor this proposed part two guidance indicate CMS’s intent to offer such a calculator tool.** We feel that a standardized tool associated with this novel program would represent an enrollee-centric approach to presenting information on the payment plan. An effective calculator tool developed by CMS would allow plan sponsors to link to a uniform instrument to guide members towards the most appropriate individual participation decision. Moreover, CMS could utilize a calculator tool landing page to caution and caveat participation in the payment plan to ensure that Part D enrollees comprehend both the benefits and risks associated with the program, such as the potential for high cost-sharing bills at the end of the coverage year.

We also recommend that CMS include information and education related to MPPP participant payment requirements in the proposed educational product under development. As noted in our response to the proposed section 30.3.3, we remain concerned about the potential for significant participant payment delinquencies under the MPPP. We fully support CMS’s efforts to promote the MPPP to individuals who are “likely to benefit” from participation but urge equivalent efforts to educate potential participants about their financial responsibilities if they elect to participate.

#### **Section 50. Pharmacy Processes**

CMS provides additional information around pharmacy processes related to the MPPP. Except as otherwise required in this guidance or under other applicable requirements, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including but not limited to, mail order, home infusion, specialty, and long-term care pharmacies.

##### Section 50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount

CMS notes that some small portion of Part D enrollees will have supplemental drug coverage impacting OOP costs. CMS intends to recommend that such enrollees seek additional advice on their individual situations prior to opting into the MPPP. CMS directs Part D plan sponsors to prepare their customer service representatives to address such situations.

**Humana Comment:** Humana appreciates the suggestions offered by CMS with regard to supplemental prescription drug coverage. We support CMS’s intent to include language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” recommending enrollees with supplemental coverage seek advice related to their specific situation prior to electing to participate in the MPPP. However, Humana also encourages CMS to include similar language in this model document aimed at Part D enrollees who may be using supplemental drug products covered by an MA-PD or PDP plan that are not Part D covered drugs. Pursuant to the IRA, such drug products are not eligible for inclusion in the MPPP. Here again, we caution CMS that enrollee confusion is possible but also urge CMS to provide complete and accurate information via the model documents.

##### Section 50.2 Pharmacy POS Notifications Late in the Plan Year

CMS cautions that the pharmacy POS notification threshold will be a static amount that does not change during the year. This may lead to scenarios in which a Part D enrollee is notified that he/she may benefit from MPPP participation late in the plan year – when the “benefit” of participation may be illusory. CMS

indicates Part D sponsors should ensure that customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election.

**Humana Comment:** In Section 60.2.4 of the final part one guidance, CMS indicates that POS notification should not occur in December when members may no longer benefit and have no ability to spread incurred costs over multiple months. Humana believes CMS should, for the sake of consistency, reaffirm this directive in the final part two guidance to ensure that the required POS notification is not provided to Part D enrollees who fill a prescription(s) in December, regardless of the out-of-pocket costs associated with that prescription.

In this vein, we also encourage CMS to revisit the POS notification requirement applicable to future calendar years. Based on informal, internal calculations, Humana believes the POS notification will only be of value to Part D enrollees during the first three quarters of the calendar year. In other words, we would strongly support a POS notification requirement that is in place from January through September of each year. We believe CMS should take extra care in developing its model materials and associated communications to reflect that late year MPPP elections are not likely to benefit Part D enrollees, with few exceptions.

#### 50.3.3 Other Pharmacy Types

For other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. This requirement should not, however, be interpreted as a requirement to delay dispensing the medication.

**Humana Comment:** Humana supports this clarification and the related flexibility to communicate with the member via their preferred contact method while ensuring that medication dispensing is not delayed.

#### Section 50.4 Readjudication of Prescription Drug Claims for New Program Participants

When a Part D enrollee receives the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription. As such, when the Part D enrollee returns to the pharmacy to pick up their prescription(s) after successfully opting into the program, all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary must be readjudicated to allow for appropriate processing by the Part D sponsor and/or PBM.

**Humana Comment:** Humana appreciates the intent to ensure members who opt into the program benefit; however, based on current NCPDP claims submission standards a Part D plan sponsor will not have the ability to recognize the scenarios outlined by CMS in this guidance. In cases where a member has left the pharmacy counter, enrolled in the MPPP program, and returned to the counter to pick up a prescription that was previously filled, it will be difficult, if not impossible, for Part D plan sponsors to recognize or clearly identify the chain of events. Updating model documents or educational materials to the member for such scenarios may be the most appropriate mechanism to ensure that members are aware that the pharmacy can reprocess the claim.

In addition, backdating the date of member opt-in would pose challenges and potentially create additional member confusion. Moreover, such an approach is seemingly counter to sections

70.3.6 – 70.3.8 of the final part one guidance, which outlines the scenarios where retrospective elections will be processed.

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

CMS outlines several additional operational requirements that Part D sponsors should be aware of and must comply with in implementing the program.

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

CMS indicates that Part D sponsors will be required to report information related to the program through PDE records and new reporting requirements. Additional guidance on PDE reporting will be issued as part of the PDE reporting instructions, which are expected to be published in spring 2024. CMS also intends to monitor and collect data about beneficiary complaints and grievances reported via the Medicare Complaints Tracking Module (CTM) to assess compliance with all Medicare Prescription Payment Plan requirements, beneficiary protections, and program integrity.

**Humana Comment:** Humana would appreciate additional clarity related to which MPPP beneficiary notifications will generate appeal rights. Additionally, Part D plan sponsors would benefit from knowing how the related appeals and grievances should be presented in the Part C & D Annual reporting as well as CMS program audit universes.

#### **Section 60.4 Audits**

CMS and/or its contractors may conduct specific audits of Part D sponsors' implementation of the MPPP and may initiate audit activity that requires additional data collection or site visits.

**Humana Comment:** Humana would appreciate additional clarification related to the types of audit activity CMS is considering. Having information related to data collection, site visits, or other implementation oversight activities in advance will ensure Part D plan sponsors can include the necessary elements during their implementation. Alternatively, Humana would suggest more informal monitoring processes for the initial year of the program to allow plan sponsors to focus efforts on the operations related to the payment plan. We believe these operations will be some of the most complex provisions from the IRA to implement, involving new enrollment, billing, and claims processing mechanisms.



hello plasease i want prescription / suboxone or subutex please Sent from my iPhone

Hello,

I am currently with Part D plan and have a few questions around the Medicare Prescription Payment Plan.

1. The Medicare Prescription Payment Plan Participation Request Form will that be used in addition to adding it to the Part D Member Enrollment form or will we only use the M3P form?
2. What will be needed when we transmit election information to Marx and what does this do?

Thanks!

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

It say leave comments but im not sure where but having health through state has helped me tremendously ..not all jobs provide health care benefits i suffer from bad panic attacks but i have insurance or had they are stopping it march first and i need my medication and cant afford out of pocket and doctor visits monthly on top of dental issues rent gas heat car insurance credit card bills thst should be almost completely paid off may not be able to be paid if i have to pay out of pocket i cant afford it ..its \$300 just for one script thats just one example i only make \$300 a week after taxes ...i need this coverage....it will help alot of people especially people thar truly need meds like me to make the world a better place. I never wanted to be on meds but i realize yes i need it..and since then my panic attacks are less ..i couldnt even be left alone nevermind have a job hope this helps you understand the importance of the help you provide ..thank you. [REDACTED]

[REDACTED]

February 16, 2024

Moca, P.R.

Part D Payments

CMS

HHS

Greetings. I hope that everybody is doing well. By this means, I acknowledge receiving and reading this message.

My comment regarding the Inflation Reduction Act.

An issue, problem, situation takes place triggering events.

A proposal is a proposal.

An act is an act. A bill is a bill. A law is a law. A regulation is a regulation. Translation gaps could cause confusion.

That is one of the reasons why non knowledgeable staff members get confused along the way.

When the law establishes an order, it will not provide the steps or mechanisms to accomplish. Regulations will give detailed procedures.

Puerto Rico is defined as an American territory not incorporated, meaning that:

Puerto Rico was granted from Spain to the United States after the Hispanoamerican War (1898 invasion through Guánica).

It is an Island located in the Caribbean having the Atlantic Ocean on the North. It is non-incorporated, meaning that it is not physically incorporated, it is located, incorporated in the big territory where the other 50 states are actually. Our flags wave one next to the other not integrating our star with the others because the history of conquest and colonization of both places were different. Puerto Rico (after being inhabited by the Taíno Indians) was conquered and colonized by Spain.

United States, was conquered and colonized by England.

Having said this, we speak about state and federal legal concepts and its applicability.

Medication development is an expensive process along with documented and legal requirements.

First:

Let's go step by step on how things are done.

Research. Upon developing a new medication or improving what is already in the market, the process is expensive.

From in vitro to in-vivo (animals like Guinea pigs. Then from in-vivo to volunteer people in clinical trials. From there to sick patients. Then launched to the market including post-marketing study and drug recalls when having to do so. If it is an effective medication it is marketed right away. If it is harmful, the clinical trials are stopped.

These steps require documentation, New Drug Application, abbreviated New Drug Application and so.

Second:

Marketing. Ensuring that the right patient receives the right medication, strength, dose, frequency, route, and so. Medication treatment and outcomes handling.

Third:

Proper storage, managing, handling.

Fourth:

Logistics. It is not the same to hand in an ordered medication across the street than to the other side of the nation. So, in the logistics, gas price varies as does keeping the product in place stored properly.

In places where there are hills, curves, frequent stops, the acceleration and deceleration will have impact in its price.

Transporting medications is more delicate than other goods because some goods are biologicals, others are thermolabile, others may even have explosive properties or characteristics. Some are pressurized, vacuum sealed, and so. Air pressure and altitudes need to be considered.

Fifth:

Safety. If the item is going to be transported to a war, belic, or harsh zone, versus not so difficult zone.

Sixth:

Paper work and vending systems. Refilling.

Seventh:

Billing for the services.

Eight:

Complaint handling.

Nineth:

Law suits. Harms. Neglects. Poisoning.

Tenth:

Receiving the medications at the pharmacies, storing, handling, receiving the order, dispensing, pouring, counting, labeling, handing or administering to the patients, patient counseling, patient monitoring, allergies or side effects and accidental poisoning or incidents managing, legal issues, and so fort.

To give an idea, the cost of annual labels and bottles for a 400 daily case patient goes beyond \$50,000.00 annually. Just the labels and empty bottles for a pharmacy that dispenses 400 products (prescription numbers) daily. That is not even considering the ink, toner used.

Dispensing process goes way beyond pouring, counting. Please be reminded that clinical interventions also take place (calling the prescribing physician, dose adjustments based on renal function, hepatic function, interadctions, medication blood concentration levels, pregnancy and breastfeeding, elderly and BEERS Criteria list, children and KIDS List, costeffective options, availability, tolerance, allergies, side effects, pharmacogenome and nutrigenome, and so forth.

Documentation and legal issues.

Submitted for your consideration. Please feel free to contact me if any doubts.

Thank you and have a nice day.

Cordially,

A solid black rectangular box used to redact a signature.



This is a joke! How does it work for people that get monthly prescriptions? Who is going to ensure payments are made on time? This is just another bureaucratic nightmare. The Biden administration is a bunch of clowns.

One of the primary challenges faced by prescribing physicians and Medicare patients is the lack of understanding by the dispensing pharmacy about why a certain drug cost has increased, which seems to usually be a result of a lack of transparency from the insurance plan, though a lack of effort from the pharmacy also probably plays a role. Dispensing pharmacists seem to be unwilling or unable to obtain the necessary information from insurance plan pharmacists who administer the formulary rules and also don't seem to be able to find out why a drug has become expensive, whether it due to the patient being in the deductible period, donut hole, a change in formulary rule, etc.. Instead, the responsibility of trying to find out that answer is routinely directed towards the prescribing physicians and staff though there are many other people who should be taking the responsibility to provide that answer and also provide prescribers with educated cost saving options instead of routinely dumping this mundane task on prescribers with a request to trial and error prescriptions for medications until an acceptable or affordable alternative is found. This low standard of transparency and effort from dispensing and insurance pharmacies also leads to recurrent and frequent lapses in access to essential medications, increasing costs and harms. Many patients would be able/willing to pay for increased cost if they knew exactly why it was necessary and were able to plan for the cost of future refills but when they are simply told to ask their doctor about it without any explanation they are reluctant make a decision. The pharmacies and insurance plans should take more responsibility to provide these answers to patients.

Second, many of these plans try to entice their patients to utilize certain mail order pharmacies. Inevitably lapses in treatment occur for unclear reasons, and patients then routinely call their physicians to prescribe short term supplies to local pharmacies to last until the mail order supplies actually arrive. These mail order pharmacies should be held more responsible for preventing lapses in therapy if the insurance plans are going to be allowed to offer cost savings to patients by encouraging them to use a preferred pharmacy.

Aloha,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Hello,

One of the footnotes states: "In addition, the program has no application to those demonstration Medicare-Medicaid Plans (MMPs) that have no Part D cost-sharing." Does this mean that MMPs with no cost-share do not have to comply with any portion of this guidance, including lettering, website requirements, enrollee outreach, and reporting? This is not clear to us in the current guidance.

Thank you for the opportunity to submit comments.

Sincerely,

Government	Percentage
Current government	85%
Previous government	15%

I am 72 years old with RA and have been taking Enbrel since 2006. It has made the difference between living productively with it versus living with the crippling effects without it.

This year my January cost was around \$2300 and February cost was around \$1100 and will be for a couple of months until I reach the \$8000 out of pocket amount.

It would be wonderful to spread my cost throughout the year instead of that high cost at the beginning of the year. I try to save up for that January bill but I don't know what it will be until I fill the prescription and cost to me goes up every year by several hundreds of dollars.

This it was hard to manage since I had some unplanned expenses in December.

Currently I have to put the charge on my credit card and pay the high interest rate to pay it off. Help for prescription cost is limited to retirees.

Thank you for listening to my situation.

**From:** [REDACTED]  
**Sent:** Thursday, February 29, 2024 12:14 PM  
**To:** CMS PartDPaymentPolicy <[PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)>  
**Subject:** Medicare Prescription Payment Plan Guidance – Part Two

In reading “*30.3.1 Overview of Election Requirements*,” it appears that the opt-in data elements and program language will be added to the MA Enrollment and Disenrollment Guidance Exhibit 1 and Exhibit 2 Model enrollment requests. These items are listed below for reference:

[CY2021 MA Enrollment and Disenrollment Guidance \(cms.gov\)](#):

- Exhibit 1: MODEL INDIVIDUAL ENROLLMENT REQUEST FORM TO ENROLL IN A MEDICARE ADVANTAGE PLAN (PART C)
- Exhibit 2: Model Employer/Union Group Health Plan Enrollment Request Form (“Election” may also be used)

If this assumption is correct, it’s important for plans that these items be updated as soon as possible. If not, we’d ask that instructions on handling these elements would be provided expeditiously.

Additionally, in reviewing “*30.3.1.1 Request to Participate in the Medicare Prescription Payment Plan*,” it appears that CMS will also be providing a stand-alone Medicare Prescription Payment Plan Participation Request Form for the opt-in process. We ask for this to also be done expeditiously so plans will be able to update processes and systems to meet this requirement.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thank you for soliciting comments on the Part D Payment Policy. I am Senior Vice President, Med Solutions at [REDACTED], an Omaha-based FMO that is likely the leading distributor for standalone Part D plans. We support 70,000 brokers nationally with technology, compliance, training and service support on behalf of carrier partners. My company has implemented a variety of technology solutions to enable a beneficiary, with the help of their servicing agent, to efficiently determine if their drugs are covered, pharmacy is in the network and how to annually identify those situations that need to be prioritized due to premium, plan or formulary changes. We have also implemented technology solutions to provide needed compliance disclaimers. We have experienced significant changes in deductibles, coinsurance, formularies, etc over the years. While well-intentioned, the Inflation Reduction Act has a number of unintended consequences including rising premiums, coinsurance instead of co-pays on Tier 3 drugs and further restrictions on formularies.

My principal worry is that many consumers don't shop annually and they may not realize a formulary change until after January 1<sup>st</sup> at which time it is too late. I suggest a Part D switch period similar to what's available for Medicare Advantage so mid-AEP formulary changes don't harm a Medicare beneficiary.

Respectfully,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

I urge you to consider a different mechanism to achieve your goals. In high cost specialty pharmaceuticals most Medicare beneficiaries qualify for copay assistance from many different charitable copay assistance foundations such as the PAN Foundation, the Healthwell Foundation, and the Patient Advocate Foundation to name a few .

The issue arises in using this copay assistance. If the payment plan is selected by the beneficiary then the specialty pharmacy will only ever see a \$0 copay for the patient and as a result will not initiate a search for charitable copay assistance. Further, even if the pharmacy knew of the patients actual high copay they still can't process a secondary copay claim for the patient because the copay from the insurer will have come back with a \$0 responsibility so no balance billing can happen.

This leaves the beneficiary in the unfortunate position of having to lay out the monthly copay amount to their respective insurer, and upon getting a receipt the beneficiary would then have to navigate a manual paper claims process to submit to the charitable copay assistance fund. That's only if the copay assistance fund allows submission of paper claims which they don't all do.

So instead of having a situation where the beneficiary would come to the pharmacy in January to fill a high cost specialty medication and receive a copay charge of \$3,300 for that fill which the specialty pharmacy could then electronically balance bill to the charitable copay organization resulting in a \$0 copay for the patient, you'd be left in a situation where the patient would often not have any charitable copay assistance because very few patients can navigate the process without a specialty pharmacies help, and would need to pay 12 separate bills over the course of the year. And if they did have the assistance, then they'd have to pay their insurer 12 times, get a receipt, and submit paper claims to the charitable copay assistance organization 12 times.

This is inefficient and likely to result in many reimbursement delays, not to mention that these charitable copay assistance organizations rely heavily on the efficiencies of electronically billed claims at the pharmacy and are not equipped to suddenly have a huge influx of paper claims from patients.

I propose you require insurers to set up a system where they return what the patients copay would normally be, and in the response message of the electronic NCPDP claim, provide secondary processing information including, BIN, PCN, ID#, and Group, which the pharmacy would then electronically bill if the patient agrees to obtain a \$0 copay and enroll the patient in the payment plan. I suggest this be allowed on a claim by claim basis to give the beneficiary the most control possible over their costs and to enable beneficiaries on high cost specialty medications to benefit from having their pharmacy electronically bill a charitable copay assistance program on their behalf so that they don't have to go through the exercise of submitting 12 bills and receipts for paper reimbursement.

Thank you for your time.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



With this new guidance on Medicare people who are having a hard time paying for housing, food, utilities and so forth YOU think they will have approximately \$350.00 extra to pay for their medicines each month if is capped at \$3800.00 divided by 12 months??????? These people do not have that kind of money they are living on a FIXED INCOME NOT like all of you with salaries of 6 or 7 figures. Another question I want to bring up is these citizens on a fixed income and have heart problems, overweight, diabetics and so forth if Medicare would pay for these people to be able to get the new FDA approved weight medications (Zepbound for instance) they would not have diabetic, heart problems and save Medicare in the long run, but I know you all know what is going on in the real world and you are ALWAYS looking out for us.....

In section 30.3.1 the guidance speaks about the election requirements but does not provide the effective date rules of the opt into the program. Will the opt in effective date always be the 1st of the month like January 1, February 1, etc.... Or can the effective date into the program be any day of the month such as January 25th, February 25th etc.....

The enrollment rules for MAPD and PDP plans are 1st of the month only for MARx so we want to see if the effective date rules for the opt in process will be the same.

[REDACTED]

[REDACTED]

I have many residents who are on Medicaid and only get \$50 a month , on a flexible payment plan they would still have more going out than in. I have some that owe their current pharmacy and can't pay any extra to reduce their current debt. Who picks up the cost of their bills if 1. They don't have the income to pay 2. Pass away while owing?

Just curious

Thank you



Payments to providers should be mandated to be at least NADAC plus the state's cost to dispense to make sure pharmacies can survive, keeping appropriate access to pharmacies. Current reimbursements are many times below the cost of the product. If this is not corrected, more pharmacies will close, impacting access for patients, which is crucial for rural areas.

[REDACTED]

[REDACTED]

I'm writing to support Medicare Part D to pay for the drugs for Parkinson's disease not currently covered namely: Rytary and Gocovri

My husband has Parkinson's disease and will be on Part D come 2025. I do not understand how Medicare could block patients from getting drugs they need. It's biased and forces us into an MA plan of which we don't want. We are not wealthy and deserve the drugs needed for his disease after paying into a system all of our lives.

What is the plan and why don't you cover these medications? Is it because you want to force us into an MA plan since Parkinson's has a host of expenses? Shame on you Medicare for not covering these drugs and other drugs for the aging population

Thank you

[REDACTED]

This is not a bad idea, but there are lots of people this won't help. I would rather see Medicare expand the amounts of money people may have in savings and still receive extra help from Medicare. My 91 year old mother has just been cut off from this, and we are having serious problems paying for her prescriptions. It would not really help for her to make payments throughout the year, when she doesn't have the income and has to go into her savings to pay.



The option of an HSA or FSA type saving account to help cover unexpected or non-covered services along with Prescription Drugs could be a very big benefit to some. This could be something that was deducted from SS to help ease the burden of the insured paying this monthly, in addition to the benefit of the SS deduction of “out of sight out of mind.”

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Medicare Prescription Payment Plan will help so many people with diabetes. It will allow them to attempt to use newer diabetes drugs that otherwise would not be considered. Please make sure that the Association of Diabetes Care and Education Specialist, the American Diabetes Association, The American Association of Clinical Endocrinologists, the American Association of Nurse Practitioners, and the American Association of Physician Assistants are aware

For every patient who has expensive out of pocket costs for 1 drug or many drugs, the patient should receive written notification of the benefit of the Payment Plan each time a drug is refilled. The communication should be able to be read by someone with a 5<sup>th</sup> grade education. The sponsors of these drugs should also have to publicize the Payment Plan on TV when any of these drugs are advertised. The consumer needs to be made aware.

Thank you for permitting my comment.

[REDACTED]

[REDACTED]



Hello,

Based on my read of the MPPP guidance, all Part D sponsors must offer a payment plan program, no exceptions. Would this still hold true for a D-SNP that utilizes the VBID program to waive all member cost-sharing? In this example, assume there is no conceivable way a member of the plan would have any Part D cost-sharing.

Thank you,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Just to clarify,

This is only helping people who would have increase in medication cost due to a short term medication??

If someone has say \$100 monthly medications cost this program would not be helpful for them.

--

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The root cause of high prescription drug costs is the added layers of expense by PBM's. Rebates, payments for position on formularies, high copays for patients while the PBM makes excessive profits is certainly not how this program was intended to function. Here are the solutions to reduce the cost of proscription drugs for all:

1. Eliminate rebates, kickbacks and formulary buy in.
2. Drugs should be priced the same for all classes of trade. If a drug is discounted to 1 group the price goes up for other groups. This would eliminate the need for the added cost of buying groups and remove significant administrative costs.
3. The actions of #1 and #2 would eliminate the need for PBM's as claims could be easily adjudicated by the insurer at a much lower cost. This would save both Medicare and patients billions of dollars.
4. Stop direct to consumer advertising on any medication that is covered by a federal program. This would eliminate a layer of cost that drug manufacturers pass on to payers and patients. Drug choice should be based efficacy, side effect profile and the professional judgement of the treating physician.

Look at the overall operational cost of the PBM's and subtract it from the total cost of prescription drugs. You will see remarkable potential for savings.

PBM's have also caused many pharmacies to close which reduces competition. The DIR fee program was implemented under the guise of improved outcomes and reduced cost. It has failed at both and simply serves to enrich the PBM industry and raise the cost to patients. This policy should end immediately.

[REDACTED]

[REDACTED]

Hi,

Will the Pharmacy Benefit Managers, such as Optum Rx (United Health), Express Scripts (BCBS Medicare), Caremark (Aetna, Silverscript), Humana (Medicare Part D) still be able to manipulate the List prices and different Tiers on to increase their earnings and pocket books? These PBMs are the reason these drug prices are so expensive. The manufacturers and the PBMs increase the list prices on medications to dramatically increase the hidden rebates to these PBMs.

Pharmacies are having to constantly dispense brand medications when a much cheaper generic is available so that the PBM (insurance company) can get their brand manufacture rebate at the expense our Medicare Part D members. It is a shame that the CMS continues to allow this happen. The FTC has probed information from the PBMs for their business practices and non-transparency. The PBMs have been allowed to continue to ignore these requests from the FTC.

I am now hearing more and more of pharmacies, especially independent pharmacies, electing to not carry brand name medications due to the unfair, non-transparent business practices of these Pharmacy Benefit Manufacturers (PBMs). Medicare members are gradually losing access to pharmacies, especially in rural areas because of the action of these PBMs and their take or leave contracts. It is the responsibility of CMS to look into this and correct the unethical and nontransparent business practices of these PBMs. These PBMs have been allowed to purchase through vertical integration all sources of the healthcare chain. PBMs now own their own mail order pharmacies, specialty pharmacies and the transmission switches for the processing of pharmacy claims.

Optum RX (United Healthcare) owns Change Healthcare which experienced a cyberattack. Pharmacies have not been able to process Medicare Part B claims for medicare beneficiary's DME and diabetic supplies not covered by Medicare Part D drug plan. These PBMs are now coercing their medicare members to use their own mail order pharmacies via cheaper copays then what is allowed at the community pharmacy. If CMS wants to have medicare members access to pharmacies and the care of their choice, CMS needs to look into this and act quickly.

A knowledgeable response on this matter would be greatly appreciated.

Thank you,



Hello – Does CMS plan to release any training or a hold a webinar on the M3P?

Best regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

From:

Sent: Wednesday, February 28, 2024 7:17 PM

To: CMS PartDPaymentPolicy <[PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)>

Subject: Medicare Prescription Payment Plan Guidance – Part Two.

Dear CMS,

High drug cost and exorbitant copays for seniors and part D beneficiaries is turning into a catastrophe. There is huge call out to all the govt agencies and lawmakers to reform predatory PBM practices.

3 PBMs control 89% prescription flow (without any clinical value add), they dictate pricing driven by arbitrary yet self serving agendas.

For example: they will charge full list price for brand name drug when the net price is one third. That is a flat out robbery of an elderly patient.

They underpay pharmacies with a clear intention to wipe out the competition. That way they can double-triple dip taxpayers and patients.

Many a times they will overcharge copays for cheaper generics. That is an indirect denial of treatment.

They would force patients on brands when generics available.

Even if you create a payment option on copays, it would only help when they are in deductible phase, what if the copay stays monthly?

There would be no meaningful progress in Part D without PBM reform.

Public opinion is rapidly changing that PBMs run govt entities such as CMS and HHS and not the other way round.

Respectfully,

As a Registered Nurse whose life circumstances changed in 2015 when I was diagnosed with a permanent disability. I have no savings left. My diagnosis of asthma requires Respiratory Inhalers which have a high copay. Every month, I have to decide between food and my prescriptions. So the need for medication is my priority.

The quality of my life is not what I expected after working for 40 years. As a retired healthcare professional, the senior population is in desperate need of the option to pay monthly. We have dedicated our lives to living a productive life. We should not have to face the additional stress of not having enough money to eat nutritious food because our life-sustaining medications have taken a big bite out of our monthly income.

Thank you



Good Morning,

I was reading up on the proposed changes and one thing to consider as you draft payment plan guidance Part 2 for Part D Rx plans is that insurers ought to be required to notify folks if their current RX's are going to be removed from the formulary for the New Year. Or the Part D insurers need to have *strong messaging* encouraging the insured to review the *new plan formulary* to make certain that all their current prescriptions will be covered in the new plan year. I had one gentlemen who was taking Vyndaqel for a rare condition, and it was an extremely expensive Rx with his out of pocket copay costs running about \$1,000/mo. He was enrolled in a Wellcare plan and had he not shopped plans and realized that drug would not have been covered in the New Year on Wellcare, he would have been stuck paying the full retail cost of that drug, which was astronomical until recently. Wellcare did not notify him that that his Vyndaqel was no longer going to be covered under their formulary in the plan year, and folks do not always think to shop their Part D plans if they been with same carrier for a while.

Thank you,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



To whom it may concern,

Helping older retired people with lower drug costs will enable us to be able to afford medications and food. Drugs are prescribed and changed many times a year.

Cost of living is expensive. Trying to live off savings and social security is almost impossible.

Unless you have millions of dollars, or even close to enough- we will be burdens to our children.

The corporations who own us- own what we pay for our drugs, electricity, gas, everything we can't plan for.

We need a break.

Sent from my iPad maybe give example of how the plan will work. So patient understands what to do. Sometimes it is hard to just read read and read.

**Johnson & Johnson**

Johnson & Johnson Services, Inc.  
1350 I Street NW  
Suite 1210  
Washington, DC 20005

T: 202.589.1015  
Robert Donnelly – Sr. Director Health  
Policy  
[rdonnel4@its.jnj.com](mailto:rdonnel4@its.jnj.com)

BY ELECTRONIC DELIVERY TO: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

March 14, 2024

U.S. Department of Health and Human Services  
Centers for Medicare & Medicaid Services  
Attn: Dr. Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director of the Center for Medicare  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Medicare Prescription Payment Plan Guidance – Part Two

Dear Dr. Seshamani:

Johnson & Johnson (J&J) is pleased to submit the following comments and recommendations in response to the Medicare Prescription Payment Plan Draft Part Two Guidance (draft guidance).

J&J is the world's most comprehensive and broadly-based manufacturer of health care products for pharmaceutical, medical devices, and diagnostic markets. For nearly 130 years, we have supplied a broad range of products and have led the way in innovation and are continuing this heritage of innovation today by bringing important new pharmaceutical and medical technology products to market to solve the world's toughest health challenges.

J&J is a member of the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO), and we support the comments that both groups are submitting on this draft guidance.

We respectfully offer the following comments and recommendations in response to the draft guidance. We support CMS's efforts to ensure that Medicare Part D sponsors fulfill their outreach, education, and communication obligations to enrollees with respect to the Medicare Prescription Payment Plan (MPPP), in conjunction with the agency's national education and outreach efforts regarding program implementation. We believe it is essential that Part D sponsors and pharmacies conduct effective, timely outreach and education for enrollees most likely to benefit from the MPPP (i.e., enrollees with substantial out-of-pocket prescription drug costs). We also acknowledge the responsibility of CMS to support and conduct outreach on the MPPP to beneficiaries and providers. Manufacturers like J&J that have significant Patient Support offerings will also consider developing educational resources on MPPP for beneficiaries and providers.

However, as discussed in more detail below, there are certain aspects of the draft guidance that could be improved to ensure that enrollees consistently receive and understand critical information regarding the MPPP across Part D plans.

## **We Urge CMS to Provide Robust Educational Resources and Tools (Section 30.1 & Section 40)**

J&J appreciates CMS's draft guidance provisions regarding general outreach and education, including requirements for Part D sponsors to use certain updated Part D materials (e.g., Membership ID card mailings, Evidence of Coverage documents, and Annual Notice of Change documents) to ensure prospective and current Part D enrollees are aware of the MPPP. We support CMS's proposed MPPP educational resources on [Medicare.gov](https://www.medicare.gov) and proposed modifications to CMS-provided Medicare Part D documents, web content, and tools (e.g., Medicare & You Handbook and Medicare Plan Finder).

However, J&J remains concerned that MPPP participants may not fully understand the program's mechanics regarding monthly billing and the related financial implications of participating in the MPPP, given how monthly bills are calculated. For example, MPPP participants could continue to receive a monthly bill after receiving a single fill of a medication, stopping a therapy mid-year, or leaving the MPPP. While we appreciate that CMS has incorporated language regarding leaving the MPPP in the proposed MPPP Election Approval Notice Model Document and provided an example of a monthly bill with drug discontinuation in the MPPP Final Part One Guidance, we encourage CMS to ensure that both the agency's and Part D sponsors' enrollee education and outreach clearly and comprehensively address the important topic of monthly billing under various scenarios. We request that CMS address these considerations in finalized guidance and/or FAQ documents.

Furthermore, we urge CMS to provide Part D enrollees with an array of helpful educational resources as soon as possible and with input from Medicare beneficiaries. In particular, we note that the agency previously referenced, in the MPPP Draft Part One Guidance, a calculator to model prospective MPPP payments that the individual would owe if they opt-in to the MPPP. However, the MPPP Draft Part Two Guidance does not provide further details regarding this important tool. We encourage CMS to provide additional details regarding this calculator tool in the MPPP Final Part Two Guidance, including design elements, development timeline, and accessibility to beneficiaries via integration into CMS websites, CMS-developed educational resources, and Part D sponsor websites. Furthermore, J&J recommends that CMS make the monthly payment calculator tool and other decision support tools available during the MPPP election process to help beneficiaries understand the potential impact of opting into the MPPP. These tools would allow prospective MPPP participants to model various scenarios and potential monthly payments, enabling greater understanding of the MPPP's monthly payment mechanism and assisting prospective MPPP participants in evaluating how the MPPP might fit their individual circumstances. Additionally, these tools may enable prospective MPPP participants to gain additional perspective into the retroactive nature of the MPPP's monthly payments, in contrast to paying out-of-pocket costs in full at the pharmacy point of sale (POS). CMS should encourage plans to link the calculator in all outreach and educational tools provided to enrollees, including plan websites.

We also encourage CMS to require Part D sponsors to provide ample educational material to MPPP participants regarding the logistics of submitting payment for MPPP bills (e.g., payment online at the Part D sponsor's website by credit/debit card, through the mail via check, and any other available payment methods). Given that patients will be billed retrospectively, the MPPP program has the potential of driving a negative experience for enrollees due to uncertainty of what their financial burden will be after enrolling.

## **We Recommend CMS Consider Additional Strategies for Identification of and Targeted Outreach to Part D Enrollees Likely to Benefit from the MPPP (Section 30.2)**

In the draft guidance, CMS details requirements for Part D sponsors to undertake targeted outreach (prior to and during the plan year) to Part D enrollees likely to benefit from the program. While we support the

agency's efforts to ensure Part D sponsors conduct targeted outreach, we believe that the current scope detailed in this draft guidance, as well as the related \$600, single prescription threshold finalized in the MPPP Final Part One Guidance, may result in under-identifying enrollees likely to benefit from the MPPP. There may be beneficiaries that take more than one prescription drug for chronic conditions that total at or below this threshold. Therefore, J&J recommends that CMS consider and include alternative methodologies or supplemental strategies that Part D sponsors may use to identify additional Part D enrollees likely to benefit from the MPPP beyond the current targeted outreach requirements (and general outreach and education requirements).

While J&J supports CMS's requirement that Part D sponsors and pharmacies deliver the agency's standardized "Medicare Prescription Payment Plan Likely to Benefit Notice" to Part D enrollees likely to benefit from the MPPP, we express concern regarding the lack of a real-time/POS election option for 2025. This means that an enrollee may wait to pick up a prescription until their MPPP participation is effective, increasing the potential for non-adherence to the prescription medication. In the final Part 1 guidance, CMS defined a process for urgent, retrospective enrollment, but we would like to further emphasize that CMS consider how access to products could be improved under the pharmacy notice. We encourage CMS to further consider how MPPP election could be improved to ensure timely access to prescription medications, including requiring education and outreach regarding the urgent MPPP plan election option beyond Part D sponsor websites.

CMS may want to consider emphasizing with Plan Sponsors the important role providers can play in MPPP (especially in making the patient aware of the MPPP before they go to the pharmacy to pick up their drug). We urge CMS and Plan Sponsors to develop targeted educational and outreach materials for providers and to use existing CMS communication channels with providers to educate them on the program.

### **We Recommend CMS Ensure Part D Sponsors Convey Critical Information from New Model Materials (Section 30.3)**

In the draft guidance, CMS encourages Part D sponsors to use newly developed CMS model materials and language when communicating with MPPP participants. The agency notes that Part D sponsors are not required to use the model materials and content verbatim, but that they must base their developed materials on the agency's model materials and must include the "elements and information" from CMS's model materials. J&J recommends CMS clarify what elements and information must be included from the agency's model materials, thereby ensuring MPPP participants receive consistent and fulsome information regarding the program. In particular, we encourage CMS to include basic program descriptions and payment calculation explanations as part of the "elements and information" from the agency's model materials. Recent findings from the Commonwealth Fund 2024 Value of Medicare Survey found that 30% of Medicare Advantage and 31% of Beneficiaries were unsure of what benefits they have leading to uncertainty about covered benefits and feeling that their coverage fell short of their expectations<sup>1</sup>. We ask that CMS take this into consideration when determining what critical information needs to be conveyed in new model materials, so beneficiaries understand the new benefit.

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<sup>1</sup> <https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage>

J&J appreciates the opportunity to provide these comments on the Medicare Prescription Payment Plan Draft Part Two Guidance. We look forward to collaborating with CMS as it works to implement this important program. Please contact us if you have any questions regarding our comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Robert Donnelly".

Robert Donnelly  
Senior Director, Health Policy  
Johnson & Johnson Worldwide Government Affairs and Policy

# JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

March 15, 2024

Meena Seshamani

Deputy Administrator and Director of the Center for Medicare

Centers for Medicare and Medicaid Services

U.S. Department of Health and Human Services

Submitted electronically via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

## **Re: Draft Part 2 Guidance on the Medicare Prescription Payment Plan**

Justice in Aging appreciates the opportunity to provide feedback on CMS' Medicare Prescription Payment Plan (MPPP) Part 2 Proposed Guidance.<sup>1</sup> Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable healthcare, economic security, and the courts for older adults with limited resources. We focus our efforts primarily on those who have been marginalized and excluded from justice such as older adults of color, older women, LGBTQ+ older adults, older adults with disabilities, and older adults who are immigrants or have limited English proficiency. Justice in Aging has decades of experience with Medicare and Medicaid and improving both programs for people dually eligible. Given our focus on low-income older adults, our feedback is primarily on the MPPP's interactions with the Part D Low-income Subsidy (LIS) and outreach to underserved communities. To the extent that these comments apply to the draft documents released February 29, 2024<sup>2</sup>, we will also include them again in our separate response to those draft documents due April 29, 2024.

### **30.1 Outreach and Education**

We appreciate that CMS finalized requirements that plans provide notice of the availability of both MPPP and LIS prior to a plan year, as well as the requirement to include information on obtaining LIS in the initial notice of failure to pay bills under the MPPP.<sup>3</sup> Additionally, we were pleased to see LIS, MSP, and other assistance programs listed (with information about how to access the programs) in the following draft documents published February 29: (1) Notice of Election Approval; (2) Notice of Failure to Pay; (3) Notice of Involuntary Termination; and (4) Notice of Voluntary Termination.<sup>4</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](#)," ("Part 2 Proposed Guidance") (February 15, 2024)

<sup>2</sup> HHS, "Agency Information Collection Activities: Proposed Collection; Comment Request," [89 FR 14847](#) (February 29, 2024)

<sup>3</sup> CMS, "[Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments](#)," ("MMMP Part One Final Guidance") at page 69.

<sup>4</sup> [89 FR 14847](#) (February 29, 2024)



**Include information that LIS can be retroactive.** Medical debt is a large and growing problem among older adults, even though the vast majority are insured through Medicare and other insurance.<sup>5</sup> MPPP documents are a prime opportunity to let enrollees know that LIS can provide assistance both going forward and for past expenses. We ask that CMS add language to MPPP notices that, in some cases, LI-NET can provide retroactive coverage and Extra Help can provide assistance with past medication costs.

**Include LIS access information on the Medicare Prescription Payment Plan Likely to Benefit notice (“Likely to Benefit notice”).** While the Likely to Benefit Notice does reference LIS briefly, the notice does not explain what LIS does or how to access it. We ask that CMS add more LIS information to the Likely to Benefit notice about what LIS is and how to access it.

**Maximize education and outreach opportunities.** We recommend that CMS continue to explore additional options for providing information on LIS and MPPP. Any time an individual is thinking about their prescription drug coverage or costs is an opportunity: Plan Finder, annual notices, explanations of benefits, Medicare & You, at the pharmacy counter, information from the prescribing provider.

**Build tools for understanding how MPP applies for individuals on LIS.** While true that MPPP may not be the best choice for someone with small, stable medication expenses, that is not always the case for LIS enrollees. We appreciate the examples of how the MPPP would work and recommend CMS include both detailed examples for advocates, providers, plans, and other stakeholders with Part D expertise, as well as simplified examples to demonstrate how the program works for Part D enrollees. These examples should compare cost-sharing with and without the MPPP for someone with LIS. We also recommend CMS create fillable online and printable worksheets for people to estimate the impact of the program on their own out-of-pocket (OOP) costs. As an alternative, an online tool could allow a Medicare enrollee to choose an example OOP cost from a dropdown menu that is similar to their own costs and the calendar month and see a side-by-side comparison with and without the MPPP applied.

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

**Make targeted outreach stronger for individuals who just lost LIS.** We appreciate CMS’ encouragement of targeted outreach before the point of sale (POS) triggers, and for mentioning targeted outreach for individuals who recently lost LIS.<sup>6</sup> We ask CMS to consider making targeted outreach to these individuals stronger, with specific instructions to plans. Consider improving data sharing with plans about individuals who just lost LIS so that plans can provide that outreach.

**Evaluate targeted outreach efforts.** We ask that CMS evaluate targeted outreach efforts to see if they are working well, especially among marginalized populations. CMS should also

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<sup>5</sup> Consumer Financial Protection Bureau, “[Medical Billing and Collections Among Older Americans](#),” (May 2023)

<sup>6</sup> [MMMP Part 1 Final Guidance](#) at 73; [MMMP Part 2 Proposed Guidance](#) at 9.



communicate the findings to consumer advocates and other stakeholders who can both provide insight and learn from them to improve their own outreach.

### **30.3.5 Notice of Voluntary Termination**

**Inform individuals of their expectations of payment following voluntary termination.** We appreciate that CMS makes clear in the draft Part 2 guidance that voluntary termination does not mean that a person is required to pay an immediate lump sum payment in full:

“After a participant voluntarily terminates their participation in the program, Part D sponsors must work with the enrollee to determine how they will pay their outstanding balance, which may include a lump sum payment; however, Part D sponsors cannot require full immediate repayment. If the enrollee chooses to continue paying in monthly amounts, Part D sponsors must continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year.”<sup>7</sup>

We ask that CMS include this information in the Notice of Voluntary Termination, and information about the steps a person who chooses to continue paying monthly amounts can take if a plan demands a lump sum or charges higher than the maximum monthly cap.

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

We appreciate CMS’ clarity around that language access and accessibility requirements applying to MPPP outreach and education documents.

**Require electronic notices.** We commend the requirement that the Likely to Benefit notice be provided electronically if it is the enrollees’ preference; such a policy is extremely important for individuals who rely on screen readers. When rolling out the slate of other new MPPP notices, if they are not currently required to be provided electronically, please do so.

**Consider accessibility for the whole process.** Please consider, in the context of accessibility, how new MPPP systems are accessible throughout the entire process of understanding, electing, and receiving MPPP. For example, a form may be readable by a screen reader, but the signature process, or the steps taken to access an online portal, may not be accessible to individuals who are blind or have low vision.

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

**Support SHIPs and community-based organizations.** We appreciate that CMS “will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates—including State Health Insurance Assistance Program (SHIP) counselors—have sufficient support and materials needed to effectively communicate the availability and

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<sup>7</sup> [MMMP Part 2 Proposed Guidance](#) at 20

nuances of this program to individuals.” The tool we mentioned above, that would help a person plug in their parameters and get an individualized understanding of what their monthly payments will be, will be very helpful for SHIP counselors and community-based organizations. Even though many LIS recipients, for example, will not benefit from an MPPP program, such an individualized tool will give reassurance to the individual that they are making an informed choice and will save the people assisting them time.

We recommend that public facing materials about prescription drug cost savings direct people to SHIPs for assistance. Because SHIPs are also in a good position to educate people about the LIS and Medicare Savings Programs, it is particularly important to leverage MPPP outreach—which will appeal to people with lower incomes—to connect people with SHIPs so that they can get the full range of financial assistance they are eligible for. SHIPs should also be encouraged to strengthen relationships with CBOs serving people with LEP. We also recommend using the MPPP outreach and education needs as leverage for securing increased funding for SHIPs from Congress.

### **60.3 Monitoring and Compliance**

**Include demographic data in reporting requirements.** We strongly urge CMS to require plan sponsors to report demographic data on MPPP enrollees to help identify any disparities in use. This information will equip CMS and plans to understand the successes and shortcomings of outreach and education strategies and reform this and other programs to address inequities in prescription drug access.

**Ensure that retroactive LIS refunds are being handled properly by plans.** As the final Part 1 guidance noted, with the implementation of MPPP, plan sponsors are now required to reimburse members who receive retroactive LIS refunds, and that reimbursement should take place within 45 calendar days.<sup>8</sup> We ask that CMS include information on the LIS approval notice that informs individuals about this requirement, and their options if a refund is not received within 45 days. We also ask that CMS monitor plans’ compliance with this requirement.

### **Conclusion**

Thank you for the opportunity to provide feedback. If any questions arise concerning this submission, please contact Rachel Gershon, Senior Attorney, at [rgershon@justiceinaging.org](mailto:rgershon@justiceinaging.org)

Sincerely,



Amber C. Christ  
Managing Director, Health Advocacy

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<sup>8</sup> [MMMP Part 1 Final Guidance](#) at 73

**Kaiser Permanente Comments on  
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**

March 15, 2024

*Submitted electronically to: PartDPaymentPolicy@cms.hhs.gov*

Kaiser Permanente<sup>1</sup> strongly supports the comments submitted to the Centers for Medicare & Medicaid Services (CMS) by America's Health Insurance Plans (AHIP) in response to this solicitation, which offer a series of recommendations to better operationalize the Medicare Prescription Payment Plan (MPPP). In particular, we wish to highlight the following:

- **Timeliness of guidance.** We recommend that CMS issue final part two guidance, system-specific file layouts, and all related model materials as soon as possible but not later than July 1, 2024 to ensure plans have the minimum lead time necessary to operationalize revisions to existing beneficiary materials prior to the 2025 annual enrollment period.
- **Required mailings with membership ID card.** We strongly recommend that CMS reconsider its proposal to require that, when mailing their members ID cards, Part D plans include (1) educational information regarding the MPPP and (2) an MPPP election request form. Due to existing regulatory requirements, the membership ID card envelope we mail is already at its maximum capacity—the vendor with whom we contract to print and mail our membership ID cards has reached its capacity limit for the number of inserts included in the mailing. Bundling these new documents with the membership ID card packet will increase administrative costs by requiring use of a larger envelope as well as increase the risk for print production errors and delays. Additionally, expanding the number of documents included in the membership ID card mailing will exacerbate an already negative member experience in which members are overwhelmed by, and are not able to read, all the documents and other materials included in the existing mailing. We encourage CMS to allow Part D plans the flexibility to mail the MPPP educational materials and election request form separately from the membership ID card.
- **Election request mechanism.** We urge CMS to delay for at least one year the proposed requirement for Part D plans to provide enrollees with a confirmation number as evidence that their MPPP election request was received. In addition, we request clarity on whether CMS is proposing to require a specific, separate confirmation number when a member enrolls in a Part D plan while simultaneously electing the MPPP. While we have implemented the technological infrastructure necessary to generate a confirmation number for Part D program enrollment, there are numerous operational complexities with adapting this infrastructure to generate a separate confirmation number for MPPP election. These

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<sup>1</sup> Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plans, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 40 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

complexities include how to manage election requests processed by web vs. telephone or paper; processing requests at the time of Part D enrollment vs. after Part D enrollment; and processing requests for existing Kaiser Permanente members vs. new to Kaiser Permanente members. An effective date of January 1, 2025 cannot accommodate the time necessary to develop, test and validate a technology solution to provide for a confirmation number as evidence of MPPP election. If CMS maintains the January 1, 2025 effective date for this requirement, we request that the agency apply enforcement discretion for plans acting in good faith to provide evidence of MPPP election to their members.

- **Identifying Part D enrollees likely to benefit prior to the plan year.** Kaiser Permanente recognizes the importance of identifying members most likely to benefit from MPPP election prior to the plan year and supports CMS' proposed threshold of \$2,000 in out-of-pocket costs through September of the current plan year. However, in the first year of the MPPP, it will be challenging to complete the data analysis, identification and outreach activities proposed by December 7, 2024. We encourage CMS to apply enforcement discretion for plans acting in good faith to issue the "Medicare Prescription Payment Plan Likely to Benefit Notice" to those members who meet the criteria prior to the plan year.
- **Identifying Part D enrollees likely to benefit during the plan year.** We recommend that CMS does not include prior authorization or other utilization management edits as a mechanism for triggering outreach to a Part D enrollee as likely to benefit from MPPP election during the plan year. Kaiser Permanente's system for requesting prior authorization and making coverage determinations is separate from the process for determining enrollee out-of-pocket costs associated with a given prescription drug, and therefore the individuals responsible for processing the prior authorization request will not have the information necessary to identify Part D enrollees likely to benefit from MPPP election.
- **Notice of acceptance of election.** We urge CMS to increase the proposed three-calendar-day timeframe for Part D plans to provide subsequent written notice of acceptance of election to an enrollee who has elected the MPPP via telephone. A three-calendar day timeframe to fulfill the written notice requirement as proposed will be challenging to operationalize, particularly on weekends and during holidays when staff resources are less available. We recommend that CMS consider a 10-calendar day timeframe from the original receipt of the request, which is comparable to other scenarios in which a beneficiary has submitted an opt-in request.
- **Pharmacy POS notifications.** We recommend that CMS reconsider the requirement that a pharmacy provide a Part D enrollee with the "Medicare Prescription Payment Plan Likely to Benefit Notice" at the point-of-sale even in instances when the enrollee declines to fill their prescription. It is neither practical nor enforceable for a Part D plan to impose this requirement on a pharmacy, as there is no available mechanism to ensure a Part D enrollee accepts a document or other materials from a pharmacy when leaving the pharmacy without a prescription.
- **Other pharmacy types.** We request that CMS clarify its proposal that mail order pharmacies notify a Part D enrollee via telephone (or other preferred contact method) of

their likelihood to benefit from MPPP election without a delay in dispensing their medication. If a Part D enrollee must receive this notification, Part D plans will need additional guidance on the process and flexibility in meeting the requirements in order to prevent dispensing delays. For example, we request that CMS provide additional details on the number of outreach attempts that must be made and through which modalities, as well as whether the Part D enrollee must respond to the outreach prior to the medication being dispensed. If the Part D enrollee must be reached and provide an affirmative response to the notice, this requirement will create administrative and operational complexities that are likely to delay medication dispensing.

- **Readjudication of prescription drug claims.** We are concerned with CMS' proposal to require that Part D plans readjudicate claims for Part D covered drugs upon MPPP election to include the prescriptions that have not yet been paid for and picked up. The readjudication process necessary to operationalize this requirement diverges from industry standard practice and is complicated by a range of circumstances, including that an individual Part D enrollee may have existing prescriptions waiting to be picked up at multiple different pharmacies. We recommend that CMS does not include these prescriptions in the readjudication process.
- **Medical loss ratio (MLR) instructions.** We strongly recommend that CMS treat unsettled balances from the MPPP as claims (i.e., in the numerator) for the purposes of calculating the MLR. Unsettled MPPP balances are directly related to claims cost, as determined by the negotiated price for Part D prescription drugs, and are not administrative costs. If CMS does not include unsettled MPPP balances in the numerator of the MLR, we encourage CMS to exclude these balances from both the numerator and denominator of the MLR calculation similar to how the agency treats unpaid premium bad debt.
- **Enforcement discretion.** Given the complexity of this new program and the increasingly tight timeline to finalize model documents, operationalize new administrative processes and implement technology solutions, we recommend that CMS apply enforcement discretion in plan year 2025 for good faith efforts made by plans to conduct enrollee outreach and process election requests. We reiterate our prior comments that CMS should apply a hold harmless policy to ensure that summary and overall Star Ratings for individual plans do not go down if lower performance results (e.g., complaints tracking module) are likely due to MPPP impacts, especially given increasing demands on customer service representatives to assist beneficiaries in navigating the new program.

\* \* \*

Kaiser Permanente appreciates CMS' consideration of these comments. Please contact Greg Berger at [gregory.b.berger@kp.org](mailto:gregory.b.berger@kp.org) if we may provide additional information or answer any questions.

Please see the below response from Longevity Health Plan:

Institutionalized beneficiaries enrolled in Special Needs Plans (SNPs) such as ISNPs or DSNPs should be excluded from the proposed changes for M3P. Institutionalized beneficiaries, by virtue of their residential status, are already protected from the concerns the M3P is designed to address. Inclusion of institutionalized beneficiaries will create redundancies, administrative burden, and unnecessary confusion.

The majority of beneficiaries residing in institutions are Medicaid eligible. MACPAC cited that 84% of nursing home residents had both Medicare and Medicaid in 2019<sup>1</sup>. They do not usually have a Part D co-pay as a result of this.

Medicare beneficiaries residing in institutionalized settings generally utilize only long-term care (LTC) pharmacies. The facility manages the pharmacy selection, ordering, and dispensing of medications. ISNP beneficiaries do not pay their copays at the point of sale with a LTC pharmacy. Any co-pay or member responsibility is already billed at a pre-set interval (generally monthly). The institution where the beneficiary resides does not withhold medications from the resident beneficiary if the co-pay or member responsibility is unable to be met.

Any institutionalized beneficiary using a retail point-of-sale for a medication would likely be doing so as a direct result of a visit with a provider outside of the facility. The beneficiary would not have the ability to wait or return to the retail pharmacy at a later date/time if opting into a M3P type of program.

It is important to note that the National Institutes of Health cites in 2022<sup>2</sup> that 68% of older adults in nursing homes/institutions have moderate or severe cognitive impairment. For this population the intricacies of this proposed program may be difficult to understand, resulting in confusion and frustration on the part of the beneficiary.

We appreciate the opportunity to provide this feedback.

<sup>1</sup> <https://www.macpac.gov/subtopic/nursing-facilities/>

<sup>2</sup>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9017032/#:~:text=U.S.%20nursing%20homes%20provide%20long,moderate%20or%20severe%20cognitive%20impairment.>

**Beth Socoski CHC, CCEP, MBA, MSW, MSCL**

Medicare Compliance Director



The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd  
Baltimore, MD 212441

March 15, 2024

Dear Administrator Brooks-LaSure,

Submitted via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

**RE: Part 2 of the Medicare Prescription Payment Plan Guidance**

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the implementation of the Medicare Prescription Payment Plan program set to take effect for Contract Year (CY) 2025 per the Memorandum ***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***, published on February 15, 2024.

Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The undersigned members of the MAPRx Coalition are pleased to provide CMS with our official commentary in response to your efforts to implement the Medicare Prescription Payment Plan (MPPP).

MAPRx appreciates the opportunity to comment on how CMS intends to implement Part D plan sponsor and agency education and outreach efforts for the MPPP, a program that will help ease beneficiary financial burdens for medications by making out-of-pocket (OOP) costs more manageable and predictable through monthly payments. When advocating for Congress to enact a true OOP cap in Medicare, MAPRx was consistently a strong proponent of this type of program. Given the critical role this program will play in alleviating financial burdens for beneficiaries, we want to ensure that beneficiaries are fully informed of this new program. Specifically, MAPRx would like to address the following issues CMS raised in this second round of guidance:

- **Part D plan general outreach and education requirements**
- **Part D sponsor website requirements**
- **Part D sponsor operational requirements**
- **Targeted outreach and education**
- **Election options**
- **Guidelines for different types of election requests**
- **Plan notifications and guidelines**
- **CMS education approach**
- **CMS' approach to updating existing Part D resources**
- **Pharmacy role in operationalizing the MPPP**
- **Other considerations to ensure the success of the education and outreach**



### **Part D plan general outreach and education requirements**

Under the proposed guidance, Part D sponsors must provide Part D enrollees with educational information on the MPPP through existing marketing materials, including the following: membership ID cards, Annual Notice of Change (ANOC), Evidence of Coverage, Explanation of Benefits, and Part D sponsor websites.

MAPRx strongly supports CMS' proposal to require plans to furnish educational information on the MPPP within in or alongside core documents received by beneficiaries, as well as on Part D sponsor websites. We encourage CMS to ensure that educational materials provided by Part D plans are created with easy-to-understand language for beneficiaries and also in multiple languages. Furthermore, to ensure consistency across the information provided by Part D sponsors about the MPPP, we request that CMS encourage Part D sponsors to rely on educational resources developed and provided by CMS. To further foster the consistency of information communicated to beneficiaries, we also request that CMS be more prescriptive with Part D sponsors about the MPPP information they provide and how they provide it. We offer additional detailed feedback on the educational resource to be created by CMS in the *CMS educational outreach to Part D beneficiaries* section of the comment letter.

### **Part D sponsor website requirements**

CMS proposes that Part D sponsors include information on the MPPP on their websites and offer an MPPP election request mechanism that enrollees can use to opt into the program and one that provides the individual with a receipt of enrollment.

Specifically, CMS specifies the type of MPPP information that plan sponsors must include on their websites. MAPRx largely agrees with CMS' requirement to include the following on plan websites:

- Overview of OOP cap and MPPP
- Enrollment options and processes
- Easy-to-understand calculation examples
- Who is likely to benefit
- Implications for failing to pay
- Information on LIS
- Complaints and grievances process
- How to obtain additional information

Of note, MAPRx believes plan sponsors should also prominently display information about the low-income subsidy (LIS) program, as prospective LIS enrollees will benefit more in LIS than in the MPPP. This distinction will help eliminate confusion and promote increased LIS enrollment by those who are eligible. We also believe plan sponsors should state clearly on websites that the MPPP is not a newly created Part D plan being marketed to beneficiaries as part of sales pitch; rather, plan sponsors should indicate the MPPP is a new Medicare program in which they can voluntarily participate and may help them better manage their prescription drug costs.

In addition to identifying the type of information plan sponsors must include, CMS should draft and publish model language that specifies how such information is to be conveyed. With this approach, CMS would ensure the consistency about how this new Medicare program will be communicated to beneficiaries. MAPRx respectfully requests that CMS require plan sponsors to include MPPP information and the election mechanism prominently on their Medicare

websites to ensure the greatest number of beneficiaries view the information. As most of the Part D plan sponsors offer other products (eg., employer-sponsored insurance, Marketplace plans), this critical information could easily get lost amid the other content on the website. Therefore, we strongly believe this information and mechanism should be front and center on the applicable Medicare pages that a beneficiary is likely to view.

In addition to the information highlighted on plan websites, we believe it is imperative the election mechanism be easy to navigate, certainly no more difficult than enrolling in the plan. We strongly encourage CMS to require a true online enrollment and not to enable plan sponsors to design the election mechanism such that it results in beneficiaries completing, for example, a PDF enrollment application that is submitted to the plan. Such a process delays enrollment and creates more opportunities for confusion, errors and mistakes to occur. We respectfully ask that the agency explore processes to prevent beneficiaries from engaging in multiple enrollments. As this scenario could easily occur, it would confuse beneficiaries and delay enrollment into the program, thereby potentially negatively affecting access to treatment. CMS could minimize this possible confusion by creating a process allowing beneficiaries to easily verify if they are enrolled in the MPPP.

#### **Part D sponsor operational requirements**

CMS also outlined several operational requirements for Part D plan sponsors, specifically focused on the following:

- Part D bidding guidance
- Medical loss ratio (MLR) instructions
- Monitoring and compliance
- Audits
- Direct and indirect remuneration (DIR) reporting guidance

Overall, MAPRx supports CMS' expectation that plan sponsors incorporate the MPPP into their compliance programs to ensure the program is meeting the needs of beneficiaries. To confirm compliance, MAPRx supports the proposed audit approach, as this action will help validate plan sponsors are implementing the new program properly. MAPRx believes CMS should adopt a standardized auditing process, which would promote consistency of reviews and also provide Part D sponsors with a clear example of implementing and administering an effective MPPP. Furthermore, to further ensure compliance, MAPRx suggests CMS require plans submit information on their MPPP and associated compliance approach in annual plan bid submissions so that the agency can proactively review them in advance of the upcoming plan year. Finally, to ensure transparency around these programs, MAPRx respectfully requests CMS to publicly release audit results at the sponsor and plan level on an ongoing basis.

#### **Targeted outreach and education**

Overall, MAPRx strongly supports a broad outreach and education to all Medicare Part D enrollees regarding the MPPP. We are concerned that a targeted approach alone will miss some beneficiaries who not only could immediately benefit from the program, but also could benefit in the future as their medication needs evolve. While we recognize targeted outreach should be for those beneficiaries most likely to benefit in the MPPP, we believe a broad educational campaign inclusive of timely and clear communication on the program and enrollment options is critical especially for the first year of the MPPP. Generally, MAPRx is supportive of the proposed requirement for Part D plan sponsors to provide notice for those who will likely benefit the most via the *Notice for Part D Enrollees Likely to Benefit*. We also strongly support Part D plans notifying enrollees based on their preferred and authorized notification

method as this approach is likely to facilitate greater program enrollment as opposed to only allowing one method of notification.

While MAPRx agrees with a targeted approach for those most likely to benefit, we respectfully disagree with one of the approaches in calculating which Part D enrollees are likely to benefit. To be clear, MAPRx supports the proposed approach of determining beneficiaries likely to benefit prior to the plan year. Informing beneficiaries with OOP costs exceeding \$2,000 in CY 2024 is a sensible approach as these beneficiaries may very well incur similar OOP costs in 2025. We urge CMS to require plan sponsors to initiate outreach a few months prior to the annual election period so Part D enrollees have adequate time to ask questions and get answers about the program prior to the enrollment period. While MAPRx supports the proposed calculation for identifying those likely to benefit prior to the plan year, we strongly recommend CMS reconsider the calculation for identifying those likely to benefit during the plan year. We appreciate the agency taking a thoughtful approach in determining who may best benefit; however, we disagree with the calculation. CMS is proposing for plans to inform beneficiaries likely to benefit during the plan year and at the point of sale (POS) if they have a single prescription cost exceeding \$600. Rather, we believe that any threshold should be based on cumulative costs, not a cost threshold for a single prescription. Calculating the threshold based on cumulative costs aligns with congressional intent that the MPPP not be limited to costs from a single prescription, and therefore, we believe CMS should adopt a revised methodology.

In addition to the overall approach for targeted outreach, MAPRx also supports the requirement for Part D sponsors to notify the pharmacy when an enrollee incurs OOP costs exceeding a defined threshold. We believe it will be important for the pharmacy to help inform those likely to benefit from participation in the MPPP. For education by pharmacists to be successful, we recommend that CMS provide effective educational materials (eg., MPPP brochures) that pharmacists can easily hand to beneficiaries at the pharmacy. Furthermore, we also recommend CMS provide model language for pharmacists to leverage when counseling patients on MPPP to ensure the interaction is as quick and informative as possible. Specifically, we support CMS providing information for pharmacists directing patients to contact their Part D plan leveraging the contact information on their Part D membership ID card.

### **Election Options**

Overall, MAPRx supports beneficiaries having wide latitude in the timing of enrollment into the MPPP, including Part D plan annual enrollment periods, initial enrollment periods, and special enrollment periods. We appreciate the agency's approach in seeking to ensure that prospective participants have multiple enrollment options, including a toll-free telephone number, website application, and fax or mail option. As there is likely to be significant variation across the Part D population in terms of preferred enrollment methods, we strongly support the requirements for plans to accept the election request regardless of format.

As mentioned previously in our comments, we largely support the requirement for Part D plans to send the *Medicare Prescription Payment Plan Participation Request Form* with the membership ID card to new Part D enrollees as we think this will help facilitate greater program participation for those who do not enroll into the MPPP upon plan enrollment. As this will be a new program for beneficiaries in 2025, there is potential for confusion. Therefore, we support CMS' requirement of plan sponsors to reach out to a prospective MPPP enrollee for any missing information following the submission of an election request. We especially agree that the plan sponsor must contact the Part D enrollee either telephonically or electronically to collect all necessary information, but we request the agency require plan sponsors to conduct this

outreach within a 72-hour time frame, so this does not adversely affect access to an important medication.

### **Guidelines for Election Requests**

MAPRx appreciates CMS outlining the Part D plan sponsor guidelines for engaging enrollees electing to participate in the MPPP. Overall, MAPRx supports the CMS proposal as it relates to the process for providing paper applications, how to address incomplete applications, enrollee signature options, and phone engagement between Part D plan sponsors and enrollees. For Part D enrollees, having the option to engage with the plan sponsor by phone or email affords enrollees with the option to communicate via their preferred method.

MAPRx agrees with the following requirements for paper elections:

- Part D sponsors should ensure that paper election requests sent to enrollees include all the information, including terms and conditions, needed to enroll the patient.
- If the request is incomplete or missing information, the sponsor must contact the enrollee by phone or email to collect the missing information.
- Paper election requests can either be filled out electronically and printed or filled out by hand by a Part D enrollee or their representative.
- Plan sponsors must have an option for either a pen-and-ink or electronic signature.

MAPRx supports CMS' process for Part D plan sponsors when receiving election request calls from enrollees. Specifically, we agree that calls received by the plan sponsor must be recorded and follow a script previously approved by the Part D sponsor to ensure the information listed in the CMS model request form is obtained during the phone call with the enrollee. We also strongly support CMS' expectation of Part D sponsors to complete the entire MPPP election process in a single telephone interaction if the Part D enrollee wishes to participate in the program. Given the potential inconvenience of multiple phone calls, engaging patients more than once could result in prospective enrollees failing to successfully enroll and participate in the program. While we support this proposal, we respectfully suggest CMS draft a model call script for plan sponsors to standardize how information listed on the CMS model request form is obtained during the call. Finally, we suggest CMS include a requirement for plan sponsors to exhaust multiple outreach attempts to a beneficiary before stopping such outreach for gaining missing information.

In addition, we appreciate CMS' proposal for providing an online election request option, including the ability to read and agree to terms and conditions through the website during the election request process. In an effort to bolster visibility and accessibility for the election request online, we recommend CMS consider two additional enhancements: offering a "pop-up" for an election request following enrollment into a Part D plan and mandating that Part D sponsors display a link to an online election request on the Medicare homepage on the plan website. Additionally, given the guidance for the pharmacy's role in operationalizing the MPPP, we recommend CMS require, not just encourage, Part D plans to submit enrollment data to pharmacies.

### **Plan notifications and guidelines**

In addition to the educational outreach from Part D plan sponsors and CMS prior to enrollment into the MPPP, communication regarding elections, failures to pay, and terminations will also be important. MAPRx largely agrees with CMS' proposed approach for these notices with several recommendations for each.

#### *Notice of Acceptance of Election*

For this notice, CMS would require the Part D sponsor to deliver a written notice of acceptance of an election in the MPPP to the program participant either via mail or electronically, depending on the participant's preferred and authorized communication method, within three calendar days of delivering the initial telephone notice. MAPRx appreciates this thorough communication process and supports the proposal.

#### *Notice of Failure to Pay*

For a beneficiary failing to make a timely payment, CMS would require the Part D sponsor to send the beneficiary an initial notice explaining that he or she has failed to pay a monthly billed MPPP amount within 15 calendar days of the payment due date.

MAPRx suggests that CMS employ a policy similar to when beneficiaries miss a premium payment. For example, if a Part D sponsor has a policy to disenroll the member when a member has not paid plan premiums, the sponsor must send an appropriate written notice of non-payment of premium to the member within 15 calendar days of the premium due date. The sponsor may send interim notices after the initial notice, and we believe Part D plan sponsors should send interim notices for missed MPPP payments. We believe CMS should align the timing of this notification to CMS' missed premium policy. Additionally, MAPRx also urges CMS to require Part D sponsors email a payment link to the beneficiary, so he or she can quickly and easily submit the missed payment, and to create a verification process for beneficiaries.

#### *Notice of Termination of Election Following End of Grace Period*

Under the proposed guidance, Part D sponsors must provide a notice of termination to Part D enrollees who have failed to pay their outstanding balance within the required grace period. This notice must be sent within three calendar days after the end of the grace period. MAPRx supports this proposal as it requires Part D plans to send a quick response to the beneficiary.

MAPRx also requests that CMS design the termination forms to ensure they are incredibly clear as to minimize confusion. Additionally, MAPRx requests that CMS require Part D sponsors to clearly state on the termination forms that while they may be terminated from the MPPP, they are not terminated from Part D coverage or enrollment in the plan. Also, the termination notices should state that termination will not inhibit future eligibility and participation in MPPP.

#### *Notice of Voluntary Termination*

After a participant voluntarily terminates their participation in the program, Part D sponsors must work with the enrollee to determine how they will pay their outstanding balance, which may include a lump sum payment; however, Part D sponsors cannot require full immediate repayment. The Part D sponsor must process the participant's voluntary termination request and send the individual a notification confirming the termination within 10 calendar days of receipt of the request.

MAPRx supports this proposal and appreciates CMS requiring Part D sponsors to allow beneficiaries to pay their balances over time. MAPRx suggests CMS require sponsors to use a prorated approach for paying outstanding balances. Similar to the *Notice of Termination of Election Following End of Grace Period*, MAPRx believes the form should be clear and underscore that voluntary termination does not prevent MPPP participation in the future or overall, Part D eligibility.

### **CMS educational outreach to Part D beneficiaries**

As mentioned throughout our comment letter, MAPRx strongly believes it is imperative to deploy a robust educational campaign to ensure Part D beneficiaries have a complete and full understanding of the MPPP well in advance of the annual election period. Given this important effort, MAPRx appreciates the role CMS will play in this process and its planning to deploy educational resources for Part D enrollees. However, MAPRx has significant concerns that the proposed approach in the Part 2 guidance falls short of effectively educating beneficiaries. In this next section, we offer our feedback on the proposed approach and offer several ideas for enhanced education.

### **CMS educational resources**

MAPRx applauds CMS' plan to develop and provide an educational product for Part D enrollees on the Medicare.gov website and through other communication channels. For this resource to effectively educate prospective enrollees on the MPPP, we strongly believe it should cover the following core topics and concepts:

- Overview of the OOP cap and the MPPP (eg, costs cannot exceed OOP cap regardless of plan or product)
- Enrollment options and processes
- Easy-to-understand calculation examples
- Who is likely to benefit
- Implications for failing to pay
- Monthly billing statement information
- Information on LIS
- Complaints and grievances process
- How to obtain additional information (eg, how to identify and contact local SHIP counselor)

In addition to these core concepts, we encourage CMS to ensure the MPPP promotional and educational materials are as easy as possible for beneficiaries to understand. We suggest the information be conveyed in plain language and in multiple languages to maximize understanding by the most beneficiaries. We also encourage CMS to convey to beneficiaries that the MPPP is not a new Medicare or Part D benefit. Rather, we suggest CMS inform beneficiaries that MPPP is a new Medicare *program* that will help patients. And, given the significant variation in health literacy among the Part D population, we strongly recommend that CMS leverage the expertise of health literacy experts to ensure the resource is broadly applicable.

Furthermore, we are also supportive of the agency encouraging Part D sponsors, pharmacies, healthcare providers, beneficiary advocates, and others to use this product for education. All these stakeholder groups will be critical in delivering effective education to Part D beneficiaries. Especially important are the patient advocacy community, many of which are members of this coalition. Given our constant interactions with patients, caregivers, and local advocates, we encourage CMS to partner with our community and leverage our expertise in developing this resource. Going further, we respectfully request that CMS provide the patient advocacy community and independent charitable foundations with model language or a script for how to discuss the MPPP with Part D beneficiaries. Healthcare providers are another critical stakeholder group as many beneficiaries trust the opinions and guidance of their providers. To that end, we believe there is a strong need to broadly educate the provider community, and it will be important for CMS to target them with these resources.

MAPRx also believes Part D plan sponsors have a significant role in providing education to these stakeholders, too. Therefore, we appreciate CMS' effort in encouraging Part D plan sponsors to provide additional information that pharmacists can give to those likely to benefit, communicate details of the educational materials to the contracted provider and other parties, and describe the MPPP in materials (eg, educational materials, communications, marketing materials). However, we believe that Part D plan sponsors should be required, not simply encouraged, to do these activities, especially communicating details to key stakeholders and describing the MPPP in plan marketing materials.

### **CMS' approach to updating existing Part D resources**

MAPRx appreciates that CMS plans to revise existing Part D resources, specifically that CMS will collaborate with interested parties to ensure stakeholders have the appropriate information to support enrollees regarding the MPPP. MAPRx suggests that CMS consider developing a more prescriptive plan for updating resources to boost effectiveness in supporting the Part D population. To help CMS with this more prescriptive effort, we recommend that CMS incorporate input from patient advocacy groups, SHIP counselors, and beneficiary advocates when updating resources. Particularly, SHIP counselors and beneficiary advocates may have valuable insights into the most frequent questions that Part D enrollees typically have and may likely ask about the MPPP.

The Medicare & You handbook is a foundational resource for Part D patients. For this resource, we recommend creating a clear, concise section focused on the MPPP. Given the handbook's length, we recommend either including pop-up images and language on cover and the table of contents to ensure readers can easily identify and navigate to the MPPP section.

While Medicare & You is a valuable tool for Part D beneficiaries, the Medicare.gov Plan Finder tool may be the most important resource in effectively reaching Part D beneficiaries as they use this tool to weigh plan options, assess annual costs, and enroll into a plan. More than any other resource, this is the one CMS must get right in educating and informing this population. To meet this objective, first, MAPRx believes Plan Finder should offer a clear enrollment mechanism on the website, similar to mechanism used to enroll into a Part D plan today. We strongly recommend Plan Finder deploy a pop-up message about the MPPP immediately following an enrollment into a Part D plan; it may also be effective to have a pop-up message if a beneficiary inputs drugs into the search function. Finally, we ask CMS to consider offering an online calculator tool to help patients understand their benefits and costs under the MPPP. For the MPPP to be successful, Plan Finder must be an effective tool, and we are hopeful that CMS will consider these recommendations to enhance it further.

### **Pharmacy role in operationalizing the MPPP**

MAPRx greatly appreciates CMS' approach in seeking to enlist pharmacists in educating Part D beneficiaries, especially at the point of sale. Specifically, we appreciate pharmacists providing the *Medicare Prescription Payment Plan Likely to Benefit Notice* at POS and that pharmacies must reprocess claims if a patient enrolls after receiving the *Likely to Benefit Notification* (triggered by a high-cost Part D covered prescription drug). As pharmacists will play a crucial role in this overall effort, we ask that CMS focus on best equipping them with helpful and efficient resources without overburdening an already-overtaxed workload.

### **Other suggestions around beneficiary education**

MAPRx is appreciative of CMS' efforts in drafting the Part 2 guidance. We recognize this is a significant undertaking, and we are thankful to be a partner with the agency in this endeavor.

While the guidance lays out some foundational steps, we believe there is more the agency can do to ensure beneficiaries are well-informed of this new benefit. In this section, we offer some additional suggestions to ensure the success of your outreach in advance of CY 2025.

#### *Name of the MPPP*

We strongly urge CMS to reconsider the name of the program. Medicare Prescription Payment Plan does not adequately convey to beneficiaries what the program is or how it may help them manage their prescription drug costs. In fact, the name may limit, rather than promote, participation as beneficiaries simply may not understand from the name that the program may help them. The Agency encountered a similar situation with the creation of the Low-Income Subsidy and subsequently adopted the term Extra Help to more effectively communicate the nature of the program. In late 2023, we conducted a focus group with SHIP counselors, and they unanimously agreed with exploring a name change. While we do not propose a specific name for the program, we believe CMS should shift the nomenclature from MPPP closer to a “budgeting” benefit, given that this may resonate more with beneficiary populations as they are generally savvy with living off a fixed income. Additionally, having the word “plan” in the name may be problematic as this may confuse beneficiaries into thinking that this is an actual Part D plan. Finally, we also believe that “Part D” should be incorporated into the name, as well.

#### *MPPP Advertising Campaign*

While we appreciate CMS’ effort in creating educational resources and updating existing ones, we believe the agency should go further in its outreach, namely through a public advertising campaign. Recalling the launch of the Marketplaces in 2013 (for the 2014 plan year), Health and Human Services and/or CMS should deploy an advertising campaign (ie., with television ads and brochures) during the summer months, well in advance of the annual election period. Going further, we urge CMS to produce and deploy public service announcements from Medicare at waiting rooms at healthcare facilities such as physician offices, federally qualified health centers, etc. As retail pharmacies will be an important healthcare site for beneficiaries, we also ask that CMS explore offering QR codes for patients to enroll/learn more about MPPP at retail pharmacy counters and check out areas. Finally, we also ask CMS to explore other avenues, such as having a focused social media play.

#### *Educational Resources*

We appreciate CMS’ detailed guidance on the various educational resources in this guidance. While CMS has offered valuable guidance to plans and stakeholders, we offer some additional feedback from our coalition. Namely, we believe CMS should create a new letter with MPPP details outside of the ANOC process and with a different color to further stand out. We believe it would be important for CMS to highlight this new letter further in the Medicare & You handbook. While we also support the monthly billing statements, we urge CMS to ensure the monthly billing statements offer clear information for the enrollee—especially the remaining balance amount, so that these statements clearly stand out from the Explanation of Benefits. And finally, throughout all materials, we ask that CMS clearly communicate that patients have to reenroll into the program on annual basis.

#### *SHIP Counselors*

MAPRx believes SHIP counselors will play a critical role in this endeavor as they engage with Part D beneficiaries on a daily basis. We strongly support that CMS ensure SHIP counselors are well resourced to educate beneficiaries on the MPPP. One idea would be to offer SHIP counselors a short tip sheet with key information that can be used at events and on SHIP websites.



#### *Part D Plan Sponsor Requirements*

We generally support CMS in holding Part D plan sponsors accountable for their role in educating beneficiaries, but we have some additional considerations. As there have been recent reports of Part D plan sponsors being non-compliant in several areas, we think this oversight is of critical importance. Specifically, we request that CMS require plans to continually send information on MPPP to beneficiaries, even if beneficiaries initially opt against enrollment. Additionally, throughout this comment letter, we have highlighted the importance of equipping SHIP counselors with the resources they need to educate beneficiaries. However, the guidance failed to discuss the role of agents and brokers in this process. Plan sponsor agents and brokers engage many prospective enrollees. Therefore, we respectfully ask that CMS require agents and brokers to educate beneficiaries on this benefit and undergo mandatory training on it.

#### *POS Enrollment Option*

As CMS is aware from prior comments and in discussions with CMS staff, MAPRx strongly believes that a Point of Sale (POS) enrollment option is critical to the successful implementation and adoption of the MPPP. While we understand it is a significant challenge to operationalize a POS option for CY 2025, and appreciate CMS' efforts to work with the beneficiary community and other stakeholders on this issue, we continue to strongly request that a POS be an option as soon as possible, but no later than CY 2026. This will be critical for the success of the program in future plan years.

#### *Beneficiary Feedback*

We recognize that CMS is seeking to design the most useful and effective program for Part D beneficiaries to help them minimize and manage their OOP costs. As the beneficiary is at the heart of all of this, we believe it is vital to continually gain their feedback on the program. To that end, we encourage CMS to conduct regular focus groups with Part D beneficiaries and to continually engage the patient advocacy community to ensure program and educational outreach are meeting objectives. Such engagement will help establish a "feedback loop" that ultimately can enhance the beneficiary experience with Part D and MPPP.

#### Conclusion

Thank you for your consideration of comments on the Part 2 guidance of the implementation of the MPPP. We have also attached a MAPRx Coalition issue brief to inform your efforts. The undersigned members of MAPRx appreciate your leadership to improve beneficiaries' access and affordability in Medicare Part D. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or [bduffy@nvgllc.com](mailto:bduffy@nvgllc.com).

ACLU Volunteers for Iowa

AiArthritis

Allergy & Asthma Network

Alliance for Aging Research

Alliance for Patient Access

ALS Association

American Association on Health and Disability

American Cancer Society Cancer Action Network  
American Kidney Fund  
Arthritis Foundation  
Epilepsy Foundation  
HealthyWomen  
HIV+Hepatitis Policy Institute  
International Myeloma Foundation  
Lakeshore Foundation  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Medicare Rights Center  
Mental Health America  
Muscular Dystrophy Association  
National Alliance on Mental Illness  
National Council on Aging  
National Health Council  
National Kidney Foundation  
National Multiple Sclerosis Society  
National Organization for Rare Disorders  
National Psoriasis Foundation  
Patient Access Network (PAN) Foundation  
The AIDS Institute  
The Assistance Fund  
The Headache and Migraine Policy Forum  
The Leukemia & Lymphoma Society  
Triage Cancer

# Minimizing Affordability Challenges and Beneficiary Confusion

## Considerations for Implementation of and Outreach Around Part D Benefit Redesign

The Inflation Reduction Act will usher in the most significant changes in Medicare Part D since the program was implemented in 2006. Specifically, Medicare beneficiaries enrolled in Part D plans will pay no more than \$2,000 in drug costs starting in 2025 and may opt to distribute out-of-pocket (OOP) costs more evenly across the year as opposed to incurring a one-time high cost. Part D beneficiaries may enroll in the Medicare Prescription Payment Plan (MPPP), a program in which participants make a monthly payment for the overall cost of a one-time OOP expense up to the OOP cap. The new benefit holds significant promise for prospective participants, especially those prescribed high-cost specialty medications, as they will have the ability to enhance affordability and better manage and predict their OOP costs for prescription drugs.

Despite the positive benefits of the MPPP, the details around participant enrollment, monthly billing, and other program features are likely to be confusing for not only those participating in the new benefits but those deciding whether to participate in the program as well. Therefore, it will be critically important for the Centers for Medicare & Medicaid Services (CMS) to deploy an effective education and outreach effort for Part D beneficiaries and other important stakeholders (eg, caregivers, pharmacists, prescribers, and counselors educating beneficiaries) on the new benefit and to require Part D plans to clearly outline enrollment options in plan materials. CMS released guidance on the program in two parts: Part 1 (released in 2023 and finalized in 2024) proposes the key components of the program while Part 2 (released February 2024) focuses on the approach to educating beneficiaries on this new program. Following the release of Part 2 of the guidance, the MAPRx Coalition is recommending critical considerations in this issue brief, informed by conversations with our members and State Health Insurance Assistance Program (SHIP) counselors, for beneficiary education around this new benefit.

### KEY FINALIZED PROVISIONS FROM PART 1 GUIDANCE



Participation in the new program is voluntary; therefore, prospective participants must opt into the program.



Program calculations will apply to all OOP Part D costs incurred, including those in the deductible phase.



Prospective enrollees may enroll in the MPPP prior to the beginning of the plan year or in any month during the plan year, including during the annual, initial, and special enrollment periods.



CMS will not offer prospective participants an option to enroll at the point of sale (POS) at the pharmacy in 2025. Without a POS option, beneficiaries interested in enrolling will have to leave the pharmacy without their prescription in order to enroll.



CMS also will require Part D sponsors to develop a mechanism to notify a pharmacy when a Part D enrollee would likely benefit, and CMS set the notification threshold at \$600 for a single prescription.

### KEY PROPOSED PROVISIONS FROM PART 2 GUIDANCE



Limited information on CMS' effort to educate Part D beneficiaries on the new program, especially the agency's national outreach campaign and education for key stakeholders such as patients, healthcare professionals, SHIP counselors, etc.



Required updates to Part D plan marketing materials, including the Evidence of Coverage, Annual Notice of Change, Explanation of Benefits, membership ID card mailing packages, and Part D plan websites.



Required process for Part D plans to conduct targeted outreach to beneficiaries likely to benefit from the program before and during the plan year.



We'd like a point of service option in 2025 just for simplicity's sake, because they'll be at the pharmaceutical counter... I think there needs to be a real effort to make it as simple, easy, and accessible as possible. Whatever those venues are for the Medicare beneficiary, they need to be the focus of this and figuring out what the best methods are for them to access them.



While the MPPP will help patients manage costs on a monthly basis, specific aspects may be confusing to this population, especially given the complex calculations, various enrollment options, and limited opt-in benefits within the program. Given this potential confusion, the educational outreach from Medicare is a critical factor in successfully enrolling Part D beneficiaries into the program. Unfortunately, Part 2 of the guidance offered a dearth of specific information as to how the agency plans to educate prospective participants. Given the lack of information provided by the agency, this issue brief seeks to outline clear and actionable steps for properly educating beneficiaries on this program.

To help gather insights around effective beneficiary education, MAPRx collated feedback from coalition members and also convened a focus group session with SHIP counselors, who are on the front line in educating Part D beneficiaries about Medicare requirements, Part D plan options, and any other questions related to the benefit. SHIP counselors are uniquely positioned to offer insights and considerations for CMS' educational outreach as they help current and prospective Part D beneficiaries navigate the initial enrollment period, review plan options, and answer any other questions related to Part D benefits, all in an unbiased manner. During the convening of the focus group(s), the SHIP counselors offered several observations of the MPPP, from the naming convention to how communications should stand out.



I actually like the term 'budgeting your prescription cost,' because that's what they're doing; they're setting a budget for month to month for their prescription cost.



## KEY INSIGHTS FROM COALITION MEMBERS AND THE FOCUS GROUP

MAPRx coalition members and the interviewed SHIP counselors offered robust feedback and insights on the educational outreach of MPPP:



**Naming Convention of MPPP:** Proposed naming of the program may sound too similar to a debt or payment plan that a patient must pay to a hospital or health system. Other counselors expressed concern that the MPPP naming convention may lead to fraud, with bad actors taking advantage of patients without a more clearly defined name.



**Point-of-Sale (POS) Enrollment Option:** It will be critically important to have a POS enrollment option in order to make this benefit as easy and accessible as possible.



**Beneficiary Education on New Program:** CMS should ensure that most of the communications come from official Medicare channels in order to stand out and not get lost like other pieces from Medicare. Furthermore, the Medicare & You handbook and other materials must be clear about this new benefit.



**Targeted Beneficiary Outreach:** CMS threshold of \$600 established in final Part 1 guidance will be helpful, but as patients generally do not listen to advertising campaigns, targeting pharmacies will be the key.



**Key Lessons From Limited Income Newly Eligible Transition Program:** The Limited Income Newly Eligible Transition (LI-NET) program offers some lessons learned as a proxy for the MPPP. Specifically, most pharmacies had limited knowledge about the program when it launched, leaving SHIP counselors to conduct most of the education then and today, CMS must focus education on pharmacies.



I think we can just see that the complexity that already CMS is driving toward by using the term (MPPP), and Medicare beneficiaries are not going to understand what that term means.



## EDUCATIONAL OUTREACH CHECKLIST

Based on the findings, MAPRx recommends these essential elements to guide CMS' education and outreach:

### POS Enrollment Option

- ✓ Offer a POS enrollment option for prospective enrollees, specifically conducting the targeted outreach via pharmacies at the POS.

## EDUCATIONAL OUTREACH CHECKLIST (CONT.)

### Naming Convention for Program

- ✓ Shift nomenclature from MPPP to something closer to a “budgeting” benefit, given that this name may resonate more with beneficiary populations.

### Educating Prospective Program Participants

- ✓ Require Part D plans to offer robust educational resources and highlight them prominently on the plans’ Medicare pages on the website.
- ✓ Deploy public service announcements from Medicare in waiting rooms at physician offices, federally qualified health centers, etc.
- ✓ Deploy a pop-up box in Medicare Plan Finder upon plan enrollment so patients can enroll following their plan selection; ideally, require them to make a Yes/No selection.
- ✓ Create an additional pop-up option for enrollment into the MPPP if a prospective enrollee inputs drug costs during Plan Finder searches in the enrollment process.
- ✓ Conduct regular focus groups with Part D beneficiaries to ensure program and educational outreach are meeting their assigned objectives.

### Participant-Facing Communications

- ✓ Deploy a **new, standardized colored letter** specifically focusing on the MPPP separate from the Annual Notice of Change communication pieces, and highlight this further in the Medicare & You handbook.
- ✓ Ensure the monthly billing statements offer clear information for the enrollee so that these statements stand out from other Explanation of Benefits.
- ✓ Clearly communicate that patients have to reenroll into the program on an annual basis.

### Equipping Key Stakeholders

- ✓ Ensure SHIP counselors are well-resourced to educate beneficiaries on the MPPP.
- ✓ Offer SHIP counselors a short tip sheet with key information that can be used at events and on SHIP websites.
- ✓ Create robust materials for pharmacists (leveraging experience from LI-NET) and healthcare providers.

### Proposed Part D Plan Requirements

- ✓ Require plans to continually send information on MPPP to beneficiaries, even if beneficiaries initially opt against enrollment.
- ✓ Require agents and brokers to educate beneficiaries on this benefit and undergo mandatory training on the MPPP benefit.



I know that CMS guidance for anything and everything is to send a letter, a form letter to beneficiaries. Those get lost in the mail, and we all know that, right? Those of us who do this every single day, it’s just more information that, quite frankly, is often confusing, and they don’t understand.



I often joke that I don’t know many people who read the Medicare & You handbook from front to end (unless they suffer from insomnia). But it’s got to be in language that is easy to understand, relatable, and hopefully mirrors whatever they are able to put on the Medicare Plan Finder.



I hope they’ll do some really good advertisements to really help promote this and to limit the amount of promotion the plans are allowed to do on this benefit... I think if you have Joe Namath talking about this, it’s going to confuse the heck out of people. And if it comes from the official Medicare resource, there’s a better chance they’re going to see this as valid.



## IMPLEMENTING OTHER PATIENT PROTECTIONS

While education around the new MPPP benefit will be critical, the benefit can only be as effective as the beneficiary protections built into the program and more broadly in Part D. The required beneficiary responsibility of \$2,000 may still be a financial challenge to some beneficiaries, especially for those just above 150% of the federal poverty level and ineligible for the Low-Income Subsidy (LIS). According to a poll of Part D beneficiaries, 75% of the respondents stated that they would have a difficult time paying for \$2,000 in OOP costs.

In addition to the lingering financial need for many Part D beneficiaries, the benefit redesign will significantly increase Part D plan financial liability. Given this new financial burden, Part D plans may react in the following ways:

- Increase monthly plan premiums.
- Reduce the number of drugs covered under plan formularies.
- Apply more utilization management across covered drugs.
- Reduce plan offerings, especially standalone prescription drug plans.
- Offer fewer benchmark drug plans in which LIS beneficiaries may enroll to receive no to nominal costs for premiums and cost-sharing.

Given these potential outcomes, it will be critical for CMS to conduct enhanced oversight in order to maintain beneficiary protections while affording plans the appropriate flexibility in managing the benefit.



These (plans) are going to increase premiums. They are going to narrow their formularies, and it's just going to happen. What CMS needs to be aware of is that they need to delve down into (this) more.



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**BY ELECTRONIC SUBMISSION VIA [PARTDPAYMENTPOLICY@CMS.HHS.GOV](mailto:PARTDPAYMENTPOLICY@CMS.HHS.GOV)**

March 4, 2024

Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director of the Center for Medicare  
Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Dr. Seshamani,

The Massachusetts Biotechnology Council (MassBio) appreciates the opportunity to comment on the Part Two draft guidance for the Medicare Prescription Payment Plan (M3P). MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio's 1,600+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

We commend CMS for requiring Part D plans to inform and educate enrollees about the M3P effectively, and for providing standardized content for some communication channels. However, we are concerned that CMS has proposed to allow too much discretion for Part D plans to deviate from the CMS-developed standardized content in other channels, such as websites and provider/pharmacy communications. This could cause confusion and inconsistency among enrollees, providers, and pharmacies, and undermine the quality and effectiveness of the M3P. We recommend that CMS mandate uniformity and consistency in the presentation and dissemination of M3P information across all plans and stakeholders.

Specifically, we request that CMS:

- Specify that Part D plans must use standardized content from CMS or obtain its prior approval for the M3P information they provide with the membership ID card.
- Establish a standardized format for plan websites as they relate to communicating information on the M3P.

- Establish a consistent and clear format for communications between plans and their contracted providers/pharmacies regarding the M3P, to improve the quality and timeliness of information exchange.
- Focus on enhancing Medicare Plan Finder as a single source of learning for enrollees about the M3P, by developing and launching an interactive tool that enables enrollees to compare how their cost sharing obligations under the M3P would vary under different scenarios of drug spending and plan selection.

We believe that these recommendations would help Part D enrollees make informed and timely decisions about the M3P and benefit from lower and more predictable Part D costs. Please do not hesitate to contact me at [Kendalle.OConnell@massbio.org](mailto:Kendalle.OConnell@massbio.org) should you have any questions or require additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Kendalle O'Connell", with a long horizontal flourish extending to the right.

Kendalle Burlin O'Connell  
CEO & President



March 15, 2024

Meena Seshamani, M.D., Ph.D.  
Deputy Administrator and Director Centers for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850  
Attn: Medicare Prescription Payment Plan Guidance – Part Two

Sent electronically via: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

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

Dear Dr. Seshamani:

McKesson Corporation (“McKesson”) is pleased to provide comments to the Centers for Medicare and Medicaid Services’ (“CMS”) entitled, **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 (the “Draft Guidance”)**. We appreciate the diligent and collaborative approach taken by the Agency to work with industry in providing guidance on stakeholder requirements and implementation aspects of the Medicare Prescription Payment Plan (the “program”).

**About McKesson**

McKesson is a global leader in healthcare supply chain management solutions, retail pharmacy, community oncology and specialty care, and healthcare information solutions. McKesson partners with pharmaceutical manufacturers, providers, pharmacies, governments, and other organizations in healthcare to help provide the right medicines, medical products, and healthcare services to the right patients at the right time, safely and cost-effectively. As a mission-driven company, we are focused on working with our customers and partners to advance health outcomes for *all*.

Our unique 360-degree view of the healthcare system offers a distinctive vantage point. McKesson monitors and engages in regulatory activities that present both opportunities and challenges for the company, its customers, and the patients they serve. McKesson strives to ensure that its views on improving healthcare prioritize what’s best for the patient.

## Comments

McKesson appreciates the opportunity to provide feedback in response to the *Medicare Prescription Payment Plan Draft Part Two Guidance*. This program is essential to improving affordability and accessibility for Medicare beneficiaries. As such, our recommendations are anchored by the core belief that operational considerations must prioritize patients and community pharmacies – the site of care that dynamically serves and interacts with patients daily. We appreciate CMS' efforts to partner with stakeholders on implementation of this new program; however, we remain concerned that the guidance, as proposed, will compromise patient experience and create confusion as beneficiaries seek guidance from both their Part D sponsors and pharmacists. Additionally, there are numerous pharmacy impacts that must be addressed, such as cash flow disruptions and increased economic burdens. Community pharmacies, especially independents, continue to navigate hurdles due to direct and indirect remuneration (DIR) reforms implemented this year<sup>1</sup> and should not be forced to take on additional challenges and financial risk.

## **Overview of Key Recommendations**

We appreciate that CMS' approach to operationalizing the program continues to evolve. Launching the program as seamlessly as possible will build beneficiary and stakeholder confidence and utilization of the new benefit that will drive affordability and accessibility. Along with making clear that the primary responsibility for patient education of and enrollment in the program is on the Part D sponsor, CMS should narrowly define and outline the pharmacist's role within this process such that the Part D sponsor is ultimately held accountable for the intent and success of the program.

- McKesson encourages CMS to reconcile all related guidance to ensure consistent application of the program. Additionally, we recommend that CMS continue to evaluate and evolve the program guidance based on learnings from the first and subsequent program years.
- McKesson supports leveraging existing technologies, established lines of communication with enrollees, and resources to further educate on the program.
- McKesson recommends standardizing the processes for communication between Part D sponsors and pharmacies as it relates to the mechanism and identification process of an enrollee who is likely to benefit from participation in the program.
- McKesson urges CMS to revise and clarify that Part D sponsors should not require long-term care (LTC) pharmacies to provide beneficiary notices.

## **Part D Sponsors Requirements**

Section 30 of the draft guidance describes Part D sponsor statutory obligations for required outreach, education, and notification process to beneficiaries. In relation to the education of enrollees, McKesson suggests that CMS:

- Provide education to enrollees beyond the traditional mailed outreach materials. This could include television advertisements, information on Medicare.gov, and CMS social media channels.
- Use the established benefit calculator on Medicare.gov for enrollees to analyze the program's benefits. Enrollees already use this valuable tool, and Part D sponsors could capitalize on the

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<sup>1</sup> CMS Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program

resource by including it on their websites and within their plan documents during the enrollment period. This would also provide a central resource for pharmacies to leverage at the point-of-sale (POS) with patients. Additionally, this could be a place for CMS to educate LTC and Indian Health Service (IHS) patients on how enrollment into this program will impact their anticipated healthcare costs.

- Require more patient-specific detail on the program within the monthly Explanation of Benefits (EOB) prior to an individual electing to enroll in the program. This would provide transparency to patients on the potential cost savings or burdens that could arise from enrolling in the program.

To reduce disruption to the pharmacy workflow and to business operations, McKesson recommends that CMS:

- Clarify that all elements in the model Election Approval Notice including member number, RxID, RxGroup, RxBin, and RxPCN must be listed on the membership ID card for the program. This will ensure that the pharmacy is able to appropriately bill the program for the Part D medication(s) dispensed as a result of enrollment.
- Educate patients on their need to present their primary benefit membership ID card as well as their program specific membership ID card at the pharmacy counter. This will ensure that patients can leverage their full benefit and that pharmacies can correctly adjudicate claims.
- Require that Part D Sponsors utilize a standardized approach for the mechanism to notify pharmacies when an enrollee is likely to benefit. While we understand that the National Council for Prescription Drug Programs (NCPDP) is working to develop new values for existing codes to facilitate this mechanism, CMS needs to identify the standards, data fields, and values that will be used to notify pharmacies so that all PBMs utilize standardized communication. Without this specificity, the notification mechanism is undefined, leaving opportunities for variance and errors in processing which could lead to disruption in care and further burden the pharmacy workflow.

### **Pharmacy Processes**

McKesson recommends that CMS exercise enforcement discretion for pharmacies in 2025 as they work through POS notification challenges within the pharmacy workflow. Additionally, we recommend that CMS provide ongoing educational support for pharmacies, through public webinars and electronic communications.

The draft guidance outlines requirements for Part D Sponsors to identify Part D enrollees likely to benefit at the POS. CMS states that Part D sponsors must have a mechanism in place to notify a pharmacy when an enrollee incurs out-of-pocket (OOP) costs for covered Part D drugs that make it likely that the individual may benefit from participation in the program. To ensure that this mechanism and process aligns with current pharmacy workflow, McKesson recommends that CMS:

- Not require that Part D sponsors be responsible for ensuring that pharmacies deliver a hard copy of a Likely to Benefit notice to an enrollee even when the pharmacy has direct contact with the enrollee. This would be a burden for both the sponsors and the pharmacies since there is not a current means for communicating this type of action.
- Permit pharmacies to electronically provide the Likely to Benefit notice to Part D enrollees, *in lieu* of a hard copy, unless a hard copy is requested by the patient. Many pharmacies currently

[www.mckesson.com](http://www.mckesson.com)

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communicate with patients via text and voicemail to inform when a prescription is ready and could use this same process to provide the notice.

- Provide clarity that pharmacies are not required to notify likely to benefit enrollees in the final months of the plan year, including November and December.
- Provide a pathway for pharmacies to be reimbursed for the additional costs (i.e., paper, ink, staff time, etc.) of distributing hard copies of the Likely to Benefit notice, should pharmacies be held to this requirement.

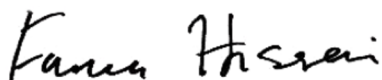
Pharmacies will experience financial and operational burdens due to reimbursement delays and additional costs incurred under the program. For example, pharmacies will now be reimbursed the patient's cost share and Part D sponsor's cost share at the same time, 14-30 days after medication(s) dispense, instead of receiving the patient's cost share at the POS. In addition, pharmacies will be further financially burdened as this process will greatly increase the number of financial transactions, which further erodes existing cash flow challenges that pharmacies face today. McKesson recommends that CMS:

- Remove the requirement for pharmacies to change the date of service of the primary Part D claim or any other claim, as doing so could negatively impact practice management systems (e.g. Drug Utilization Review [DUR]), create billing challenges, including secondary payer reimbursement, and burden pharmacy workflow. A date change could also conflict with state laws and have implications for the timing of prescription refills.
- Provide reimbursement for additional costs incurred when re-adjudicating claims due to the burden of additional transaction fees on the pharmacy.
- Leverage quality measures to mitigate potential pharmacy price concessions from Part D sponsors. CMS must ensure that pharmacies do not experience increased price concession fees from Part D sponsors in relation to quality.
- Broaden the scope of the Medicare Complaints Tracking Module (CTM) to allow pharmacy submissions of complaints and grievances to CMS regarding operational challenges or missing Part D sponsor reimbursements related to the program. Because CMS has an existing way to monitor and collect data about beneficiary complaints and grievances reported via the CTM to assess compliance with all program requirements, beneficiary protections, and program integrity, pharmacies should have access to the CTM, or a similar module that addresses unanticipated pharmacy reimbursement challenges that will inevitably arise in the first year of the program.

## Conclusion

McKesson looks forward to working with CMS as an industry partner on emerging data exchanges, technology priorities, and the pharmacy and patient impacts related to operationalizing the Medicare Prescription Payment Plan. If you have questions or need further information, please contact Fauzea Hussain, Vice President of Public Policy, at [Fauzea.Hussain@McKesson.com](mailto:Fauzea.Hussain@McKesson.com).

Sincerely,



Fauzea Hussain

Greetings,

Comments and/or request for clarity are included for several topic:

Please clarify from Section 30 of Part 2 Guidance if the \$2,000 threshold is incorporating the requirement of supplemental benefits under Enhanced Alternative plans that also will apply to the TrOOP in 2025?

Also, Section 30.2 – Targeted Outreach and Education Requirements for Part D Sponsors, states, that CMS proposes requiring Part D sponsors to undertake targeted outreach to Part D enrollees if they become aware in advance of a new high-cost prescription (through PA or UM) for an enrollee that would trigger the pharmacy POS notification process. Part D sponsors would be required to provide the Medicare Prescription Payment Plan Likely to Benefit Notice to the identified enrollee within the same timeframe that applies to the coverage determination for the associated utilization management requirement. Clarify if providing the Likely to Benefit Notice will be required when the coverage determination is denied? We recommend only providing the Likely to Benefit Notice in cases where the coverage determination is approved to minimize confusion in the members. Finally, regarding Prioritization of Premium Payments, clarify if payments towards Late Enrollment Penalty (LEP) must be prioritized over Medicare Prescription Plan Payments?

Lastly, regarding Section 30.1.1- Required Mailings with Membership ID Card Issuance, Currently MCS has a process in place that handles printing of the membership Id card, regulatory required inserts, folding and sealing automatically. This integrated process ensured that our members receive their Ids more quickly and accurately to achieve high levels of members satisfaction. However, the machine equipment to perform this process has limitations regarding the maximum dimension and weight of the documents in the envelope. In this regard, the mandate of adding 4 pages containing the Medicare Prescription Payment Plan election request form and information about the program will affect the automatic process we have in place, the accuracy, timing, and service for our membership. Our proposal would be to send these two documents in a separate mailing daily and including a prepaid envelop for the participants that opt into the Program. We believe that with this change the law mandate will be upheld. In addition, our current

membership Id card process considers existing members and new enrollees. If we must implement the requirement of including the two documents, all the members will receive them with the Ids since the process is not separated.

Regards,

**Erika Ortega Torres**

Compliance Specialist

Compliance

Medical Card System, Inc.

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t: 1.787.758.2500 ext. 5646

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Submitted Electronically to: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

March 16, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Administrator Brooks-LaSure:

The National Association of Specialty Pharmacy (NASP) welcomes the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) Medicare Prescription Payment Plan (MPPP) Guidance issued in February 2024. NASP appreciates the agency's efforts to solicit pharmacy feedback to support implementation of the Inflation Reduction Act's provisions to establish the *Maximum Monthly Cap on Cost-Sharing Payments Program*. NASP's goal is to ensure the new Medicare Part D benefit is accessible to Part D enrollees, supporting their initial and ongoing medication access and adherence while also ensuring implementation is not overly complicated or burdensome on specialty pharmacy operations. NASP offers its comments on the guidance, referencing each section of the guidance and welcomes the opportunity to continue working with CMS on implementation of the MPPP.

NASP's members are committed to the practice of specialty pharmacy with a focus on the patients served to ensure better clinical outcomes while reducing overall healthcare costs. NASP represents the entire spectrum of the specialty pharmacy industry, including the nation's leading specialty pharmacies and practicing pharmacists; nurses and pharmacy technicians; pharmacy benefit managers (PBMs); pharmaceutical and biotechnology specialty drug manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; and technology, logistics and data management companies. With over 3,000 members, NASP is the unifying the voices of specialty pharmacy.

### **Section 30.2.2: Education – Identifying Beneficiaries Likely to Benefit Prior to Plan Year**

NASP appreciates that CMS has already drafted handouts about the benefit that can be provided to beneficiaries in advance of the new plan year. Providing advance time for consideration of the new benefit is especially important for beneficiaries with life altering and sometimes threatening specialty conditions, such as cancer, MS, rheumatoid arthritis, organ transplantation. Specialty patients typically encounter high drug costs to treat their condition and are most likely to enroll in the new Part D benefit. NASP believes it is most critical that Medicare work to avoid, to the greatest extent possible, a situation where a beneficiary is not first informed of the MPPP option until they are at the point of sale. Delaying an opportunity to enroll in the program could result in a beneficiary forgoing beginning treatment with a medication or disrupting continued adherence to a medication regimen due to cost.

We expect that specialty drugs will make up the most significant portion of the \$600 threshold that beneficiaries meet before they are first notified about the MPPP. It is critically important that these beneficiaries are given the earliest opportunity to learn about the new Medicare Part D benefit and how it works.

### **Section 50.3.3: Other Pharmacy Types**

Specialty pharmacies differ significantly from mail order pharmacies given the high-touch services they provide as they manage complex patients, regardless of whether the patient receives their medication by walking into a specialty pharmacy or via courier from a specialty pharmacy. We appreciate CMS' effort to not burden pharmacies with providing additional MPPP counseling or education other than providing information on eligibility. However, as specialty pharmacies that regularly provide patient's information on options to support drug affordability for frequently high-cost specialty drugs, we believe specialty pharmacies could serve as an essential partner to ensuring enrollees have accurate information and understand how the MPPP could help them afford their high-cost drugs – particularly for patients starting a new therapy. Patients will have questions for their pharmacists, who they trust and rely upon to support the management of their complex specialty conditions, about what the MPPP benefit is and how it operates to support drug affordability.

### **Section 50.4: Readjudication of Prescription Drug Claims for New Program Participants**

NASP appreciates CMS's efforts to not place undue burden on pharmacies when working to stand up the MPPP. We want to ensure that any and all efforts to inform Part D enrollees about their enrollment opportunities and the process to then enroll them once they opt in and readjudicate any past claims, ultimately does not ever result in a beneficiary walking away from their medications in order to address the enrollment process. We should collectively strive to ensure that a beneficiary never walks away from their dispensed medication – at the time of



dispensing or otherwise. This is particularly important with specialty drugs, which require adherence or risk life altering setbacks or life-threatening circumstances when beneficiaries are not adherent.

NASP is very concerned that the guidance seems to accept that beneficiaries walking away from their medications is allowable for them to first take the time to enroll in the MPPP through their insurer. We cannot allow an administrative process to enroll to circumvent timely access to medication. Research shows that if a beneficiary does not receive their medications when dispensed, they are more likely to significantly delay or otherwise abandon the prescription. Specialty drug treatments support patients who have cancer, MS, HIV, and other life-threatening conditions, where if they miss a dose or delay treatment, the beneficiary could face immense setbacks in their health or even death.

Furthermore, specialty pharmacies are often assessed by a Part D plan/PBM on patient medication adherence. If a beneficiary chooses not to get their medication to separately address enrollment in the MPPP, the dispensing pharmacy may be negatively assessed by a plan/PBM. This situation would be grossly unfair for pharmacies.

NASP strongly recommends that the focus of education around the MPPP and the enrollment process always be conducted during open enrollment. NASP also urges CMS to allow for a process that permits beneficiaries to enroll the same day in which they receive their medications, even if later in the day, and to permit a process where they can have their claims re-adjudicated by the plan after doing so.

Separate from the MPPP, specialty pharmacies already face immense pressure to provide the level of service required under contract to support the dispensing of drugs and management of specialty patients. Over the years, PDP and MA-PD dispensing fees provided to specialty pharmacies have significantly eroded. NASP is concerned that erosion will further progress with the direct MPPP-related management requirements that will inevitably occur at the specialty pharmacy. We urge CMS to request that Part D sponsors provide pharmacies a reasonable incremental add-on payment to offset pharmacy processing costs associated with the MPPP.

## **Conclusion**

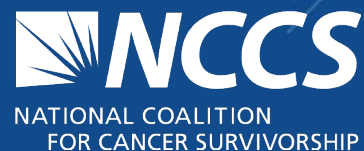
NASP appreciates the opportunity to provide comments on the Medicare Prescription Payment Plan (MPPP) Guidance and is happy to work with CMS further on the recommendations offered.

For additional information, please contact me at [Sheila.arquette@naspnet.org](mailto:Sheila.arquette@naspnet.org) or (703) 842-0122.

Sincerely,

A handwritten signature in black ink, appearing to read "Sheila Arquette", followed by a large, stylized circular flourish.

Sheila M. Arquette, R.Ph.  
President and Chief Executive Officer



# STATE OF SURVIVORSHIP

## 2023 Study

Findings from In-depth Interviews and National Surveys  
of Cancer Patients, Survivors, and Caregivers

# Methodology

## PHASE 1

### In-depth Interviews with Cancer Patients and Caregivers

- Fifteen (15) virtual interviews, approximately 60 minutes-each, February-March 2023
- Focused on a few audiences:
  - 10 Caregivers
  - 5 Patients, Employed
- Nationwide recruit: mix of cancer types, stages, time since diagnosis, treatment status, and income

## PHASE 2

### Nationwide Survey of Adult Cancer Patients, Survivors, and Caregivers

- Nationwide sample of n=1809, fielded May 9<sup>th</sup> – June 6<sup>th</sup>, 2023
  - Patients n=1303
  - Caregivers n=506
- Set quotas to make sure the sample was representative by age, gender, race/ethnicity, and region (using ACS and NCI data)
- Surveys were recruited through an online non-probability sample with quotas set to ensure demographically representative audiences, following AAPOR best practices

## PHASE 3

### Nationwide Survey of “NCCS Connected” Patients and Survivors

- Nationwide sample of n=536, same field period as nationwide survey
  - Patients n=507
  - Caregivers n=29
- Emailed invitation to all NCCS email contacts, inviting them to take the survey + 2 reminders
- Survey link also sent to partner organizations

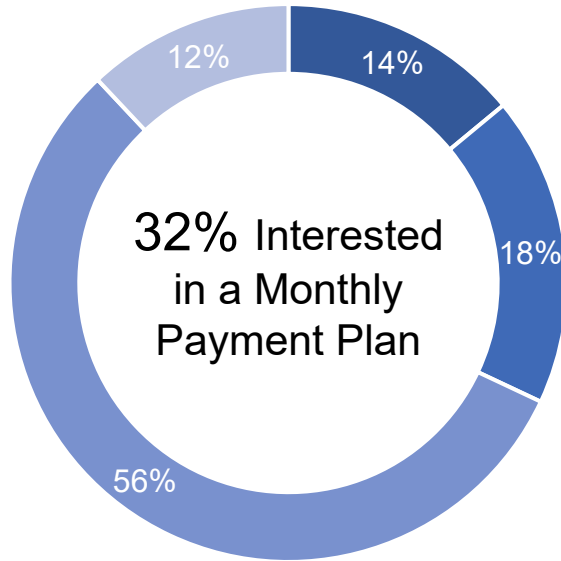
Blue/red = statistically higher/lower by audience | ▲ ▼ = change from 2022 survey

*Full text of survey questions is in the notes section of slides*

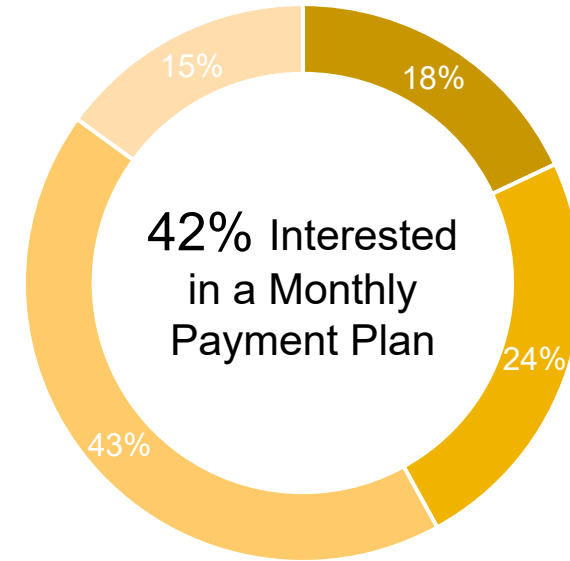
# Monthly Prescription Payment Plan

*Only a third of Patients are interested, and interest drops among those who have Medicare.*

National Patients



NCCS Connected Patients



■ Very interested ■ Somewhat interested ■ Not interested ■ Not sure ■ Very interested ■ Somewhat interested ■ Not interested ■ Not sure

**24%** of Medicare Patients are interested

42% Non-Medicare

*21% of Medicare Patients also have supplemental or gap insurance*

**31%** of Medicare Patients are interested

48% Non-Medicare

*30% of Medicare Patients also have supplemental or gap insurance*

Source= National Patients (n=1303); NCCS Connected Patients (n=507)

# National Patients

## Gender

49% Male  
51% Female

# NCCS Connected Patients

22% Male  
78% Female

## Age

7% Age 18-39  
40% Age 40-64  
53% Age 65+

18% Age 18-39  
50% Age 40-64  
31% Age 65+

## Education

17% Less than college  
37% Some college/2-year degree  
23% Bachelor's degree  
23% Postgraduate degree

8% Less than college  
28% Some college/2-year degree  
23% Bachelor's degree  
40% Postgraduate degree

## Income

15% Less than \$25k  
21% \$25k-\$50k  
21% \$50k-\$75k  
16% \$75k-\$100k  
24% More than \$100k

10% Less than \$25k  
13% \$25k-\$50k  
14% \$50k-\$75k  
14% \$75k-\$100k  
33% More than \$100k

## Insurance

57% Medicare  
15% Medicaid  
20% Private/employer  
7% Private/spouse or parents

36% Medicare  
7% Medicaid  
36% Private/employer  
16% Private/spouse or parents

## Race/Ethnicity

81% White  
10% AA/Black  
7% Hispanic  
4% Other

73% White  
11% AA/Black  
12% Hispanic  
8% Other

## Treatment

22% Biomarker testing, 24% Genetic counseling

40% Biomarker testing, 55% Genetic testing

## Region

19% Northeast  
22% Midwest  
40% South  
19% West

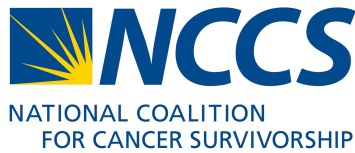
19% Northeast  
16% Midwest  
35% South  
30% West

## LGBTQ+

5% Yes

10% Yes





March 16, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Meena Seshamani, M.D., Ph.D.  
Deputy Administrator  
Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Submitted Electronically to** [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

Dear Administrator Brooks-LaSure and Dr. Seshamani:

The National Coalition for Cancer Survivorship (NCCS) is a national organization representing survivors of all forms of cancer in efforts to ensure access to quality care from cancer diagnosis through long-term survivorship. Quality cancer care must be readily accessible and affordable. Access obstacles and cost burdens mean that patients cannot obtain the treatment prescribed to them, treatment that could extend their lives or cure their cancer. NCCS is pleased to comment on Medicare Prescription Payment Plan Draft Part Two Guidance and to share its views on an important initiative that helps address prescription drug affordability.

We commend the Centers for Medicare & Medicaid Services (CMS) for its work in developing outreach, education, and communication requirements related to the Medicare Prescription Payment Plan for Part D sponsors. In general, we think that CMS has done a solid job in developing requirements for Part D plan sponsors, including the requirement to identify Part D enrollees likely to benefit during the plan year. We also think that there are advantages to the requirement that Part D sponsors use model materials.

The Part Two Guidance states:

CMS will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates – including State Health Insurance Assistance Program (SHIP) counselors – have sufficient support and materials needed to effectively communicate the availability and nuances of this program to individuals.

We are pleased that CMS has acknowledged the need to work not only with Part D sponsors but also with pharmacies, providers, and beneficiary advocates. However, we recommend that CMS

provide more information about ways that the agency will work with providers and beneficiary advocates. We offer advice about those tactics.

Each year, NCCS conducts a study, called the State of Survivorship Survey, which includes findings from in-depth interviews and national surveys of more than 1,800 cancer patients and survivors and 500 caregivers. We have two cohorts of respondents, a nationally representative sample of approximately 1,300 survivors, of which 57% are Medicare beneficiaries, and an “NCCS Connected” cohort, defined as patients who have a relationship with NCCS and awareness of the organization’s resources, programs, and advocacy.

As part of the 2023 study, we asked patients about their interest in a monthly payment program for prescription drugs. We did not specifically refer to the Medicare Prescription Payment Plan by name, since the program has not been launched, but rather we described it as in “a monthly payment plan to spread your prescription drug costs out over the year, rather than paying all at once”. Only 32% of the patients in the nationally representative cohort said they are interested such a program, and that number drops to 24% of Medicare beneficiaries surveyed. Among the NCCS Connected patients, 42% are interested in a payment program, with that number dropping to 31% of connected patients who are Medicare beneficiaries.

The survey did not include follow-up questions about the Medicare Prescription Payment Plan, and there are limits in our ability to interpret the findings above. However, we believe that the findings represent limited awareness of the program overall and that limited knowledge is reflected in the answers about “interest” in the plan. We also note that those who are NCCS Connected Patients have a stronger interest in the plan, which again we believe is reflective of greater basic knowledge of the plan. These findings, with their limits, suggest to us that advocacy organizations like NCCS and provider organizations representing cancer care professionals can play an important role in outreach and education of potential plan enrollees.

We anticipate that stakeholders representing Medicare beneficiaries with different conditions, diseases, or health care needs would be able to offer valuable advice to CMS. We are confident to offer the advice and services of cancer providers and advocacy organizations because of our relationships with Medicare beneficiaries with cancer. We believe we are well-positioned and well-informed to provide guidance regarding outreach and education. Moreover, it is especially important that CMS receive information about outreach to cancer patients, who may be among those most likely to benefit from the Medicare Prescription Payment Plan.

We recommend a number of activities that CMS should undertake:

- Consultation with pharmacy, provider, and advocacy organizations regarding model materials about the Medicare Prescription Payment Plan, to occur during the development of the materials and prior to their publication.
- Attendance at consultative meetings with cancer provider and advocacy organizations to discuss outreach activities, with the meetings convened by advocacy organizations. CMS engaged with a broad cross section of the cancer community during the design and implementation of the Oncology Care Model, and we recommend that practice be replicated in this case.
- Participation in patient education webinars and other events, to increase basic understanding of the model. These efforts should be especially intense during open enrollment, when beneficiaries are considering their coverage option and again at the



beginning of the benefit year when beneficiaries are considering their health care spending and needs.

Attached please find data from NCCS' 2023 State of Survivorship Survey about the Medicare Prescription Drug Program, including demographic breakdowns of the two cohorts. The full survey results are available on our website at [www.canceradvocacy.org/survey](http://www.canceradvocacy.org/survey).

We appreciate the opportunity to comment on the Part Two Guidance on the Medicare Prescription Payment Plan.

Sincerely,

A handwritten signature in black ink, appearing to read "Shelley Fuld Nasso". The signature is fluid and cursive, with the first name "Shelley" being the most prominent part.

Shelley Fuld Nasso



Submitted electronically via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

March 14, 2024

Meena Seshamani, M.D., Ph.D.,  
CMS Deputy Administrator and Director of the  
Center for Medicare  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, MD 21244

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

Deputy Administrator Seshamani,

The National Community Pharmacists Association (NCPA), The American Pharmacists Association (APhA), the National Association of Chain Drug Stores (NACDS), the American Society of Consultant Pharmacists (ASCP), the National Alliance of State Pharmacy Associations (NASPA), and the American Society of Health-System Pharmacists (ASHP) appreciates the opportunity to provide feedback on CMS' *Medicare Prescription Payment Plan [M3P]: Draft Part Two [Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments](#)*. We also sincerely appreciate CMS for listening to the pharmacy communities' feedback on the Medicare Prescription Payment Plan ("M3P"). We encourage CMS to maintain its position of requiring interested beneficiaries to enroll through their Part D sponsor or Pharmacy Benefit Manager (PBM) in the final guidance and future guidance on this matter beyond 2026. It is very difficult to conceive how pharmacists and pharmacies could take on the additional burden of beneficiary enrollment in the future without fair and adequate reimbursement to help facilitate that service.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

ASCP is the only international professional society devoted to optimal medication management and improved health outcomes for older adults. ASCP's thousands of pharmacist members manage drug therapies and improve the quality of life of geriatric patients and others living in various settings, including sub-acute and long-term care facilities (LTCF), skilled nursing facilities (SNFs), assisted living communities, psychiatric hospitals, hospice programs, correctional facilities, home and community-based care.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients. In addition, ASHP is the accrediting body for pharmacy residency and technician training programs, and provides comprehensive resources to support pharmacy professionals through every stage of their careers.

We advocate that CMS should make significant changes to this proposed draft guidance, or it will cause mass upheaval and confusion at the pharmacy counter where pharmacies are already facing [significant economic pressures](#) in Medicare Part D stemming from the implementation of CMS' *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; etc.* [Final Rule](#), and other cash flow concerns [noted](#) by CMS.

In addition to the specific recommendations addressed in the provisions of the draft guidance below, we provide a summary of overarching recommendations applicable to this guidance:

**Summary of Recommendations:**

- To help ensure that CMS' goals are met of participants' having timely, uniform, seamless and consistent experiences and access, as mentioned in the [part one final guidance](#) CMS should *require* that plan sponsors and PBMs provide timely, reasonable, and appropriate reimbursement to pharmacies to cover drug's acquisition cost and dispensing fees for M3P-related pharmacy costs under the coordination of benefits (COB) methodology approach.
- To minimize administrative burden, we ask for flexibility to permit electronic delivery of the Likely to Benefit Notice, which could be automated upon notification from the PBM. We support allowing for other forms of POS notifications from the plan to the pharmacy to the enrollee. Instead of merely allowing for hard copies, we advise that a hard copy be available to beneficiaries upon request, but pharmacies can also provide the notifications via SMS text messaging, QR codes, patient portal, or other electronic methods.
- With respect to the "Medicare Prescription Payment Plan Likely to Benefit Notice," the guidance is silent on whether this notice needs to be provided by the pharmacy for initial medication fills, refills, and transfers once the beneficiary has been enrolled into the M3P. Again, a pharmacy should have flexibility similar to the plans as to how this notice is distributed to patients (e.g., written, electronic, QRC, etc.). We recommend that the notice only be provided for initial fills and prescription transfers to satisfy this requirement to help ensure continuity of care at the pharmacy counter.
- CMS' guidance must call for unique nomenclature so that pharmacies may easily identify the relevant coverage information for the COB transactions. Specifically, we suggest the Processor Control Number (PCN) should begin with the letters "MPPP" so that pharmacy staff as well as pharmacy practice management systems, can easily and properly identify and process these claims to the M3P.
- We recommend that CMS specify a standardized means by which all Part D sponsors shall notify the pharmacy that the likely-to-benefit threshold has been met and the model notice should be offered to the enrollee. We also recommend use of the "Beneficiary Likely to Benefit from <TBD acronym>" value in NCPDP Approved Message Code (548-6F) field for this purpose.
- With respect to enrollee notification, we support CMS' proposal to not require pharmacies to provide counseling or consultation on the matter. We believe that CMS should adopt this proposal in the final guidance to prevent undue and unnecessary burden on pharmacies, and that enrollee counseling and consultation are the responsibilities of plan sponsors and their pharmacy benefit managers (PBMs).
- As CMS is aware, pharmacies are already [struggling to stay afloat](#) under the heavy burden of low reimbursement and direct and indirect remuneration (DIR) fees imposed by plan sponsors and their PBMs. If a pharmacy must readjudicate multiple claims for new program participants, this could create additional financial and administrative strain on the

pharmacy team and breed disruption in patient care. As such, it is also imperative for pharmacies to not change the date of service of the primary Part D claim to reflect the M3P enrollment date due to practice management systems (e.g., Drug Utilization Review (DUR), billing challenges, including secondary payor reimbursement, patient refills, and pharmacy workflow. The service date is not intended to change and could lead to serious system failure, including cycle fill logic, across the pharmacy enterprise. We recommend that the claim transaction date and the M3P enrollment date remain separate for clarity, billing processes, and seamless patient care. We note that while this is beneficial to patients, given that there are multiple transactions for each drug, there will be a significant burden and cost to pharmacy. Furthermore, systems that are capable of sending the M3P claim without reversing the primary claim should be allowed to do so.

- In regard to pharmacy processes, we agree that pharmacies play a vital role in operationalizing the M3P. However, we are concerned that the draft part two guidance does not address how pharmacies will be notified if a “likely to benefit” beneficiary declines to enroll in the M3P. We recommend CMS require that plan sponsors and their PBMs create a process for beneficiaries to decline to participate in the M3P and then notify a pharmacy if the beneficiary declines participation in M3P to help pharmacies stay informed and comply with CMS’ guidance.
- As stated in our previous meetings with HHS and CMS, we request that CMS ensure pharmacies’ reimbursements are protected as PDP and MA-PD plan sponsors and their PBMs may decide to recoup the costs of implementing the M3P through clawbacks, similar to DIR fees, and implement new pharmacy auditing requirements for the *“Medicare Prescription Payment Plan Likely to Benefit Notice”* and subsequently claw back reimbursement. Specifically, we encourage CMS to explicitly state that a pharmacy is not required to document that the pharmacy has made such notification. Said differently, PBMs should not be allowed to audit and claw back payment from pharmacies without documentations related to the enrollee notification. Again, CMS’ failure to take such steps likely would be devastating to pharmacists, pharmacies, and the patients we serve.
- We are encouraged by CMS’ action in recent months to hold PBMs more accountable. To that end, we respectfully request that CMS explicitly state in the final guidance that pharmacies should not pay transaction fees for retroactively rebilling claims, and that the Part D sponsors and PBMs should timely reimburse pharmacies under the M3P.
- To help ensure a seamless approach for beneficiaries, we urge CMS to ensure that any communication from plan sponsors and PBMs to pharmacies regarding the M3P is clear and standardized to align with the CMS’ standardized educational materials. Pharmacies should not be expected to have to issue plan-specific education materials as it would be unduly burdensome for pharmacies to manage unique documents for ten, twenty, thirty plans or more.
- We strongly recommend CMS consider establishing a pathway for pharmacies to have some form of recourse if they are improperly reimbursed by a plan sponsor or a PBM by leveraging the Medicare Complaints Tracking Module (CTM) under the new M3P.
- Lastly, given the difficulty envisioning how LTC pharmacies can communicate the Likely to Benefit Notice with no point-of-service that is traditionally found in retail pharmacy,

**we request that CMS exempt LTC pharmacies from being required to communicate this Notice, and that CMS should require that the Part D sponsors work directly with LTC beneficiaries and facilities and not LTC pharmacies to effectuate this guidance.**

## 20. Overview of the Medicare Prescription Payment Plan

CMS discusses how Part D sponsors must perform general and targeted education and outreach to Part D enrollees and provide communications to program participants, including instructions on using CMS-provided model materials that will be issued through the OMB ICR process. In Section 30.3 of the draft guidance, CMS states that “Though Part D sponsors are not required to use the model materials and content verbatim, they must base their developed materials on CMS’s model materials and must include the elements and information included in CMS’s model materials in their developed materials. CMS notes that the ‘Medicare Prescription Payment Plan Likely to Benefit Notice,’ [...] is a standardized material that Part D sponsors are required to use in the form and manner provided by CMS.” **We support CMS providing such model materials.**

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

The draft guidance mentions that under section 1860D-2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism in place to notify a pharmacy when an enrollee incurs OOP costs for covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the Medicare Prescription Payment Plan. **We request CMS to provide clarification on the nature of that “mechanism” in its final guidance.** The draft guidance further states that Part D sponsors must also “ensure” that a pharmacy, after receiving such notification, informs the Part D enrollee about the program. **We stress that CMS should emphasize that a pharmacy must demonstrate willful negligence of this draft guidance, not merely that the pharmacy did not document providing the Likely to Benefit Notice to the Part D enrollee before the Part D sponsor or PBM addresses the pharmacy.** For example, the pharmacy should not be penalized for instances where the patient may not want to opt-in but also does not bother to opt-out, and asks the pharmacy to stop relaying the message from the plan. Continuing to provide paper notices is a waste of pharmacy and natural resources. **We ask CMS only require pharmacies to provide one copy of the Likely to Benefit Notice for initial fills and transfers. Requiring one Likely to Benefit Notice per prescription would require great administrative burden on the pharmacy and a redundancy of notices to the beneficiary.**

### 30.1.1 Required Mailings with Membership ID Card Issuance

The draft guidance states that under § 423.2267(e)(32), the membership ID card is a model communications material that Part D plans must provide to Part D plan enrollees. The Part D plans must provide the card to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment in the Part D plan or by the last day of the month prior to the plan effective date, whichever is later. The membership ID card must be provided in hard copy, and Part D plans may also provide a digital version, in accordance with § 423.2267(d). **We ask CMS if the membership ID card will have “4RX information” (i.e., BIN/IIN-PCN-Group-ID) needed to process the payment plan coordinated benefit.**

Additionally, the draft guidance states that “Part D sponsors are encouraged to provide the CMS-developed educational product, described in section 40.1 of this guidance, to satisfy the requirement to furnish information regarding the Medicare Prescription Payment Plan alongside the election request form in the membership ID card issuance packet. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed educational product to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V.” CMS mentions this again in similar language in 30.2.2.1 and 30.2.2.2 of the draft guidance. **We ask CMS to prohibit Part D sponsors and PBMs from using alternative information materials to steer patients to vertically integrated or preferred pharmacies.**

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

To support Part D sponsors in meeting this requirement, CMS states that it is “developing a standardized notice for Part D enrollees identified as likely to benefit from the Medicare Prescription Payment Plan, the ‘Medicare Prescription Payment Plan Likely to Benefit Notice.’ Part D sponsors are required to use this standardized notice to satisfy their obligation to perform targeted outreach to Part D enrollees who are identified as likely to benefit prior to and during the plan year, including those identified through the pharmacy notification process. This outreach, when performed outside of the pharmacy POS notification process, may be done via mail or electronically (based on the Part D enrollee’s preferred and authorized communication methods). If the enrollee is identified through the pharmacy notification process, this outreach must be completed at the pharmacy POS (see section 30.2.2.3 below).”

**To minimize administrative burden, we ask for flexibility to permit electronic delivery of the Likely to Benefit Notice, which could be automated upon notification from the PBM. We support allowing for other forms of POS notifications from the plan to the pharmacy to the enrollee. Instead of merely allowing for hard copies, we advise that a hard copy be available to beneficiaries upon request, but pharmacies can also provide the notifications via SMS text messaging, QR codes, patient portal, or other electronic methods.**

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

According to the draft guidance, “CMS encourages Part D sponsors to provide pharmacies with additional educational material on the Medicare Prescription Payment Plan, such as the CMS-developed educational product described in section 40.1, which could also be distributed to Part D enrollees along with the notice.” **We ask CMS to prohibit Part D sponsors and PBMs from forcing pharmacies through contract terms to hand out this additional educational material, or using additional educational material to steer patients to vertically integrated or preferred pharmacies.**

Additionally, according to the draft guidance, “When a Part D enrollee opts into the Medicare Prescription Payment Plan after receiving the ‘Medicare Prescription Payment Plan Likely to Benefit Notice’ from the pharmacy, in addition to providing the notice of acceptance of election, as described in section 30.3.2 of this guidance, the Part D sponsor is responsible for clearly communicating additional necessary next steps to the Part D enrollee. Next steps may include,

but are not limited to, how to proceed with filling any outstanding prescriptions.” **We ask CMS to prohibit Part D sponsors and PBMs from using this language to steer patients to vertically integrated or preferred pharmacies.**

#### 30.4 Language Access and Accessibility Requirements

According to the draft guidance, under section 1860D–2(b)(2)(E)(v) of the Act, both CMS and Part D sponsors are required to provide Medicare Prescription Payment Plan information and educational materials to Part D enrollees. CMS requires outreach materials and communications be provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds. **We assert that the obligation to provide this material falls solely on Part D plans and that pharmacies should not be required to provide these materials.**

#### 50. Pharmacy Processes

In the guidance, CMS states that pharmacies play an important role in operationalizing the Medicare Prescription Payment Plan. **We remind CMS that pharmacies are facing [significant economic pressures](#) in Medicare Part D stemming from the implementation of CMS’ *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; etc. Final Rule*, and other cash flow concerns. In this draft guidance, CMS does not contemplate reimbursement for pharmacies to operationalize the Medicare Prescription Payment Plan, creating yet another unfunded mandate and administrative burden for pharmacies. Therefore, we request that CMS provide guidance to Part D Sponsors to reimburse pharmacies for costs (paper, M3P COB claim transaction fees, beneficiary education, etc.) to operationalize the Medicare Prescription Payment Plan.**

CMS also states that under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program. Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the M3P. Given this statutory requirement, Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees.

**We are wary that by requiring Part D sponsors to “ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan” creates an audit liability for pharmacies. We request that CMS provide clarity in its final guidance for instances where the Part D enrollee receives notification from the pharmacy that the beneficiary may benefit from participating in the program, yet takes no action to enroll or decline the Medicare Prescription Payment Plan. Would a rejection pop up on the screen that needs to be acknowledged? As stated above, continuing to provide paper notices is a waste of pharmacy and natural resources.**



#### 50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount

In this draft guidance, CMS refers to the Part 1 guidance that “CMS stated that the likely to benefit notification required at the pharmacy POS will be based on the OOP costs incurred for a single prescription.” In addition, the Part 1 final guidance sets the cost-sharing threshold for a single covered Part D drug at \$600 or more and, if the beneficiary has not already opted into the program, the Part D sponsor will be required to notify the pharmacy to inform the individual about the program. Our organizations recommend CMS clarify that the M3P only applies through the initial coverage phase up to the \$2,000 OOP spending threshold under the 2025 Part D Redesign Program. **We ask CMS to only require pharmacies to provide one copy of the Likely to Benefit Notice for initial refills or transfers. Requiring one Likely to Benefit Notice per prescription would require great administrative burden on the pharmacy and a redundancy of notices to the beneficiary.**

**We are concerned that the notification process outlined in this section is very general. We recommend that CMS specify a standardized means by which all Part D sponsors shall notify the pharmacy that the likely-to-benefit threshold has been met and the model notice should be offered to the enrollee. We also recommend use of the “Beneficiary Likely to Benefit from <TBD acronym>” value in NCPDP Approved Message Code (548-6F) field for this purpose.**

**We also want to clarify that as this section does not indicate where the beneficiary should “seek advice” from, CMS should explicitly state that the beneficiary should seek advice from the plan, PBM, or an insurance agent.**

**We also concur with the NCPDP recommendation that CMS change the term “primary Part D claim response” to “Medicare Part D claim response.”**

#### 50.2 Pharmacy POS Notifications Late in the Plan Year

**Like the above section, we are concerned that the notification process outlined in this section is very general. We recommend that CMS specifically call out the use of the Approved Message Code values in the final guidance. Additionally, we also recommend standardization for providing information utilizing the NCPDP Approved Message Codes applicable to the M3P program.**

#### 50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies

CMS states that it is aware that some pharmacy types may not have direct contact with Part D enrollees and/or may lack a practical means for providing a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” directly to the Part D enrollee, and that pharmacies may also choose to provide the Likely to Benefit notice in other modes of communication such as through a patient portal or secure e-mail. **As also stated above, to minimize administrative burden, we ask for flexibility for all pharmacies to permit electronic delivery and/or notification through the individuals’ residential care facility of the Likely to Benefit Notice, which could be automated upon notification from the PBM. We support allowing for other forms of POS notifications from the plan to the pharmacy to the enrollee. Instead of merely allowing for hard copies, we advise that a hard copy be available to**

beneficiaries upon request, but pharmacies can also provide the notifications via SMS text messaging, QR codes, patient portal, or other electronic methods. Please see our additional comments in section 50.3.1 regarding LTC pharmacies.

We also request clarification from CMS that a PBM or a plan sponsor auditing for compliance shall not penalize a pharmacy for providing the Likely to Benefit Notice in advance, and documenting the date, of the first claim.

Additionally, we argue that the Part D sponsor cannot “ensure” that the pharmacy provides the Likely to Benefit Notice and pharmacies should not be held liable for failure to provide this notice, and Part D sponsors should “encourage” rather than “ensure” such an event. Additionally, CMS should note that if the beneficiary does not come pick up the medication, there is no way for the pharmacy to give the Likely to Benefit Notice to the beneficiary.

#### 50.3.1 Long-Term Care Pharmacies

In the guidance, CMS states that long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident). CMS should note that LTC pharmacies take care of LTC patients in a variety of settings. **We ask CMS to clarify if this section applies to all patients residing in a LTC facility including assisted living, group homes, other types of congregate living as well as patients residing at home and receiving LTC pharmacy at home services and not exclusively patients residing in a skilled nursing facility. We also seek clarification from CMS on the method to determine whether the likely-to-benefit notification processes for a long-term care pharmacy are dependent on a characteristic of the enrollee or the pharmacy (e.g., residence, level of service, pharmacy permit type, LTC provider network, etc.).**

For LTC pharmacies, CMS states in the guidance that the “pharmacy delivers medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee). As such, when the POS notification is received by a long-term care pharmacy, the plan sponsor is not required to ensure that the long-term care pharmacy provides the ‘Medicare Prescription Payment Plan Likely to Benefit Notice’ prior to dispensing the medication.” In LTC pharmacy, we note that medication can be dispensed at the facility or directly to the enrollee (i.e., assisted living residents). However, often there is no direct pharmacy to enrollee visibility, and billing is done at the end of the month, with medication dispensed and consumed prior to billing. **Therefore, we have difficulty envisioning how LTC pharmacies can communicate the Likely to Benefit Notice with no point-of-service that is traditionally found in retail pharmacy. LTC pharmacies send bills for copays in most cases to the responsible party which is usually family members. Furthermore, dispensing pharmacists are often not the same as the consultant pharmacists often found in long-term care, which creates a situation where the dispensing pharmacist does not know the enrollee at all. This makes enrollee notification and education of the LTC beneficiary even more difficult.**

CMS maintains in the guidance that “the plan sponsor can require the long-term care pharmacy to provide the notice to the Part D enrollee at the time of its typical billing process.” **However, we ask CMS if “at the time of...typical billing process...” refers to when online billing is done, or monthly invoice of private-pay portion to the enrollee’s responsible party?** The ability for the LTC pharmacy to provide any kind of notice directly to the Part D enrollee is limited, as there is often no way for the LTC pharmacy to make contact with the beneficiary. If the LTC pharmacy is able to make contact, the enrollee is unlikely to be able to understand and/or respond. In the final guidance, CMS should amend language stating that the plan sponsor “can require” the long-term care pharmacy to provide the notice to language stipulating that the LTC pharmacy “can attempt” to deliver the notice so that individual plan sponsors are not penalizing LTC pharmacies unable to get this notice to the correct individual or responsible party. The additional administrative burden on LTC pharmacies involves many steps and workflow changes to the pharmacy. CMS should compensate pharmacies for any additional administrative burden.

Finally, we request clarification from CMS that the Likely to Benefit Notice does not apply to residents covered by Medicare Part A as their medications are subject to the Consolidated Billing requirement.

#### 50.4 Readjudication of Prescription Drug Claims for New Program Participants

CMS states that for claims to be processed appropriately using the M3P BIN/PCN methodology, the date of service on the primary Part D claim and the additional program-specific transaction must be on or after the date of program effectuation. **We appreciate this clarification, so that Part D sponsors all have the same policy regarding effective date and ineligibility of old claims. However, it is also imperative for pharmacies to keep the date of service/transaction of the primary Part D claim due to practice management system (Drug Utilization Review (DUR), billing challenges, including secondary payer reimbursement, and pharmacy workflow). The service date is not intended to change and could lead to serious system failure across the pharmacy enterprise. We recommend that the claim transaction date and the M3P enrollment date remain separate for clarity, billing processes, and seamless patient care. Further, we request that the date of program effectuation be the first day of the month in which the Part D enrollee opts into the Medicare Prescription Payment Plan to minimize the number of claims needed to be reversed in order for the cost share to be applied to the payment plan.**

CMS also states that when the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess all three claims, so the program participant pays \$0 at the pharmacy for all three drugs. **We note that while this is beneficial to patients, given that there are multiple transactions for each drug, there will be a significant burden and cost to pharmacy for which the pharmacy could be paid a fee in the M3P COB claim. Furthermore, systems that are capable of sending the M3P claim without reversing the primary claim should be allowed to do so.**

CMS notes that, “in general,” plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for by the Part D enrollee. **We ask that CMS prohibit plans and PBMs from requiring pharmacies to reverse and reprocess claims under the M3P that have already been paid and picked up by the Part D enrollee, as this would cause a date of service conflict.**

## 50.5 Processing of Covered Part D Claims for Program Participants in Special Settings

### 50.5.1 Long-Term Care Pharmacies

Regarding the diversity of payment arrangements between residents, LTC pharmacies and LTC facilities, CMS states that “In some situations, long-term care pharmacies do not collect Part D cost-sharing from the enrollee but instead bill the long-term care facility for the final patient OOP responsibility. When such an arrangement is in place between a long-term care pharmacy and a long-term care facility, and an enrollee in a long-term care facility is participating in the M3P billing the participant’s Part D plan’s M3P BIN/PCN for the participant’s OOP costs (when the pharmacy would not have otherwise directly billed the enrollee) may result in additional financial burden on that participant. In such cases, CMS encourages Part D sponsors to take the participant’s particular circumstances into account when considering M3P billing practices and to work with the participant, their authorized representative, and the long-term care pharmacy to understand the best billing approach for the participant.”

We are concerned this guidance is unclear and provides minimal direction to Part D sponsors about actively working with patients and LTC pharmacies to ensure patients who would benefit from M3P receive appropriate notice can benefits while also ensuring it does not raise costs on participants. We encourage CMS to be more direct in its guidance and promote a system in which the long-term care facility and Part D plan coordinate directly and provide the participant and their authorized representatives with a detailed M3P billing plan that does not increase costs to the participant into which they might opt in. Lastly, given the difficulty envisioning how LTC pharmacies can communicate the Likely to Benefit Notice with no point-of-service that is traditionally found in retail pharmacy, we request that CMS require that the Part D sponsors work directly with LTC beneficiaries and facilities and not LTC pharmacies to effectuate this guidance.

## **Conclusion**

We thank CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact NCPA at [steve.postal@ncpa.org](mailto:steve.postal@ncpa.org) (Steve Postal, Director, Policy and Regulatory Affairs), APhA at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org) (Mike Baxter, Vice President, Federal Government Affairs), NACDS at [cboutte@nacds.org](mailto:cboutte@nacds.org) (Christie Boutte, Senior Vice President, Reimbursement, Innovation and Advocacy), ASCP at [jlewis@ascp.com](mailto:jlewis@ascp.com) (Jim Lewis, Senior Director of Policy & Advocacy), NASPA at [jcover@naspa.us](mailto:jcover@naspa.us) (Joni Cover, Vice President of Strategic Initiatives), and ASHP at [jschulte@ashp.org](mailto:jschulte@ashp.org) (Jillanne Schulte Wall, Senior Director, Health and Regulatory Policy).



March 16, 2024

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-8013

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

Dear Administrator Brooks-LaSure:

The National Council on Aging (NCOA) is pleased to provide the Centers for Medicare & Medicaid Services (CMS) comments on the second draft guidance document for the Medicare Prescription Payment Plan (MPPP). The following includes NCOA background, overview of key recommendations, and detailed comments on specific provisions.

**NCOA Background**

NCOA is a respected national leader and trusted partner helping people aged 60+ meet the challenges of aging. Our mission is to improve the lives of millions of older adults, especially those who are struggling. NCOA's advocacy is informed by its collaboration with diverse community-based organizations, senior centers, Medicare State Health Insurance Assistance Program (SHIP) counselors, Benefit Enrollment Center (BEC) staff, as well as by its federal, state, and local advocacy partners.

Below summarizes NCOA's areas of focus, which are explained in further detail in the attachment.

- Part D plan outreach and education requirements;
- CMS outreach and education requirements; and
- Pharmacy outreach and education requirements.

Thank you for the opportunity to submit comments. We welcome further discussion. For additional information or questions, please contact Matthew Hubbard at [Matthew.Hubbard@NCOA.org](mailto:Matthew.Hubbard@NCOA.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Ramsey Alwin", written over a horizontal line.

Ramsey Alwin, President and CEO  
National Council on Aging

## **Attachment: NCOA Recommendations - Detailed Comments**

### **General comments**

To help NCOA better understand what effective MPPP-related communications to relevant stakeholders ought to be, NCOA and the MAPRx coalition (MAPRx) – NCOA is also a member of this coalition – convened a half-dozen or so State Health Insurance Assistance Program (SHIP) directors/ counselors in November 2023. NCOA and MAPRx also conducted an online survey of the same counselors in March 2024. NCOA's recommendations are based in part on these SHIP counselors' recommendations. Other NCOA conversations with Medicare counselors in 2023 also informed our responses to CMS.

### **Name of the program**

**NCOA has concerns** about the name of the program given that including the word “plan” might confuse enrollees into thinking that the program is separate from Medicare Part D or their Part D plan. In our November focus group with SHIP counselors, a few counselors expressed misgivings about the name of the program as well. Many suggested renaming the program so that it included the words “budgeting tool”. NCOA would like to highlight that we agree with this sentiment. Moreover, we feel that “Medicare Prescription Payment Plan” does not adequately convey to beneficiaries what the program is or how it may help them manage their prescription drug costs. In fact, the name may limit, rather than promote, participation as beneficiaries simply may not understand from the name that the program may help them. Throughout the March 2024 SHIP counselor survey, counselors expressed concerns about the potential for confusion around MPPP and the need for CMS to be prescriptive on the materials plans provide/create. The following comment captures these concerns: “CMS should require plans to use CMS-provided language and templates so it is clear that MPPP is a Medicare benefit, not a plan-specific benefit.” NCOA also agrees with this sentiment.

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

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

**CMS proposes** having plans provide information about MPPP to potential enrollees via membership ID cards, the Annual Notice of Change (ANOC), the Evidence of Coverage (EOC), and the Explanation of Benefits (EOB).<sup>1</sup>

**NCOA supports** CMS's proposal to have plans provide education and outreach around MPPP through the resources proposed here. We ask that CMS provide model language for plans to use to provide consistency. Within this model language for the resources discussed in this section of the draft guidance, we recommend that CMS have plans clarify the nature of the program and its relationship to plans. In response to the March 2024 MPPP survey, a SHIP counselor said that “CMS should be prescriptive to avoid confusion and make it clear this is a standard option across all plans. Information on plan-specific documents and websites should include a disclaimer that the MPPP is available to all Medicare beneficiaries and all Part D drug plans.”

According to the Medicare counselors NCOA works with, beneficiaries are more likely to look at the EOB than they are the ANOC or EOC. Yet we recommend that CMS add this MPPP language to all three resources to reach the greatest number of beneficiaries as possible.<sup>2</sup>

Given our uncertainty around the impact of the ANOC and EOC, NCOA recommends requiring plans to also send out a unique document separate from the ANOC, EOB, and EOC that only explains the MPPP and does so in a clear, easy-to-understand way. In our fall 2023 focus group with SHIP counselors, a few counselors recommended such a unique document and indicated that it ought to be sent out on colored

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<sup>1</sup> CMS. “Medicare Prescription Payment Plan: Draft Part Two Guidance.” 15 February 2024. 01 March 2024. <https://protect-us.mimecast.com/s/c4TwC4xDDXFZBqRFV7Kje?domain=cms.gov>. Pages 6-8.

<sup>2</sup> CMS may wish to survey beneficiaries to get a sense of the extent to which they use these three resources.

paper, perhaps on paper that would stand out and not be confused with another colored paper the beneficiary would receive around the same time.

NCOA also believes it is critical to also mention the \$2,000 yearly out-of-pocket (OOP) prescription costs cap throughout these materials. We believe it's key to highlight that the cap applies regardless of whether one applies to MPPP. It's also important to communicate that enrollees aren't receiving discounts. We also feel that it's critical to link MPPP to Part D to allay fears that the new program supplants or is separate from Part D.

### **30.1.1 Required Mailings with Membership ID Card Issuance**

Following a Part D beneficiary's enrollment in a plan, **CMS proposes** having Part D sponsors mail the enrollee their plan membership ID card along with 1) information on the MPPP program and 2) an MPPP election form.

**NCOA supports** the proposal, but we would also like to highlight concerns around the potential for beneficiary confusion. In the March 2024 survey on the draft part 2 guidance, a SHIP counselor recommended not including the MPPP election form together with the Membership card to avoid confusion. This counselor explained by saying that "members may mistakenly believe they are required to complete the MPPP form to use their member card." NCOA recommends that CMS have plans include language in their election form that would help avoid such confusion.

### **30.1.5 Part D Sponsor Websites**

**CMS proposes** requiring Part D plans to maintain websites with certain elements such as an overview of the program, how to opt in and out of the program, and an election request mechanism so Part D beneficiaries can enroll online.<sup>3</sup> CMS also proposes having plans provide information on applicable conditions and limitations, premiums, cost sharing, and any other information associated with receipt of the benefit.<sup>4</sup>

**NCOA supports** the proposed Part D sponsor website requirements and asks CMS to consider ways to offer more robust website requirements to dispel any possible beneficiary confusion.

We also would like to suggest specific website features for CMS's consideration as elements we hope CMS will require plans to include on their MPPP web pages. NCOA would also like to propose that CMS have plans include a website feature where enrollees can check to see if they're already enrolled in MPPP. Also, NCOA would like to request that CMS have plans use a model disclaimer that states clearly that their website is not run by Medicare/the federal government.

We would also like to recommend that CMS consider ways to make the online election mechanism user friendly. Some beneficiaries may not be the most comfortable navigating websites, so we ask CMS to place the election mechanism front and center and make the mechanism as easy to use as possible.

We also ask CMS to ensure that plans prioritize the end user's experience. Plans may list information most important to them in a particular order that may not be most advantageous to the enrollee. Enrollees/end users may not have enough interest to read through a website, so we ask CMS to be prescriptive about the order in which information is provided on plan websites. We believe CMS ought to require plans to first list explanatory and other critical information first. Furthermore, CMS ought to consider having plans use a certain font and font size to ensure that information does not get lost.

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<sup>3</sup> CMS. "Medicare Prescription Payment Plan: Draft Part Two Guidance." Pages 7-8.

<sup>4</sup> Pages 7-8.

NCOA also recommends that CMS require plan sponsors to prominently display information about the low-income subsidy (LIS) program, as prospective LIS enrollees will benefit more in LIS than in the MPPP. This distinction will help eliminate confusion and promote increased LIS enrollment by those who are eligible.

## 30.2 Targeted Outreach and Education Requirements for Part D Sponsors

**CMS proposes** having plans provide the “Notice for Part D Enrollees Likely to Benefit” to certain Part D enrollees prior to and during the plan year.<sup>5</sup>

**NCOA supports** the proposed cadences for having plans send the notice.

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

According to **CMS’s proposal**, enrollees identified through the plan-pharmacy notification process would have their outreach take place at the pharmacy.<sup>6</sup>

For beneficiaries identified outside of the pharmacy’s point-of-sale (POS) notification system, **CMS proposes** having plans provide the “Notice for Part D Enrollees Likely to Benefit” to Part D enrollees likely to benefit from MPPP via mail or electronically based on the enrollee’s preferred communication method.<sup>7</sup> Furthermore, **CMS proposes** that plans would have to use the model “Likely to Benefit Notice” provided to them by CMS.<sup>8</sup>

**NCOA strongly supports** the proposal to require plans to provide the model notice either themselves in the two formats proposed or to then have pharmacies provide the notice to enrollees at the POS. We would also like to highlight our thoughts on the placement of information within the model notice CMS would provide to plans. Given our thoughts on the need for a much broader definition around beneficiaries likely to benefit (our comments are detailed below) than the narrower one identified in the final part 1 guidance document,<sup>9</sup> we ask that CMS require plans to place information about the types of individuals most likely to benefit from the program in a prominent place on the first page of the “Likely to Benefit Notice”. Placement of this information here is beneficial to the enrollee regardless of whether CMS were to revise its formula for calculating which beneficiaries are most likely to benefit from MPPP.

### 30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year

CMS recognizes that individuals deemed not “likely to benefit” from the MPPP program are able to sign up for the program and may find that they benefit from the program.<sup>10</sup>

NCOA thanks CMS for its recognition that its targeted outreach proposal may not reach all individuals likely to benefit from the program. We believe it would be best for all Part D beneficiaries to already know about MPPP just in case they later face new, expensive prescription drug costs.

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

CMS reaffirms that MPPP is open to all Part D beneficiaries, but indicates that enrollees with substantial out-of-pocket costs, for instance, in the first half of the calendar year are more likely to

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<sup>5</sup> Page 10.

<sup>6</sup> Page 10.

<sup>7</sup> Ibid.

<sup>8</sup> Ibid.

<sup>9</sup> CMS. “Medicare Prescription Payment Plan: Final Part One Guidance.” 29 February 2024. 05 March 2024. <https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf>. Page 4.

<sup>10</sup> CMS. “Medicare Prescription Payment Plan: Draft Part Two Guidance.” Page 11.



benefit from the program.<sup>11</sup> CMS proposes to not send the “Likely to Benefit Notice” to individuals deemed not likely to benefit.<sup>12</sup> CMS gives one example of individuals who would not benefit: enrollees who incur new, substantial drug costs in the last few months of the year and end up under the MPPP program paying more out of pocket than they would have had they not enrolled in the program.<sup>13</sup>

**NCOA has concerns** about the proposal to use retrospective data to estimate whether an individual would likely benefit from the program. For many older adults, unexpected medication costs are not uncommon and CMS’s proposed use of retrospective, prescription data has its limitations. We feel a narrower outreach strategy misses those individuals whose medical costs unexpectedly change. For beneficiaries with chronic diseases such as ALS and certain types of cancer, patient drug needs and expenses can quickly change. Beneficiaries are also frequently prescribed new medications based on changes in health status.

We believe that a wider outreach strategy is needed especially since the beneficiary cannot enroll into the program at the pharmacy point of sale. With these things in mind, NCOA recommends that CMS consider having plans send the “Likely to Benefit Notice” to all Part D beneficiaries.

Regarding plan year 2025, **CMS proposes** having plans provide the “Likely to Benefit Notice” to enrollees in October, November, or December (no later than December 7) each year.<sup>14</sup> Also, for plan year 2025, **CMS proposes** that Part D sponsors must use claims from January to September to assess whether an individual is likely to benefit from the MPPP program in the coming year.<sup>15</sup>

**CMS proposes** that Part D sponsors may develop additional strategies for identifying Part D enrollees likely to benefit from the MPPP program, but Part D sponsors must apply the supplemental analysis to all enrollees in each plan.<sup>16</sup>

**NCOA supports** the proposal to have plans conduct outreach during October, November, and up to December 7. We encourage CMS to annually reassess whether plans can only use data from January to September to determine an individual’s eligibility for MPPP prior to a plan year. In a more interoperable future that may not be too far away, plans will hopefully be able to use the most recent claims data to make assessments throughout the Part D open enrollment period running from October 1 to December 7 of each year. For future plan years after 2025, NCOA strongly encourages CMS to also study whether requiring plans to begin their outreach to Part D beneficiaries earlier in the plan year leads to greater uptake of the MPPP program. During the open enrollment period, enrollees are sometimes overwhelmed with information and it may be helpful for Part D plans to start their outreach earlier.

**NCOA supports** CMS’s proposal to allow Part D sponsors to run a supplemental analysis of individuals likely to benefit from the program. We also appreciate CMS’s thoughtful proposal to require that Part D sponsors apply this supplemental analysis to all beneficiaries in all plans.

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

**CMS proposes** that pharmacists would be encouraged, but not required to provide additional counseling or education after receiving notification from the Part D sponsor that the pharmacy customer would likely benefit from the MPPP.<sup>17</sup>

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<sup>11</sup> Page 11.

<sup>12</sup> Page 11.

<sup>13</sup> Ibid.

<sup>14</sup> Page 12.

<sup>15</sup> Page 12.

<sup>16</sup> Ibid.

<sup>17</sup> Page 14.

Given our concerns around the unfunded burden such pharmacy instruction would place on pharmacy employees, **NCOA supports** the proposal to encourage pharmacists to provide this education to beneficiaries deemed likely to benefit from the program. We strongly encourage CMS to explore ways to reimburse pharmacists in the future when they provide this critical education at the POS. According to one SHIP counselor NCOA surveyed in March 2024, pharmacy employees other than the pharmacist should be encouraged by CMS to provide this education so that the pharmacist can focus on the tasks only they can complete.

After the beneficiary opts into the MPPP elsewhere after receiving the “Likely to Benefit Notice” at the pharmacy, **CMS proposes** that the Part D sponsor would have to clearly communicate to the enrollee any necessary additional steps needed to effectuate MPPP enrollment including how to fill any outstanding prescriptions.<sup>18</sup>

**NCOA supports** CMS’s proposal to oblige plans to operationalize MPPP enrollment after the “Likely to Benefit Notice” is provided at the pharmacy and after the beneficiary has opted into the program elsewhere. Given that the enrollee may have received the notice at the pharmacy and held off on filling any necessary prescriptions until after their MPPP opt in, it is critical that the plan help ensure that the beneficiary not delay picking up their prescription(s) any longer.

### 30.2.3 Communications with Contracted Providers and Pharmacies

**CMS proposes** to encourage Part D sponsors to add educational MPPP information in their communications with contracted providers.<sup>19</sup> **CMS encourages** plans to target subgroups of providers based on provider specialty types that would be most likely to prescribe high-cost Part D medications.<sup>20</sup>

**NCOA has concerns** about the optional nature of the proposal and instead asks that CMS consider making outreach to providers mandatory, if not in 2025 hopefully in plan year 2026. We feel it is especially important to ensure that Part D sponsors provide MPPP-related information in their communications with the specialty providers mentioned in the draft guidance. Given that the patient populations these specialty providers serve would be likely to benefit from the program, NCOA believes that making this a requirement would likely prove fruitful and lead to greater MPPP program enrollment.

**CMS proposes** to encourage plans to include educational information on the MPPP program in their information to pharmacies.<sup>21</sup>

**NCOA has concerns** that plans have the option to educate pharmacists about the program. It’s essential for plans to educate pharmacists to inform their work and so that pharmacy staff are better equipped to explain the program to the beneficiary at the point of sale should they wish to.

### 30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors

Given the great degree to which plan brokers educate and have relationships with enrollees, NCOA strongly encourages CMS to require in the final guidance document that Part D sponsors continually educate their brokers on the MPPP program. SHIP counselors in our November 2023 focus group provided this thoughtful recommendation. NCOA encourages CMS to consider whether it should require brokers to direct individuals to trusted sources of MPPP-related information such as Medicare.gov.

In response to a March 2024 survey question around potential advantages and disadvantages to having brokers serve as an educational resource for educating beneficiaries on MPPP, one counselor highlighted

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<sup>18</sup> Page 14-15.

<sup>19</sup> Page 15.

<sup>20</sup> Page 15.

<sup>21</sup> Ibid.

the advantage of having brokers educate beneficiaries given limited SHIP resources. The counselor went on to, however, give the disclaimer that “agents and brokers could make it sound like the MPPP is a plan-specific perk to encourage enrollment.” NCOA believes that robust CMS/plan-provided model materials for brokers would mitigate this potential downside.

### 30.3.1 Overview of Election Requirements

**CMS proposes** to encourage plans to use model materials (excluding the “Likely to Benefit Notice,” which “is a standardized material that Part D sponsors are required to use in the form and manner provided by CMS”) provided to them by CMS.<sup>22</sup>

**NCOA has concerns** about the proposal to provide plans with such a large degree of flexibility around how they communicate about the MPPP program in materials outside of the “Likely to Benefit Notice”. Part D sponsors will likely want to try to minimize their MPPP administrative costs wherever there is the flexibility to do so. It’s critical for CMS to ensure that additional MPPP plan educational materials include a standard set of components to communicate the necessary things that beneficiaries need to know about the MPPP program.

Within plan MPPP communications, **CMS proposes** having plans provide information on the Part D LIS and how to enroll.<sup>23</sup> Also, **CMS proposes** having plans note here that it might be more advantageous for LIS-eligible beneficiaries to enroll in LIS than MPPP.<sup>24</sup>

**NCOA strongly supports** the requirement for plans to educate beneficiaries on the LIS program. We strongly encourage CMS to oblige plans to also provide some high-level information on LIS eligibility such as income thresholds and information on how assets affect the LIS eligibility determination.

#### 30.3.1.1 Request to Participate in the Medicare Prescription Payment Plan

**CMS proposes** having plans accept MPPP election requests regardless of the format they’re submitted (email or letter).<sup>25</sup> When the plan receives a request in an alternate format and required information is missing, **CMS proposes** that the plan must contact the enrollee or their representative either electronically or telephonically to collect any missing information.<sup>26</sup>

As this will be a new program for beneficiaries in 2025, there is potential for confusion. Therefore, **NCOA supports** CMS’ proposed requirement for plan sponsors to reach out to a prospective MPPP enrollee for any missing information following the submission of an election request. We especially agree that the plan sponsor must contact the Part D enrollee either telephonically or electronically to collect all necessary information, but we request the agency require plan sponsors to conduct this outreach within a 72-hour time frame, so this does not adversely affect access to an important medication.

#### 30.3.1.2 Paper Election Requests

**CMS proposes** that a paper election request can either be filled out electronically and then printed out or filled out by hand and that there would be an option for a signed or electronic signature.<sup>27</sup>

**NCOA supports** the proposal since it allows the enrollee (or caregiver) several ways to submit a paper application.

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<sup>22</sup> Ibid.

<sup>23</sup> Page 16.

<sup>24</sup> Page 16.

<sup>25</sup> Ibid.

<sup>26</sup> Ibid.

<sup>27</sup> Page 17.

**CMS proposes** that the enrollee’s program election date would be the date of receipt of the mailed application.<sup>28</sup>

**NCOA has concerns** about the proposal because we feel that beneficiaries should not be penalized for delays in mail going from the enrollee to the plan. Delayed mail is not an uncommon feature of the mail service this decade. Instead, we recommend using the post marked date as the date of election.

### 30.3.1.3 Telephonic Election Requests

For enrollee election requests made by a telephone call, **CMS proposes** having the call be recorded and follow a script previously approved by the Part D sponsor based on content from the model “Medicare Prescription Payment Plan Participation Request Form.”<sup>29</sup> CMS also “expects Part D sponsors to complete the entirety of the Medicare Prescription Payment Plan election process in that single telephone interaction if the Part D enrollee wishes to participate in the program.”<sup>30</sup>

**NCOA supports** CMS’s proposal to have telephonic election requests recorded and follow a Part D-sponsor-approved script that consists of elements from a model CMS document. We strongly encourage CMS to recommend to Part D sponsors that their plans ought to do their best to try to obtain all needed information during a single phone call since having to engage with prospective enrollees on more than one call would not only be an inconvenience for all parties, but could delay or even prevent enrollment into the program.

### 30.3.1.4 Website Election Requirements

NCOA strongly encourages CMS to require a true online enrollment and not to enable plan sponsors to design the election mechanism such that it results in beneficiaries completing, for example, a PDF enrollment application that is submitted to the plan. Such a process delays enrollment and creates more opportunities for confusion and mistakes to occur.

## 30.4 Language Access and Accessibility Requirements

CMS clarifies that existing requirements for plans to provide education and outreach materials to enrollees with Limited English Proficiency (LEP) – that Part D sponsors must provide translated materials to Part D enrollees on a standing basis whenever a non-English language is the primary language of at least five percent of the individuals in the plan service area – also apply to all plan-produced MPPP materials such as the “Likely to Benefit Notice” and the ANOC.<sup>31</sup> Also, CMS clarifies that Part D sponsors are held to existing auxiliary aids and services access standards when sending plan-produced MPPP materials to enrollees when the latter either request auxiliary aids and services or the plan becomes aware of the enrollee’s need for such a format.<sup>32</sup> Furthermore, CMS clarifies that existing requirements around Part D sponsors’ use of multi-language inserts informing the reader of the availability of translation services also applies to all MPPP materials.<sup>33</sup>

NCOA would like to thank CMS for the inclusion of this clarification in the draft part 2 guidance document. We truly appreciate CMS’s continued commitment to ensuring access to plan materials for all Medicare Parts C and D beneficiaries.

## 40. CMS Part D Enrollee Education and Outreach

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<sup>28</sup> Page 17.

<sup>29</sup> Ibid.

<sup>30</sup> Page 18.

<sup>31</sup> Pages 20-21.

<sup>32</sup> Page 21.

<sup>33</sup> Page 21.

## 40.1 Information on the Medicare Prescription Payment Plan

**CMS proposes** to use Medicare.gov and other educational resources to educate beneficiaries on the MPPP benefit.<sup>34</sup>

**NCOA strongly supports** CMS's proposal to use these resources in this manner. We would like to express our sincere appreciation for thinking through how to use existing CMS resources to educate beneficiaries and other stakeholders on the program.

**NCOA has concerns**, however, that the proposed resources in this section are not descriptive enough for advocacy groups to be able to gauge whether they will be effective for educating the various populations of enrollees, providers, etc. We would like to recommend that CMS describe in its final part 2 guidance more details around what it would include. We encourage CMS to provide more details around whether its resources would include – and we strongly encourage CMS to include these features: 1) information on MPPP and the yearly OOP cap; 2) enrollment information; 3) clear, easy-to-understand examples of the types of individuals who would benefit from the program; 4) implications for failing to pay under the program; 5) information on LIS and LIS eligibility; 6) information on the complaints and grievances process; and 7) how to obtain additional information. Also, we encourage CMS to have the online election mechanism be front and center on Medicare.gov. Furthermore, we ask CMS to include a calculator tool on their Medicare.gov MPPP page so beneficiaries can determine if they are likely to benefit from the program.

**CMS proposes** to encourage plans and pharmacies to use these CMS MPPP resources to educate beneficiaries.<sup>35</sup> Under this proposal, plans' use of these resources would satisfy requirements to provide information on MPPP 1) alongside their "Likely to Benefit Notice"; 2) on their website; and 3) along with the election request form that's sent with the membership ID mailing.<sup>36</sup> Furthermore, **CMS proposes** to encourage plans to use these educational resources to educate pharmacists, communicate with contracted providers and interested parties, and describe the MPPP in any additional plan educational materials sent to enrollees.<sup>37</sup>

**NCOA has concerns** about the proposal to merely encourage plans, pharmacists, and other stakeholders to use CMS's resources to understand the program. Similarly, **NCOA has concerns** that plans may not take the opportunity to educate providers and pharmacists on the program. We strongly urge CMS to reconsider the optional nature of these provisions and will require itself and plans to use these CMS resources.

## 40.2 Modifications to Existing Part D Resources

**CMS proposes** to make updates to resources such as the *Medicare & You* Handbook as well as Medicare Plan Finder so that individuals have the resources to understand the program before the start of a new plan year.<sup>38</sup>

In a March 2024 NCOA/MAPRx survey of SHIP counselors, counselors supported CMS's proposal to add MPPP information to both Medicare.gov and Medicare Plan Finder. NCOA also appreciates CMS's consideration of making updates to these resources. With these things in mind, **NCOA strongly supports** CMS's proposal to provide MPPP resources to Plan Finder and the *Medicare & You* Handbook. **NCOA has concerns**, however, that the proposed language in this section does not provide enough details around how CMS plans to use these resources to educate beneficiaries and other stakeholders.

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<sup>34</sup> Page 22.

<sup>35</sup> Page 22.

<sup>36</sup> Ibid.

<sup>37</sup> Ibid.

<sup>38</sup> Ibid.

Regarding the handbook, NCOA strongly recommends that CMS ensure that the information on MPPP is clear and concise. We also encourage CMS to use pop up images or boxes in the handbook to draw attention to the information on the program. For the upcoming handbook for plan year 2025, we also encourage CMS to put a sticker on the front of the handbook that directs individuals to a certain handbook page where they can learn more about a “new” option for distributing their high prescription drug costs more evenly throughout the year. Given the limited space available in the handbook, we strongly recommend that CMS direct individuals to Medicare.gov to learn more about MPPP (if CMS were to decide to make Medicare.gov a robust source of MPPP information). In response to a March 2024 survey question on how CMS ought to best use their resources to educate enrollees, one SHIP counselor said that information in the handbook ought to “use plain language and simple examples to explain the payment option, when a person is likely to benefit, and the implications of enrollment. Don’t overwhelm folks with the behind-the-scenes math.” NCOA strongly agrees with the counselor’s suggestion that CMS provide simple examples.

In our focus group session and survey with SHIP counselors in November 2023 and March 2024, NCOA gathered insights on how counselors believe Plan Finder ought to be tailored to best educate enrollees. In response to a March 2024 survey question on resources that would be helpful to SHIP counselors, one counselor said the following: “Plan Finder needs to be updated to display projected costs under the MPPP compared to non-MPPP costs so counselors are not expected to do the math.” Furthermore, one counselor, for instance, recommended in November 2023 that Plan Finder have an MPPP pop-up box that displays after an individual enrolls in a plan. Also, counselors in November 2023 recommended creating an additional Plan Finder pop-up describing MPPP once individuals input the names of prescriptions with high OOP costs. NCOA too supports such suggestions for Plan Finder.

NCOA feels that these Plan Finder pop-up boxes can only contain so much information, so we recommend having the pop-up direct individuals to Medicare.gov if CMS were to develop valuable resources there. We feel the aim should be to direct individuals to Medicare.gov where they can learn more about the program and then possibly decide to enroll. This, we feel, is preferable to giving individuals the option to enroll in MPPP directly from Plan Finder.

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

**CMS proposes** to work with interested parties such as SHIP counselors to make sure that the various CMS and plan resources are well suited to educate their intended audiences.<sup>39</sup>

**NCOA strongly supports** CMS’s proposal to support SHIP and other Medicare counselors such as those at Area Agencies on Aging and Aging and Disability Resource Centers. We encourage CMS to have ongoing meetings with beneficiary advocacy groups and conduct regular SHIP counselor and enrollee focus groups to solicit feedback on what is and is not working well in the program.

In the November SHIP counselor focus group, a counselor mentioned two specific resources they felt might help them educate beneficiaries: 1) a tip sheet and 2) resources they can add to their state SHIP websites. NCOA agrees with these suggestions. In March 2024’s questionnaire, one SHIP counselor said the tip sheet could provide the key steps to enroll someone while they’re walking the beneficiary (or their caregiver) through the process of opting into MPPP. Given the diverse number of Medicare beneficiaries SHIP counselors serve, NCOA would also like to recommend that tip sheet materials be available in multiple languages in addition to English and Spanish.

In the March 2024 questionnaire, other surveyed SHIP counselors provided suggestions around SHIP counselor technical assistance (TA). One SHIP counselor, for instance, stated that MPPP-related training

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<sup>39</sup> Ibid.

ought to be added to the Part D CMS NPT training module. Also, another counselor suggested that “the SHIP TA Center should create an MPPP module.” NCOA agrees with these recommendations.

## 50. Pharmacy Processes

In the final part 1 guidance for the MPPP, CMS indicated that it would not require real-time POS election into MPPP.<sup>40</sup> NCOA continues to encourage CMS to study how to effectuate this option by January 2026. In the November focus group with SHIP counselors, the counselors expressed strong support for allowing beneficiaries to opt into the program at the pharmacy counter “in order to make this benefit as easy and accessible as possible.”

**CMS proposes** requiring plans to notify a pharmacy when an enrollee’s out-of-pocket costs reach a certain threshold and are “likely to benefit” from enrolling in MPPP.<sup>41</sup>

**NCOA supports** CMS’s plan to notify pharmacists when an enrollee would likely be a good candidate for MPPP. Furthermore, we ask CMS to ensure that such notifications are incorporated into existing data feeds to pharmacies to better guarantee a smooth roll out of the notification feature.

CMS finalized part 1 MPPP guidance says that a beneficiary’s single prescription total of \$600 or more would trigger a MPPP-related “likely to benefit” notification to the pharmacy.<sup>42</sup> NCOA strongly encourages CMS to in the near-term reconsider this “single fill” provision and to instead have the total of multiple prescription drugs purchased in a single day count towards the definition and pharmacy notification. Individuals with lupus, for instance, may fill multiple medications such as immunosuppressives and steroids that do not separately hit the \$600 threshold, but do so cumulatively.<sup>43</sup> Calculating the OOP cost based on a cumulative calculation also aligns with congressional intent that the MPPP not be limited to costs from a single prescription, and therefore, we believe CMS should adopt a revised methodology.

For education by pharmacists to be successful, NCOA also recommends that CMS provide effective educational materials (eg., MPPP brochures) that pharmacists can easily hand to beneficiaries at the pharmacy counter. Furthermore, we also recommend CMS provide model language for pharmacists to leverage when counseling patients on MPPP to ensure the interaction is as quick and informative as possible. Specifically, we support CMS providing information for pharmacists directing patients to contact their Part D plan leveraging the contact information on their Part D membership ID card.

### 50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies

**CMS proposes** requiring that Part D sponsors ensure that pharmacies – regardless of setting – provide the “Likely to Benefit Notice” to the Part D enrollee.<sup>44</sup>

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<sup>40</sup> CMS. “Medicare Prescription Payment Plan: Final Part One Guidance.” Page 31.

<sup>41</sup> CMS. “Medicare Prescription Payment Plan: Draft Part Two Guidance.” Page 23.

<sup>42</sup> CMS. “Medicare Prescription Payment Plan: Final Part One Guidance.” Page 20.

<sup>43</sup> Lupus Foundation of America. “Medications used to treat Lupus.” 04 August 2021. 05 March 2024.

<https://www.lupus.org/resources/medications-used-to-treat-lupus>. The possibility for combination drug therapies is also something the American Diabetes Association says that since diabetes-treatment prescriptions “act in different ways to lower blood glucose levels, they may be used together to help meet your individualized diabetes goals. For example, metformin and a DPP-4 inhibitor may be used together shortly after being diagnosed with type 2 diabetes to help keep blood glucose levels at goal. That said, many combinations can be used. Work with your health care provider to find the combination of medicines that work best for you and your lifestyle and help you meet your health goals. Insulin may also be used to treat type 2 diabetes.” American Diabetes Association. “What are my options for type 2 diabetes medications?” 05 March 2024. <https://diabetes.org/health-wellness/medication/oral-other-injectable-diabetes-medications>.

<sup>44</sup> CMS. “Medicare Prescription Payment Plan: Draft Part Two Guidance.” Page 24.

**NCOA supports** the requirement to have plans guarantee that pharmacists provide the notice to individuals who meet the defined threshold for being “likely to benefit” once plans provide such qualifying information about the beneficiary to the pharmacy.

The Limited Income Newly Eligible Transition (LI-NET) program offers some lessons learned as CMS considers how best to conduct outreach to pharmacists around MPPP. In a March 2023 conversation with SHIP counselors, one individual stated they found that pharmacists at small, local pharmacies were not aware of the LI-NET program. This counselor provided an informed guess as to one of the reasons this may be occurring: small pharmacy pharmacists may be skeptical about issuing the discount given that they do not, relative to larger pharmacy chains, have as much money to work with. This counselor then said they had previously made CMS aware of what they felt was driving this behavior among small pharmacies. In response to the March 2024 NCOA SHIP counselor survey, one counselor said they believe pharmacy staff turnover is faster than the rate at which individuals are being educated on LI-NET.

NCOA believes that these insights offer lessons around what may lead pharmacists in the future to also be unaware of MPPP. In response to the March 2024 survey question asking about specific lessons from pharmacist education around LI-NET that could inform pharmacist education around MPPP, one SHIP counselor said the following: “Having standardized materials for pharmacists and dedicated helplines is essential. Ongoing education is necessary to address loss of expertise with turnover.” In response to the same survey’s question on challenges with educating pharmacists on both LI-NET and MPPP, the same SHIP counselor highlighted the “lack of [a] clear pathway to address grievances with pharmacists who, unfamiliar with the program, refuse to complete necessary next steps.”

In a July 2023 meeting with the CMS Office of Communications, NCOA said to CMS that it had heard from SHIP counselors that small business pharmacies in some cases had not heard of the LI-NET program. We then asked CMS and its contractor to increase its outreach to small business pharmacies. In response, CMS said it would further internally discuss its targeted outreach to small, local pharmacies.

At a meeting of Area Agency on Aging counselors in September 2023, one counselor spoke to how pharmacist education around LI-NET was not only a problem at small, local pharmacies, but also at larger, chain ones as well. Other counselors in the room confirmed that they had also found this to be the case. Finally, at the November 2023 SHIP focus group meeting on the MPPP, counselors expressed that, given that “most pharmacies” have limited knowledge about the program, SHIP counselors felt the need to conduct most of the education around LI-NET.

## 60. Part D Sponsor Operational Requirements

### 60.4 Audits

**CMS proposes** that it or its contractors may conduct audits of Part D sponsors’ implementation of MPPP.<sup>45</sup> Under the proposal, CMS or its contractor may then initiate additional data collection or site visits.<sup>46</sup>

**NCOA supports** the proposed audits and follow-up activities. NCOA asks that CMS make its audit findings public. We also strongly encourage the Department of Health and Human Services’ Office of the Inspector General to also conduct its own audit and then make its findings and recommendations publicly available.

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<sup>45</sup> Page 30.

<sup>46</sup> Page 30.





March 15, 2024

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

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

Submitted electronically to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) in response to the *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* (draft Part Two guidance).

Created by and for patient organizations more than 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of 170 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

As a vocal supporter of the MPPP and its potential benefits to people with chronic diseases and disabilities, the NHC appreciates CMS' guidance on Part D sponsor duties in the draft Part Two guidance. While implementing this new program, it will be critical that CMS work with patients, patient advocacy groups, and other stakeholders to support choice and access to clear, understandable, and actionable information. This collaboration is particularly significant for people with chronic diseases and disabilities who are most likely to benefit from this new program. The NHC supports the development and use of processes and tools that enhance beneficiary experience, making interactions with the MPPP smoother and more intuitive for all beneficiaries. It is vital that communication, both for beneficiaries and for health care providers and pharmacists, adhere to these principles. The considerable discretion granted to Part D

sponsors in operationalizing the program, while offering flexibility, also raises concerns about potential inconsistencies and unintended consequences that could impact beneficiary participation. To mitigate this, the NHC recommends that CMS refine its monitoring and oversight mechanisms, ensuring that all communication regarding the MPPP is inclusive, accessible, and accommodating of diverse needs, including but not limited to those with sensory or other disabilities and those with limited English proficiency (LEP). This includes standardization of materials and the use of CMS-provided language as well as examples of payment calculations to prevent confusion and variations in information provided by different plans and pharmacies.

Additionally, recognizing the complexity of health care information, the NHC underscores the need for CMS to partner with trusted messengers, such as patient organizations to co-create and/or review communication materials for usability and understandability, ensuring they are meaningful and actionable for all Medicare beneficiaries. Robust education, outreach efforts, and continuous monitoring and feedback mechanisms will be instrumental in ensuring the successful launch of this new program.

The NHC provides the following technical comments on the MPPP Part Two guidance.

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

The NHC appreciates CMS' guidance detailing Part D sponsors' responsibilities in informing Medicare beneficiaries about the MPPP both prior to and during the plan year but is concerned over the emphasis on primarily targeting those likely to benefit from the program. This focus might overshadow the broader necessity of ensuring all beneficiaries receive comprehensive information about the program, potentially limiting informed decision-making opportunities for the wider Medicare population. The NHC underscores the importance of balancing focused outreach with widespread educational efforts to fully support beneficiary engagement and understanding across the entire spectrum of Medicare enrollees.

The NHC appreciates the mechanisms set forth for Part D sponsors to notify pharmacies — and, in turn, for pharmacies to inform beneficiaries — when a beneficiary's out-of-pocket (OOP) costs for covered Part D drugs suggest potential benefits from participating in the MPPP. A similar mechanism would be helpful for health care providers to offer additional guidance and support to patients about the program. This collaborative approach between pharmacies and health care providers can create a comprehensive support system to ensure beneficiaries are well-informed to make decisions regarding their health care.

However, the NHC believes that the guidance would be further strengthened by explicitly emphasizing the involvement of patients and patient advocacy groups in the development, review, and refinement of educational materials. This collaborative effort will ensure that the materials are not only informative but also resonate with beneficiaries' experiences and needs, thereby enhancing the effectiveness of the communications and ensuring that they are truly patient-centered.

Moreover, the NHC recommends that CMS consider introducing additional tools and resources, such as decision aids or interactive online platforms such as a monthly cost calculator, to aid beneficiaries in understanding the potential impacts of the MPPP on their personal prescription drug costs. These tools can empower beneficiaries with the information necessary to make more informed choices regarding their enrollment in the MPPP.

Lastly, the NHC stresses the importance of continuous monitoring and evaluation of the outreach, education, and communication strategies to identify areas for improvement. This ongoing assessment will ensure that the information needs of all beneficiaries, especially those facing language and accessibility barriers, are adequately met. The NHC is eager to continue its collaborative efforts with CMS to enhance the MPPP's outreach and education initiatives, ensuring its successful implementation for the benefit of all Medicare beneficiaries.

### *30.1 General Outreach and Education*

While the NHC appreciates CMS' outlined approach to outreach and education in the draft Part Two guidance, additional clarity regarding CMS' strategies for widespread information dissemination to ensure that all Medicare beneficiaries, not just those immediately identified as likely to benefit, is needed. The NHC recommends that CMS collaborate with patient advocacy groups and beneficiaries to develop communications materials to ensure a patient-centered approach and that materials resonate with the diverse needs of the Medicare population. Additionally, the NHC recommends that CMS provide guidelines to ensure online content on plan websites is user-friendly and accessible to all beneficiaries, including those with disabilities or LEP. Furthermore, the NHC emphasizes the importance of deploying an accessible and reliable monthly cost calculator as described in the draft Part One guidance.<sup>1</sup> This tool will be essential for providing beneficiaries with a clear understanding of their potential monthly expenses under the program and should be prioritized by CMS to ensure that beneficiaries have the necessary information to make informed decisions regarding their participation.<sup>2</sup>

The NHC supports the requirement to include MPPP details and an election request form with membership ID card mailings to new enrollees, ensuring immediate and clear communication upon plan entry. We recommend that CMS and Part D sponsors ensure these materials are concise, easily understandable, and tailored to meet the unique needs of all enrollees, including those with visual or cognitive impairments, leveraging CMS-developed educational products for uniformity while adapting them to specific enrollee needs.

Additionally, incorporating beneficiary feedback and pilot testing of revised Evidence of Coverage documents can ensure that MPPP information clarifies rather than

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<sup>1</sup> Centers for Medicare & Medicaid Services. (2023). 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. Retrieved from <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>

<sup>2</sup> National Health Council. (2023). NHC comments on maximum monthly cap on cost-sharing payments. Retrieved from <https://nationalhealthcouncil.org/wp-content/uploads/2023/09/NHC-MPPP-Comments.pdf>

complicates coverage understanding. For the Annual Notice of Change, accessible language that accommodates varied health literacy levels is vital. We recommend that CMS offers Part D sponsors best practices for clearly explaining the MPPP. Similarly, updating the Explanation of Benefits to include visual aids and examples will clarify MPPP's impact on cost-sharing and coverage.

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

The NHC supports the targeted outreach and education requirements outlined in the draft Part Two guidance but recommends a more inclusive and adaptive approach to communication strategies. The reach and effectiveness of CMS' and Part D sponsors' outreach efforts can be enhanced by integrating patient feedback and employing various communication channels, ensuring that all eligible Part D enrollees are well-informed to make decisions about their MPPP participation. Establishing a foundational knowledge level for all Part D beneficiaries is essential for ensuring those most likely to benefit from the program receive the necessary information to take action.

The NHC appreciates CMS' standardized approach to the "Likely to Benefit Notice," ensuring consistent information across Part D sponsors. However, to improve understanding of the MPPP's impact on prescription drug costs and health care decisions, the NHC suggests augmenting this notice with additional educational resources, such as FAQs or interactive online tools. We acknowledge CMS' efforts in requiring Part D sponsors to submit detailed MPPP participation data through established systems. However, to further empower beneficiaries and stakeholders, the NHC recommends CMS publicly report aggregated data on MPPP enrollees, including those terminated from the program and denied reentry in subsequent years. This data should be analyzed to identify trends and areas for improvement, facilitating ongoing program refinement and stakeholder engagement. Such transparency would not only uphold accountability but also enable stakeholders to contribute to the program's continuous improvement, ensuring it better serves the evolving needs of Medicare beneficiaries.

The NHC appreciates the inclusion of a standardized framework by CMS to determine which enrollees are "likely to benefit" from the MPPP before and during the plan year by utilizing Prescription Drug Event (PDE) records to predict enrollees' OOP expenses. The NHC supports the minimum requirement for Part D sponsors to undertake targeted outreach to enrollees who are anticipated to incur high OOP costs for new prescriptions, potentially making them eligible for the MPPP, which will inform enrollees about the program before they face financial hardship at the pharmacy point-of-sale (POS). Additionally, while CMS mandates that any additional identification criteria applied by Part D sponsors must be uniformly applied to all enrollees, the NHC encourages CMS to provide more explicit guidance on what these supplemental strategies might entail and how they can be implemented in a manner that ensures fairness and transparency.

The NHC expresses strong concerns regarding CMS' revised criteria for notifying pharmacies about Part D enrollees' eligibility for the MPPP based solely on single prescription thresholds. The shift to a single prescription threshold for alerting beneficiaries about potential MPPP benefits represents a significant departure from the draft Part One guidance, which considered cumulative OOP costs. This change could

significantly narrow the pool of beneficiaries who are informed about the MPPP, potentially excluding individuals who cumulatively meet the eligibility threshold through multiple, less expensive medications. Many Medicare beneficiaries depend on a fixed income, primarily from Social Security, and meticulously budget for their health care costs on a monthly basis rather than per transaction. Given the diverse circumstances of beneficiaries, a one-size-fits-all approach based on single prescription thresholds could significantly restrict access to the MPPP for those who might benefit from it the most. Recognizing the varied financial situations of Medicare beneficiaries, the NHC recommends a more inclusive criterion that considers cumulative OOP costs to ensure that all beneficiaries who could benefit from the MPPP are adequately informed and supported. To ensure comprehensive beneficiary support, the NHC requests that CMS direct Part D sponsors to conduct targeted outreach for beneficiaries whose total OOP costs within a defined recent period reach the established eligibility threshold. This broader approach would help identify beneficiaries taking multiple lower-cost medications that cumulatively impose significant financial burdens, ensuring they are not inadvertently excluded from benefiting from the MPPP. Such targeted outreach should complement the existing mechanisms, bridging the gap to include a wider range of beneficiaries potentially eligible for the program and fostering more inclusive and informed decision-making among the Medicare population. Moreover, while the NHC appreciates the requirement for pharmacies to inform the Part D enrollees about the MPPP upon receiving a notification, we call for additional support and resources for pharmacies to ensure these conversations are as informative and helpful as possible. Given the complexity of the MPPP and its potential impact on enrollees' health care decisions, it is vital that pharmacies are equipped with comprehensive, easy-to-understand information that can be readily shared with enrollees. This support could include detailed FAQs, training sessions for pharmacy staff, and clear guidelines on how to handle enrollees' questions or direct them to further assistance.

The NHC recognizes the essential role of pharmacies and health care providers in facilitating informed discussions regarding prescription drug costs with Medicare beneficiaries, and we support CMS' directive for Part D sponsors to alert pharmacies when a beneficiary's OOP costs for covered Part D drugs reach a threshold that suggests they might benefit from the MPPP. This provision ensures timely and crucial information is relayed to beneficiaries at a critical decision-making juncture, potentially alleviating the financial burden of prescription medications. Furthermore, the encouragement for Part D sponsors to engage in targeted communication with health care providers, particularly those in specialties more likely to prescribe high-cost medications, is a proactive approach to ensure that the prescribers are also aware of the MPPP and can guide their patients accordingly. However, the NHC recommends that CMS consider additional measures to enhance the effectiveness of these communications. Specifically, CMS could develop standardized training or informational sessions for pharmacy staff and health care providers to ensure they have a comprehensive understanding of the MPPP. This training could include case studies, FAQs, and scenarios to better prepare them for patient inquiries and to facilitate more meaningful discussions about the program. Moreover, the NHC suggests that CMS explore the development of digital tools or platforms that could assist pharmacies and providers in identifying eligible beneficiaries more efficiently and in providing personalized information about the benefits of enrolling in the MPPP. These tools could integrate with existing systems such as real-time benefit tools to flag eligible patients



automatically and provide tailored information based on the patient's medication regimen and financial situation.

### *30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors*

The NHC acknowledges CMS' comprehensive approach to offering election options and the emphasis on providing additional information to enrollees to ensure they fully understand the financial implications of participating in the MPPP. The NHC strongly supports the provision that allows Part D enrollees to opt into the MPPP at any point during the plan year or during enrollment periods, which offers flexibility and ensures that beneficiaries can benefit from the program when they need it most. However, the NHC believes that further clarification and guidance on the process for electing to participate in the MPPP would be beneficial. Specifically, clear, straightforward instructions on how to opt into the program through various methods (paper, telephone, and website) should be provided to ensure the process is accessible to all, especially those with limited technological skills or access. Moreover, the NHC recommends that Part D sponsors not only provide estimates of monthly payments under the MPPP but also offer additional tools and resources, such as decision aids or interactive online platforms such as a monthly cost calculator, to help beneficiaries understand how the program affects their specific situation, particularly for those with complex medication needs or those considering the MPPP alongside other assistance programs like LIS. This personalized approach can help prevent confusion and ensure beneficiaries make informed decisions based on their unique circumstances. Finally, the NHC underscores the importance of clear communication regarding the LIS program as an alternative or additional avenue for managing prescription drug costs. Given that LIS enrollment might offer more benefits for those who qualify, it's crucial that Part D sponsors effectively inform enrollees about their options. The NHC suggests that CMS develops and provides resources, model language, training, and support to Part D sponsors to ensure these communications are as clear and effective as possible, thus enabling beneficiaries to navigate their options with confidence.

The NHC appreciates CMS' initiative in developing model documents to assist Part D plan sponsors and Medicare Advantage (MA) organizations satisfy the education and outreach responsibilities for Part D sponsors and MA organizations for the MPPP in: 1) the likely to benefit notice ("Consider Managing Your Monthly Drug Costs with the Medicare Prescription Payment Plan"), 2) the election request form ("Medicare Prescription Payment Plan participation request form"), 3) the notice of election approval ("Part D Sponsor Notice to Acknowledge Acceptance of Election to the Medicare Prescription Payment Plan"), 4) the notice of failure to pay ("Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan"), 5) the notice of involuntary termination ("Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan"), and 6) the notice of voluntary termination ("Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan"). These model documents are critical tools to ensure that enrollees are well-informed about and can seamlessly opt into or out of the MPPP, enhancing patient-centered care and access to affordable prescription medications. The NHC is reviewing these documents and intends to submit detailed feedback to CMS,

but generally, to ensure that the MPPP is accessible, understandable, and beneficial to all Part D enrollees, we propose the following recommendations for CMS:

1. **Enhance form accessibility and inclusivity:** Ensure all forms, across all election methods, are designed with accessibility in mind, ensuring usability by individuals with various disabilities, including visual, auditory, and cognitive impairments, uses clear, jargon-free language accessible to enrollees with varying levels of health literacy, and made available in multiple languages to accommodate the diverse Medicare population, including those with LEP.
2. **Establish a robust support system for enrollees:** Provide comprehensive guidance on the impact the MPPP's impact on prescription drug costs and personalized assistance to help enrollees make informed decisions, extending beyond the initial request to participate, encompassing ongoing education about the program's benefits, potential changes, and how enrollees can maximize its value.
3. **Ensure prompt and proactive sponsor communication:** Part D sponsors should be required to actively collect any missing information and confirm enrollees' understanding of the program's terms and conditions, particularly when enrollees submit election requests in non-standard formats.
4. **Monitor and evaluate the effectiveness of the election process:** Identify and address any barriers that enrollees might face in opting into the MPPP to ensure a smooth enrollment experience.
5. **Test model documents with diverse user groups:** Ensure documents are understandable, meet the needs of all potential enrollees, and widely available and easily accessible in diverse settings, including but not limited to community centers, health care facilities, and, for paper election requests, through direct mail options to reach those without internet access. Digital election requests should be user-friendly, accessible, and compliant with the latest web accessibility standards.
6. **Provide detailed instructions and support for paper forms:** Part D sponsors should be required to offer detailed instructions and support services, such as a dedicated helpline, for completing paper forms. This assistance should be available in multiple languages and accessible formats to accommodate all enrollees, including those with visual or cognitive impairments.
7. **Incorporate safeguards against inadvertent disenrollment:** Develop and disseminate clear, step-by-step guidance for beneficiaries on how to initiate an appeal if they are involuntarily disenrolled from the MPPP before termination and information on support services for financial difficulties. It is crucial for this guidance to be accessible in various formats and languages to accommodate all beneficiaries. Additionally, the NHC advocates for compassionate consideration of individual circumstances in both notices and urges CMS to incorporate provisions for hardship exceptions or extended grace periods in certain situations. This approach should balance the need for financial policies with the protection of vulnerable beneficiaries, ensuring the process is supportive, informative, and considers beneficiaries' financial vulnerabilities.

Furthermore, given the complexity of health care information and the diverse needs of Medicare beneficiaries, the NHC recommends that CMS issue guidance to Part D sponsors on employing a variety of communication methods beyond the required

telephonic and written notices. This could include informational videos, interactive online Q&A sessions, and community outreach events to educate beneficiaries about the MPPP and ensure they fully understand the implications of their election decisions. While the NHC commends the steps to notify beneficiaries of their election into the MPPP outlined in the draft Part Two guidance, we encourage CMS and Part D sponsors to continue seeking ways to enhance beneficiary communications. By making information more accessible, understandable, and actionable, we can ensure that all beneficiaries are well-equipped to make informed decisions about their participation in the MPPP. By addressing these considerations, CMS and Part D sponsors can ensure that the process for voluntary termination from the MPPP is transparent, patient-centered, and aligned with the best interests of Medicare beneficiaries.

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

The "Language Access and Accessibility Requirements" outlined in the draft Part Two guidance are critically important for ensuring that all Part D enrollees, particularly those with LEP and diverse cultural and ethnic backgrounds, can access and understand information about the program. The NHC commends CMS for its commitment to providing materials in a culturally competent manner and for requiring Part D sponsors to adhere to these crucial standards.

The NHC appreciates the emphasis on making all vital information related to enrollment, benefits, health, and rights available in multiple languages and accessible formats. This approach is fundamental to removing barriers to information and ensuring that every beneficiary has the opportunity to make informed decisions about their health care. The requirement for Part D sponsors to provide translated materials in any non-English language that is the primary language of at least five percent of individuals in a Plan Benefit Package (PBP) service area is a step in the right direction towards addressing health disparities and promoting equity in health care access.

Moreover, the NHC supports the inclusion of multi-language inserts (MLIs) in CMS-required materials, which inform beneficiaries about the availability of free interpreter services. This is an essential tool for beneficiaries who may not be proficient in English or who prefer to receive health care information in their primary language. It is crucial that these MLIs are prominently placed in all relevant materials to ensure they are easily noticed by those who need them.

The NHC also recognizes the importance of compliance with anti-discrimination provisions, such as Section 508 of the Rehabilitation Act, which requires Part D sponsors' websites and materials to be accessible to individuals with disabilities. Ensuring that websites and materials are compatible with screen reader technology and other auxiliary aids is vital for providing equal access to information for all beneficiaries, including those with visual impairments or other disabilities.

However, the NHC believes that beyond compliance, there should be a proactive effort to engage with communities that have historically been underserved or face language barriers. This could include partnerships with community organizations, health care providers, and advocacy groups to disseminate information about the MPPP in a manner that is culturally and linguistically tailored to the needs of diverse communities.



Furthermore, the NHC suggests that CMS and Part D sponsors consider the use of visual aids, infographics, and video materials that can transcend language barriers and provide an intuitive understanding of the MPPP. Such materials can be particularly effective in conveying complex information in a more digestible format, potentially increasing program comprehension and engagement among beneficiaries with varying literacy levels.

Related to these requirements, the NHC seeks clarity on how pharmacies, especially in the context of distributing the MPPP “Likely to Benefit” notice, will navigate language access obligations. It is imperative that the final guidance specifies whether these responsibilities extend to pharmacies and delineates how they should determine the appropriate language(s) for communication, ensuring inclusivity and accessibility for all beneficiaries.

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

The NHC commends CMS for recognizing the critical need to provide comprehensive educational materials to Part D enrollees about the MPPP. Ensuring broad education on the program's availability is essential for empowering beneficiaries to make informed health care decisions. Overall, we feel CMS still needs to be clearer on how it will develop new, standardized educational resources and update existing ones to include information about the MPPP. Additional clarity will greatly assist the patient advocacy community in understanding what CMS will do – and what our community must do – to raise awareness among Part D enrollees.

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

The NHC supports the development of educational resources for Part D enrollees, available on the Medicare.gov website and other communication channels. CMS' inclusion of various stakeholders, such as Part D sponsors, pharmacies, providers, and beneficiary advocates, in using and disseminating this product is a commendable approach that will ensure a wide reach of the program's information.

The requirement for Part D sponsors to use this educational product on their websites, in membership ID card mailings, and alongside the "Medicare Prescription Payment Plan Likely to Benefit Notice" is a strategic approach to ensure consistent messaging across different communication mediums. This requirement will help streamline information dissemination and ensure that enrollees have multiple touchpoints to learn about the MPPP.

The encouragement for Part D sponsors to provide additional information to pharmacies and to communicate with contracted providers and other interested parties using the educational product will foster a collaborative environment. It ensures that all parties involved in beneficiary care are well-informed about the MPPP, facilitating better support for enrollees considering the program.

However, the NHC suggests that CMS consider involving patient advocacy groups and beneficiaries in the development of these educational materials to ensure they are patient-centered and address the real-world concerns and questions of enrollees. Additionally, the NHC recommends that CMS develop interactive and user-friendly

tools, such as cost calculators or decision aids, to accompany the educational product, providing enrollees with practical resources to assess their potential benefits from the MPPP.

#### *40.2 Modifications to Existing Part D Resources*

The NHC appreciates CMS' commitment to modifying existing Medicare Part D documents, web content, and tools to include information about the MPPP. This approach ensures that beneficiaries have access to updated and comprehensive resources to understand the program's potential benefits relative to their individual needs.

The inclusion of information about the MPPP in widely used resources such as the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder will significantly enhance program visibility and understanding among enrollees. The NHC encourages CMS to offer greater clarity on how the Agency will do this and how you will ensure that these modifications are made in an easily understandable manner, catering to the diverse literacy levels and language needs of the Medicare population.

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

The NHC supports CMS engagement with a diverse array of stakeholders, including State Health Insurance Assistance Program (SHIP) counselors, to improve national outreach and education efforts for the MPPP. This collaborative approach is crucial for disseminating accurate, comprehensive information about the program widely, especially to those who may benefit the most from the program. To further enhance outreach and education efforts, the NHC recommends that CMS integrate patient perspectives into the creation of educational materials and interactive tools by engaging Medicare beneficiaries, experts in health literacy and cultural competence, and the patient community, in discussions to guide the creation of educational content and interactive tools. These trusted messengers can assist CMS incorporate real-life scenarios and FAQs to make these resources resonate more with beneficiaries. Additionally, by leveraging relationships with trusted messengers within communities, CMS can overcome barriers to information access and understanding, further broadening the program's reach as it implements targeted outreach initiatives to reach vulnerable populations who may face barriers to accessing program information. The NHC appreciates CMS' outlined approach in providing beneficiaries with essential information to make informed health care decisions. We encourage the continued development and broadening of these efforts, focusing on tailoring information dissemination to match the preferred communication methods of beneficiaries, whether in-person, digital, telephonic, or otherwise. By ensuring messages are consistent across platforms, and tools are readily accessible in various formats, CMS can minimize confusion and boost program engagement, facilitating a more straightforward decision-making process for all beneficiaries.

### **50. Pharmacy Processes**

Given the complexity and breadth of the "Pharmacy Processes" section in the draft Part Two guidance of the MPPP, the NHC appreciates the emphasis on the pivotal role

pharmacies play in operationalizing the MPPP and agrees with the requirement for Part D sponsors to notify pharmacies when a Part D enrollee's OOP costs indicate potential eligibility for the MPPP. The NHC supports the mandate for pharmacies to inform Part D enrollees about the MPPP upon notification from Part D sponsors, highlighting the importance of direct communication in enhancing enrollee awareness and participation in the program. However, the NHC continues to urge CMS to work with pharmacies and pharmacists to implement POS enrollment in the MPPP as soon as possible.

#### *50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount*

The NHC recognizes the complexity introduced by supplemental coverage and appreciates CMS' acknowledgment of how such coverage can impact the final patient pay amount, potentially affecting the enrollee's perceived benefit from the MPPP. We recommend that CMS provide clear and detailed guidance for Part D sponsors and pharmacies on handling cases with supplemental coverage, ensuring that enrollees receive accurate information about their potential benefits from the MPPP.

#### *50.2 Pharmacy POS Notifications Late in the Plan Year*

The NHC is concerned about scenarios where late-year notifications could lead to enrollees being required to pay the full amount as part of their first month's bill under the MPPP and suggests exploring mechanisms to adjust the billing in such cases to prevent financial hardship for enrollees opting into the program late in the plan year.

#### *50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies*

The NHC encourages CMS to ensure offering of the "Medicare Prescription Payment Plan Likely to Benefit Notice" to enrollees at the POS in pharmacies with direct enrollee contact is implemented smoothly across all pharmacy settings to maximize enrollee engagement and understanding. For pharmacy settings without direct enrollee contact, the NHC appreciates CMS' efforts to provide guidance and encourages the development of innovative strategies to ensure enrollees receive timely and effective notifications. The NHC acknowledges the unique challenges presented by long-term care pharmacies and supports CMS' approach to allow flexibility in the provision of the "Likely to Benefit Notice" within these settings. We encourage continued dialogue with stakeholders in the long-term care sector to ensure that enrollee notifications are handled appropriately and effectively. The NHC recognizes the special considerations necessary for Indian Health Services (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies and supports the exemption from the requirement to notify the pharmacy of an enrollee's potential eligibility for the MPPP. We suggest that CMS and Part D sponsors engage with I/T/U pharmacies to ensure that IHS-eligible Part D enrollees are aware of the MPPP and understand how their coverage through I/T/U pharmacies interacts with the program. For pharmacies without in-person encounters, such as mail-order pharmacies, the NHC appreciates CMS' guidance on alternative notification methods. However, clarity is also needed regarding online or digital-forward pharmacies. For example, clarity on whether these pharmacies must send hard copy notifications in addition to digital notices at the POS is needed. Furthermore, the implementation challenges posed by digital transactions, where

prescription selection and payment are simultaneous, necessitate clear CMS guidance to prevent any disruption in beneficiary experience.

We encourage CMS to collaborate with Part D sponsors to ensure that these methods are effective in reaching enrollees and providing them with the necessary information to make informed decisions about the MPPP.

#### *50.4 Readjudication of Prescription Drug Claims for New Program Participants*

The NHC supports the process for the readjudication of prescription drug claims to ensure that new program participants pay \$0 at the POS for covered Part D drugs. We recommend clear communication and guidelines for pharmacies to ensure this process is conducted smoothly and without undue burden on the enrollee.

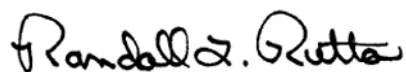
#### *50.5 Processing of Covered Part D Claims for Program Participants in Special Settings*

The NHC acknowledges the complexity of processing Part D claims for beneficiaries in special settings, such as long-term care facilities and I/T/U pharmacies. The unique billing arrangements and the potential financial implications for participants in these settings necessitate careful consideration and tailored approaches to ensure that beneficiaries' interests are safeguarded.

### **Conclusion**

The NHC appreciates the opportunity to comment on the draft Part Two guidance. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these comments in greater detail. He is reachable via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive, flowing style.

Randall L. Rutta  
Chief Executive Officer



March 15, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Administrator Brooks La-Sure:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the *CMS Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025* (the “Draft Part Two Guidance”), issued by the Centers for Medicare & Medicaid Services (CMS) on February 15, 2024.<sup>1</sup> NHIA is a trade association that represents companies that provide medically necessary infusion therapies to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and alternate site infusion community, we write to share our feedback regarding CMS’s Draft Part Two Guidance on the Medicare Prescription Payment Plan (MPPP) for contract year (CY) 2025.

NHIA is pleased that the Inflation Reduction Act’s (IRA) MPPP will provide Part D enrollees the option to pay their out-of-pocket (OOP) costs for drugs covered by Medicare Part D over the course of the plan year beginning January 1, 2025. This change may lead to greater prescription adherence and improved access to care in the home setting for certain infused medications. Our recommendations regarding certain sections of the Draft Part Two Guidance are below.

Section 30.2 Targeted Outreach and Education Requirements for Part D Sponsors

CMS states that a critical component of the MPPP’s success will be notifying Part D enrollees likely to benefit from the program early – prior to reaching the point-of-sale (POS) at the pharmacy. CMS proposes to require Part D sponsors to undertake targeted outreach directly to enrollees likely to benefit from the MPPP both prior to and during the plan year. NHIA agrees that the timing of notification and election to participate in the MPPP is important and ideally

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



happens before the pharmacy is processing a prescription for dispensing. NHIA supports CMS exploring a POS election process in the future years.

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

Based on an analysis of Part D enrollee OOP costs in 2021 and 2022, CMS will require Part D sponsors to evaluate their current Part D enrollees' prescription drug costs from the current year and conduct outreach to those who incurred \$2,000 in OOP costs through September of that year for covered Part D drugs. NHIA agrees that CMS's threshold of \$2,000 in Part D OOP costs in the first nine months of the year will be an appropriate measure for identifying Medicare Part D enrollees who are "likely to benefit" from the MPPP in the subsequent year.

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

When a Part D sponsor determines that it is likely a Part D enrollee may benefit from participating in the MPPP, it is required to notify the pharmacy and ensure that the pharmacy inform the Part D enrollee of such determination by providing the "Medicare Prescription Payment Plan Likely to Benefit Notice." CMS notes that this requirement does not obligate the pharmacy to provide additional counseling or consultation to the Part D enrollee about the MPPP. In addition, pharmacies are encouraged, but not required, to provide educational materials regarding the MPPP to identified enrollees when they are provided with the "Likely to Benefit" notice.

In order to assist pharmacies in voluntarily providing additional educational materials regarding the MPPP – and to ensure that those materials are consistent and accurate – NHIA suggests that CMS create an on-demand video for enrollees about the MPPP and how to enroll, which pharmacies could share with enrollees identified as likely to benefit from the program.

#### Section 30.2.3 Communication with Contracted Providers and Pharmacies

CMS notes that pharmacists play a key role in conversations with patients about cost-of-care related to their prescription drug costs. CMS states that all pharmacies would benefit from resources about the MPPP and an in-depth understanding of how the program works. NHIA agrees with CMS's observations and appreciates the agency's acknowledgement that pharmacists play a key role in informing patients about their cost of care.

#### 40.3 National Outreach and Education Efforts

CMS states that it will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates have the support and materials necessary to effectively





communicate about the MPPP and its nuances. NHIA appreciates and supports the national outreach and education efforts.

### 50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies

CMS notes that for pharmacy settings with direct contact with Part D enrollees, Part D sponsors must ensure that a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is given to enrollees who are identified as likely to benefit when a prescription is picked up. Some pharmacy settings, however, do not have direct (face-to-face) contact with Part D enrollees. CMS recognizes that pharmacies may choose additional strategies to communicate with enrollees identified as likely to benefit, such as via a patient portal or secure email. NHIA appreciates CMS’s flexibility in this area and requests CMS allow pharmacies to utilize an agent or virtual process to accomplish notification in instances where the patient is remote to the pharmacy.

#### 50.3.3 Other Pharmacy Types

CMS states that pharmacy settings that lack in-person encounters must be required to notify Part D enrollees by phone or other preferred contact method regarding their identification as likely to benefit from the MPPP. CMS emphasizes that this notification requirement should not be a reason to delay dispensing the medication to the enrollee, and that existing touchpoints should be used to discuss the content of the MPPP Likely to Benefit Notice prior to processing payment for the relevant prescription. CMS suggests that Part D sponsors work with pharmacies to establish reasonable procedures regarding timing and the number of attempts to notify Part D enrollees identified as likely to benefit from the MPPP.

NHIA agrees that pharmacies that do not have in-person encounters with enrollees identified as likely to benefit from the MPPP should be allowed to notify them by phone or other means and that the dispensing of medication should not be delayed. NHIA is concerned with allowing Part D plans to establish what are considered reasonable procedures regarding the timing and number of attempts to notify Part D enrollees and asks CMS to consider setting maximum thresholds or guidelines in this area.

### 5.4 Readjudication of Prescription Drug Claims for New Prescription Participants

CMS states that after an enrollee opts into the MPPP program, all claims for covered Part D drugs from prior dates of service not yet picked up and paid for must be readjudicated. Part D sponsors also must have systems in place to reimburse enrollees for cost-sharing for an urgent prescription when an enrollee is allowed to retroactively opt into the MPPP. NHIA does not believe that pharmacies should be required to reprocess claims for retroactive election of MPPP.



This would be administratively burdensome for pharmacies, which have no visibility into or control of this process.

NHIA appreciates the opportunity to provide comments on the Draft Part Two Guidance and welcomes the opportunity to work with CMS to improve the Medicare Part D benefit for all beneficiaries. For questions or additional information, please contact me at [connie.sullivan@nhia.org](mailto:connie.sullivan@nhia.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Sullivan", is written above the typed name.

Connie Sullivan, B.S. Pharm  
President and Chief Executive Officer





March 15, 2024

Meena Seshamani, MD, PhD  
Deputy Administrator and Director  
Center for Medicare  
Centers for Medicare and Medicaid Services

Comments submitted electronically via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

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

Dear Dr. Seshamani,

Thank you for the opportunity to submit comments regarding the Medicare Prescription Payment Plan Draft Part 2 Guidance. Medicare Part D is a critical program that provides Americans access to healthcare. It is essential for individuals living with chronic conditions who rely on its coverage for access to needed drugs/therapies. With the implementation of the Inflation Reduction Act (IRA), the National Multiple Sclerosis Society (Society) is pleased that Part D is poised to provide even greater benefits. The Society looks forward to partnering with CMS to ensure that Medicare Part D beneficiaries living with multiple sclerosis (MS) can access the medications they need to live their best lives and that the process for accessing necessary medications is simple and transparent. Approximately 25-30% of people living with MS in the United States are on Medicare, and many rely on Part D to access necessary drugs that allow them to live their best lives. The changes to the Part D program due to the IRA constitute the most significant changes since the creation of the Part D program, and we appreciate the opportunities that CMS has stated it will provide stakeholders throughout the implementation process. We urge CMS to ensure stakeholders have ample opportunity to provide input throughout the implementation and, if necessary, adjust to ensure maximum beneficiary impact.

MS is an unpredictable disease of the central nervous system. Currently, there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated 1 million people live with MS in the United States. Early diagnosis and treatment are critical to minimize disability. Significant progress is being made to achieve a world free of MS.

The Society, founded in 1946, is the global leader of a growing movement dedicated to creating a world free of MS. The Society provides global leadership, funds research for a cure, drives change through advocacy, and provides programs and services to help people affected by MS live their best lives. Additionally, the Society sees itself as a partner to the government in many critical areas. While we

advocate for the government's involvement in accelerating the discovery, development, and delivery of new treatments, we do so as an organization whose research investment exceeds \$1.2 billion.

## **Background**

The Society has supported a program to ease the financial burden of chronic diseases by allowing Medicare beneficiaries to spread out-of-pocket (OOP) prescription drug costs over predictable monthly payments. Given the Medicare Prescription Payment Plan's (MPPP) goal of alleviating beneficiaries' financial burdens, we want to ensure that beneficiaries are fully informed of this new program. Therefore, while implementing the MPPP, it will be critical that CMS work with patients, patient advocacy groups, pharmacies, and other stakeholders to provide individuals with access to clear, understandable, and actionable information to support the decision-making process. This is particularly true for individuals living with chronic diseases and disabilities, who are most likely to benefit from this new program.

The Society recommends that all communication regarding the MPPP be clear, actionable, and accessible to Part D beneficiaries, including those with sensory, cognitive, or other disabilities and those with limited English proficiency. We also encourage CMS to educate providers who will need information to help guide their patients on how best to access needed prescription drugs. Finally, Part D plans and pharmacies need consistent, standardized, plain language information to provide to beneficiaries to prevent confusion. Finally, CMS must engage with individuals with lived experience and patient advocacy groups to review communication materials for usability and understandability. Since this is a new program, these education and outreach efforts will require continuous monitoring and opportunities for beneficiaries to provide feedback to ensure a successful launch that benefits enrollees as intended.

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

The Society appreciates CMS's guidance detailing Part D sponsors' responsibilities in informing Medicare beneficiaries about the MPPP before and during the plan year; however, we are concerned that CMS plans primarily target those likely to benefit from the program. While we understand that CMS chose this approach to minimize beneficiary confusion, this focus might undermine the necessity of ensuring all beneficiaries receive comprehensive information about the program. The Society underscores the importance of balancing focused outreach with widespread educational efforts to fully support beneficiary engagement and understanding across the spectrum of Medicare enrollees.

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

As stated above, while the Society appreciates CMS's outlined approach to outreach and education in the draft guidance, additional clarity regarding CMS's strategies for widespread information dissemination to ensure that all Medicare beneficiaries, not just those immediately identified as likely to benefit, is needed. To ensure a patient-centered approach to the implementation of the MPPP, the Society recommends that CMS collaborate with patient advocacy groups, individuals with lived experience, and health literacy experts to develop communications materials. This will help CMS to develop materials that resonate with the diverse needs of the Medicare population. Additionally, the Society recommends that CMS provide guidelines to ensure online content on Part D plan websites is user-friendly and accessible to all beneficiaries, including those living with visual impairments, cognitive difficulties, or limited English proficiency. Furthermore, the Society emphasizes the importance of

deploying an accessible and reliable monthly cost calculator as described in the draft Part One Guidance. This tool will be essential for providing beneficiaries, particularly those on fixed incomes, with a clear understanding of their potential monthly expenses. CMS should prioritize the development of this calculator to ensure that beneficiaries have the necessary information to make informed decisions regarding their participation in the MPPP.

The Society supports the requirement to include MPPP details and an election request form along with membership ID card mailings to new enrollees, ensuring immediate and clear communication upon plan entry. We recommend that CMS and Part D sponsors ensure these materials are concise, easily understood, and tailored to meet the unique needs of all enrollees, including those with visual and/or cognitive impairments and limited English proficiency.

We urge CMS to utilize focus groups/pilot testing and incorporate beneficiary feedback into revised Evidence of Coverage documents to ensure that MPPP information clarifies rather than complicates coverage understanding. For the Annual Notice of Change, we recommend utilizing accessible language accommodating varied health literacy levels. Additionally, we recommend that CMS provide Part D sponsors with best practices for clearly explaining the MPPP. Similarly, updating the Explanation of Benefits to include visual aids (i.e., infographics) and providing examples will clarify MPPP's impact on cost-sharing and coverage.

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

While the Society supports the targeted outreach and education requirements outlined in the draft guidance, we recommend that CMS utilize more inclusive and adaptive outreach efforts. These efforts can be enhanced by integrating patient feedback and employing various communication channels to ensure that all eligible Part D enrollees are properly equipped to make decisions regarding their MPPP participation. It is essential to ensure that those most likely to benefit from the program receive the necessary information to act.

The Society appreciates CMS's standardized approach to the "Likely to Benefit Notice," as this will ensure consistent information is disseminated across Part D sponsors. However, to improve understanding of the MPPP's impact on an individual's prescription drug costs and healthcare decisions, the Society suggests augmenting this notice with additional educational resources, such as FAQs or interactive online tools. Additionally, continuous monitoring and feedback from Part D enrollees and stakeholders can provide valuable insights for refining these materials and strategies over time, ensuring they meet the evolving needs of Medicare beneficiaries.

The Society also appreciates the inclusion of a standardized framework to determine which enrollees are "likely to benefit" from the MPPP before and during the plan year by utilizing Prescription Drug Event (PDE) records to predict enrollees' OOP expenses. The Society supports the minimum requirement for Part D sponsors to undertake targeted outreach to enrollees who are anticipated to incur high OOP costs for new prescriptions. This will inform enrollees about the program before they face financial hardship at the pharmacy point-of-sale (POS). Additionally, while CMS mandates that any additional identification criteria applied by Part D sponsors must be uniformly applied to all enrollees, the Society encourages CMS to provide more explicit guidance on what these supplemental strategies might entail and how they can be implemented to ensure fairness and transparency.

The Society expresses strong concerns regarding CMS's revised criteria for notifying pharmacies about Part D enrollees' eligibility for the MPPP based solely on single prescription thresholds. This change from the draft Part One guidance, which considered cumulative OOP costs, significantly narrows the pool of beneficiaries alerted about potential MPPP benefits. To ensure comprehensive beneficiary support, the Society requests that CMS direct Part D sponsors to conduct targeted outreach for beneficiaries whose total OOP costs within a defined recent period reach the established eligibility threshold. This broader approach would help identify beneficiaries taking multiple lower-cost medications that cumulatively impose significant financial burdens, ensuring they are not inadvertently excluded from benefiting from the MPPP. Such targeted outreach should complement existing mechanisms, bridging the gap to include a broader range of beneficiaries potentially eligible for the program and fostering more inclusive and informed decision-making among the Medicare population. While the Society appreciates the requirement for pharmacies to inform the Part D enrollees about the MPPP upon receiving a notification, we call for additional support and resources for pharmacies to ensure these conversations are as informative and helpful as possible. Given the complexity of the MPPP and its potential impact on enrollees' healthcare decisions, pharmacies must be equipped with standardized, comprehensive, easy-to-understand information that can be readily shared with enrollees. This support could include detailed FAQs, pharmacy training sessions, and communication strategies. The reach and effectiveness of CMS's and Part D sponsors' outreach efforts can be enhanced by integrating enrollee feedback and employing various communication channels, ensuring that all eligible Part D enrollees are well-informed to make decisions about their MPPP participation. Establishing a foundational knowledge level for all Part D beneficiaries is essential for ensuring those most likely to benefit from the program receive the necessary information to act.

The Society recognizes the essential role of pharmacies and healthcare providers in facilitating informed discussions regarding prescription drug costs with Medicare beneficiaries, and we support CMS's directive for Part D sponsors to alert pharmacies when a beneficiary's OOP costs for covered Part D drugs reach a threshold that suggests they might benefit from the MPPP. This provision ensures timely and crucial information is relayed to beneficiaries at a critical decision-making juncture, potentially alleviating the financial burden of prescription medications. Furthermore, encouraging Part D sponsors to engage in targeted communication with healthcare providers, particularly those in specialties more likely to prescribe high-cost medications, is a proactive approach to ensure that the prescribers are aware of the MPPP and can guide their patients accordingly. However, the Society recommends that CMS consider additional measures to enhance the effectiveness of these communications. Specifically, CMS could develop standardized training or informational sessions for pharmacy staff and healthcare providers to ensure they comprehensively understand the MPPP. This training could include case studies, FAQs, and scenarios to better prepare them for patient inquiries and facilitate more meaningful discussions about the program. Additionally, the Society suggests that CMS explore the development of digital tools or platforms that could assist pharmacies and providers in identifying eligible beneficiaries more efficiently and provide personalized information about the benefits of enrolling in the MPPP. These tools could integrate with existing systems (e.g., real-time benefit tools) to flag eligible patients automatically and provide tailored information based on an individual's medication regimen and financial situation.

### *30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors*

The Society acknowledges CMS's comprehensive approach to offering election options and the emphasis on providing additional information to enrollees to ensure they fully understand the financial implications of participating in the MPPP. The Society strongly supports the provision that allows Part D

enrollees to opt into the MPPP at any point during the plan year or during enrollment periods, which offers flexibility and ensures that beneficiaries can benefit from the program when they need it most. However, we believe that further clarification and guidance on the process for electing to participate in the MPPP would be beneficial. Specifically, clear, straightforward instructions on how to opt into the program through various methods (e.g., paper, telephone, and website) should be provided to ensure the process is accessible to all, especially those with limited technological literacy or access. Additionally, the Society recommends that Part D sponsors not only provide estimates of monthly payments under the MPPP but also offer additional tools and resources (e.g., decision aids, an interactive online platform, and a monthly cost calculator) to help beneficiaries understand how the program affects their specific situation, particularly for those with complex medication needs or those considering the MPPP alongside other assistance programs like Low-Income Subsidy (LIS). This personalized approach can help prevent confusion and ensure beneficiaries make informed decisions based on their unique circumstances. Finally, the Society underscores the importance of clear communication regarding the LIS program as an alternative or additional avenue for managing prescription drug costs. Given that LIS enrollment might offer more benefits for those who qualify, Part D sponsors must inform enrollees about their options. The Society urges CMS to develop and provide resources, model language, training, and support to Part D sponsors to ensure these communications are as clear and effective as possible, thus enabling beneficiaries to navigate their options with confidence.

The Society appreciates CMS's initiative in developing model documents to assist Part D plan sponsors and Medicare Advantage (MA) organizations in satisfying the education and outreach responsibilities for Part D sponsors and MA organizations for the MPPP. To ensure that the MPPP is accessible, understandable, and beneficial to Part D enrollees, we provide the following recommendations to CMS:

1. **Enhance form accessibility and inclusivity:** Ensure all forms, across all election methods, are designed with accessibility in mind, ensuring usability by individuals with various disabilities, including visual, auditory, and cognitive impairments. Additionally, all forms should use clear, plain language accessible to enrollees with varying levels of health literacy and be made available in multiple languages to accommodate the diverse Medicare population, including those with limited English proficiency.
2. **Establish a robust support system for enrollees:** Provide comprehensive guidance on the MPPP's impact on prescription drug costs and personalized assistance to help enrollees make informed decisions. This guidance should extend beyond the initial request to participate, encompass ongoing education about the program's benefits, include information on potential changes, and assist enrollees in maximizing its value.
3. **Ensure prompt and proactive sponsor communication:** Part D sponsors should be required to collect any missing information and confirm enrollees' understanding of the program's terms and conditions, particularly when enrollees submit election requests in non-standard formats.
4. **Monitor and evaluate the effectiveness of the election process:** Identify and address any barriers enrollees might face in opting into the MPPP to ensure a smooth enrollment experience.
5. **Test model documents with diverse user groups:** Ensure documents are understandable and meet the needs of all potential enrollees and are made widely available and easily accessible in diverse settings, including but not limited to community centers, health care facilities, and to reach those without internet access, through direct mail options. Digital election requests should be user-friendly and compliant with the latest web accessibility standards.
6. **Provide detailed instructions and support for paper forms:** Part D sponsors should be required to offer detailed instructions and support services, such as a dedicated helpline, for completing

paper forms. This assistance should be available in multiple languages and accessible formats to accommodate all enrollees, including those living with visual, auditory, or cognitive impairments.

7. **Incorporate safeguards against inadvertent disenrollment:** Include provisions for a review or appeal process before termination and provide information on support services for financial difficulties. These notices must be accessible in various formats and languages to accommodate all beneficiaries. Additionally, the Society advocates for the compassionate consideration of individual circumstances in both notices and urges CMS to incorporate provisions for hardship exceptions or extended grace periods in certain situations. This approach should balance financial policy needs with protecting vulnerable beneficiaries, ensuring the process is supportive, informative, and considers beneficiaries' financial vulnerabilities.

Given the complexity of healthcare information and the diverse needs of Medicare beneficiaries, the Society recommends that CMS issue guidance to Part D sponsors on employing various communication methods beyond the required telephonic and written notices. This could include informational videos, interactive online Q&A sessions, and community outreach events to educate beneficiaries about the MPPP and ensure they fully understand the implications of their election decisions. While the Society commends the steps to notify beneficiaries of their election into the MPPP outlined in the draft guidance, we encourage CMS and Part D sponsors to continue seeking ways to enhance beneficiary communications. By making information more accessible, understandable, and actionable, we can ensure that all beneficiaries are well-equipped to make informed decisions about their participation in the MPPP. Likewise, CMS and Part D sponsors can ensure that the process for voluntary termination from the MPPP is transparent, patient-centered, and aligned with the best interests of Medicare beneficiaries.

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

The "Language Access and Accessibility Requirements" outlined in the draft Part Two guidance are critically important for ensuring that all Part D enrollees, particularly those with limited English proficiency and diverse cultural and ethnic backgrounds, can access and understand the program. The Society commends CMS for its commitment to providing materials in a culturally competent manner and for requiring Part D sponsors to adhere to these crucial standards.

The Society appreciates the emphasis on making all vital information related to enrollment, benefits, health, and rights available in multiple languages and accessible formats. This approach is fundamental to removing barriers to information and ensuring that every beneficiary can make informed decisions about their healthcare. The requirement for Part D sponsors to provide translated materials in the primary language of at least five percent of individuals in a Plan Benefit Package (PBP) service area is a step in the right direction towards addressing health disparities and promoting equity in healthcare access. Additionally, the Society supports the inclusion of multi-language inserts (MLI) in CMS-required materials, informing beneficiaries about the availability of free interpreter services. This is an essential tool for beneficiaries who may not be proficient in English or prefer to receive healthcare information in their primary language. These MLIs must be prominently placed in all relevant materials to ensure they are easily noticed by those who need them.

The Society also recognizes the importance of compliance with anti-discrimination provisions, such as Section 508 of the Rehabilitation Act, which requires Part D sponsors' websites and materials to be accessible to individuals living with disabilities. Ensuring that websites and materials are compatible with

screen reader technology and other auxiliary aids is vital for providing equal access to information for all beneficiaries, including those with visual impairments or other disabilities.

However, the Society believes that, beyond compliance, there should be a proactive effort to engage with historically underserved or marginalized communities. This could include partnerships with community organizations, healthcare providers, and advocacy groups to disseminate information about the MPPP in a manner that is culturally and linguistically tailored to the needs of diverse communities. Furthermore, the Society suggests that CMS and Part D sponsors consider using visual aids, infographics, and video materials that can transcend language barriers and provide an intuitive understanding of the MPPP. Such materials can effectively convey complex information in a more digestible format, potentially increasing program comprehension and engagement among beneficiaries with varying literacy levels. We encourage CMS and Part D sponsors to meet with a diverse group of beneficiaries when developing these materials to ensure cultural appropriateness and sensitivity.

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

The Society commends CMS for recognizing the critical need to provide comprehensive educational materials about the MPPP to Part D enrollees. Ensuring broad education on the program's availability is essential for empowering beneficiaries to make informed healthcare decisions. Overall, we feel CMS needs to be clearer on how it will develop new standardized educational resources and update existing ones to include information about the MPPP. Additional clarity will greatly assist the patient advocacy community understand what CMS will do – and what our community must do – to raise awareness among Part D enrollees.

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

The Society supports the development of educational resources for Part D enrollees, available on the Medicare.gov website and via other communication channels. CMS's inclusion of various stakeholders, such as Part D sponsors, pharmacies, providers, and beneficiary advocates, in using and disseminating this product is a commendable approach that will ensure a wide reach of the program's information.

The requirement for Part D sponsors to use this educational product on their websites, in membership ID card mailings, and alongside the "Medicare Prescription Payment Plan Likely to Benefit Notice" is a strategic approach to ensure consistent messaging across different communication mediums. This requirement will help streamline information dissemination and ensure enrollees have multiple touchpoints to learn about the MPPP. Encouraging Part D sponsors to provide additional information to pharmacies and communicate with contracted providers and other interested parties using the educational product will foster a collaborative environment. It ensures that all parties involved in beneficiary care are well-informed about the MPPP, facilitating better support for enrollees considering the program.

However, the Society suggests that CMS consider involving patient advocacy groups and beneficiaries in the development of these educational materials to ensure they are patient-centered and address enrollees' real-world concerns and questions. Additionally, the Society recommends that CMS develop interactive and user-friendly tools (e.g., cost calculators and decision aids) to accompany the educational product, providing enrollees with practical resources to assess their potential benefits from the MPPP.

##### *40.2 Modifications to Existing Part D Resources*

The Society appreciates CMS's commitment to modifying existing Medicare Part D documents, web content, and tools to include information about the MPPP. This approach ensures that beneficiaries can access updated and comprehensive resources to understand the program's potential benefits relative to their needs.

Including information about the MPPP in widely used resources such as the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder will significantly enhance program visibility and understanding among enrollees. The Society encourages CMS to offer greater clarity on how the Agency will do this and how it will ensure that these modifications are made in an easily understandable manner, catering to the diverse literacy levels and language needs of the Medicare population.

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

The Society supports CMS working with various stakeholders, including State Health Insurance Assistance Program (SHIP) counselors, to bolster national outreach and education efforts for the MPPP. This collaborative approach is crucial for ensuring that accurate and comprehensive information about the program reaches a broad audience, particularly those who may benefit the most from the program. The Society recommends that CMS include patient voices in developing educational materials, creating interactive tools, and leveraging existing networks and partnerships within the healthcare community to maximize the reach of these outreach efforts. Additionally, the Society suggests that CMS consider implementing targeted outreach initiatives to reach vulnerable and marginalized populations who may face barriers to accessing program information.

### **50. Pharmacy Processes**

Given the complexity and breadth of the "Pharmacy Processes" section in the draft Part Two guidance, the Society appreciates the emphasis on the pivotal role pharmacies play in operationalizing the MPPP and agrees with the requirement for Part D sponsors to notify pharmacies when a Part D enrollee's OOP costs indicate potential eligibility for the MPPP. The Society supports the mandate for pharmacies to inform Part D enrollees about the MPPP upon notification from Part D sponsors, highlighting the importance of direct communication in enhancing enrollee awareness and participation in the program. However, the Society continues to urge CMS to work with pharmacies and pharmacists to implement point-of-sale enrollment in the MPPP as soon as possible.

#### *50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount*

The Society recognizes the complexity introduced by supplemental coverage and appreciates CMS's acknowledgment of how such coverage can impact the final patient OOP amount, potentially affecting the enrollee's perceived benefit from the MPPP. We recommend that CMS provide clear and detailed guidance for Part D sponsors and pharmacies on handling cases with supplemental coverage, ensuring enrollees receive accurate information about their potential benefits from the MPPP.

#### *50.2 Pharmacy POS Notifications Late in the Plan Year*

The Society is concerned about scenarios where late-year notifications could require MPPP enrollees to pay the total amount in their first month's bill. We suggest exploring mechanisms to adjust the billing to prevent financial hardship for enrollees opting into the program late in the plan year.



### *50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies*

The Society encourages CMS to ensure that offering the "Medicare Prescription Payment Plan Likely to Benefit Notice" to enrollees at the POS in pharmacies with direct enrollee contact is implemented smoothly across all pharmacy settings to maximize enrollee engagement and understanding. The Society appreciates CMS's efforts to provide guidance for pharmacy settings without direct enrollee contact (i.e., mail-order pharmacies). We encourage the development of innovative strategies to ensure enrollees receive timely and effective notifications. We encourage CMS to collaborate with Part D sponsors to ensure that these methods effectively reach enrollees and provide them with the necessary information to make informed decisions about the MPPP. Likewise, the Society acknowledges the unique challenges presented by long-term care pharmacies. We support CMS's approach to allow flexibility in providing the "Likely to Benefit Notice" within these settings. We encourage continued dialogue with long-term care stakeholders to ensure enrollee notifications are handled appropriately and effectively.

The Society recognizes the special considerations necessary for Indian Health Services (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies. We support the exemption from the requirement to notify the pharmacy of an enrollee's potential eligibility for the MPPP. We suggest that CMS and Part D sponsors engage with I/T/U pharmacies to ensure that IHS-eligible Part D enrollees are aware of the MPPP and understand how their coverage through I/T/U pharmacies interacts with the program.

### *50.4 Readjudication of Prescription Drug Claims for New Program Participants*

The Society supports the process for the readjudication of prescription drug claims to ensure that new program participants pay \$0 at the POS for covered Part D drugs. We recommend clear communication and guidelines for pharmacies to ensure this process is conducted smoothly without burdening the enrollee.

### *50.5 Processing of Covered Part D Claims for Program Participants in Special Settings*

As mentioned above, the Society acknowledges the complexity of processing Part D claims for beneficiaries in special settings, such as long-term care facilities and I/T/U pharmacies. The unique billing arrangements and potential financial implications for participants in these settings necessitate careful consideration and tailored approaches to safeguard beneficiaries' interests.

Thank you again for the opportunity to comment on the MPPP Draft Part 2 Guidance. We look forward to working with you as you implement the changes to the Medicare Part D program outlined in the IRA and acting as a partner as you work toward educating Americans about their Part D benefit changes. If you have any questions, please contact Nicole Boschi, Director of Regulatory Affairs, at [nicole.boschi@nmss.org](mailto:nicole.boschi@nmss.org).

Sincerely,

A handwritten signature in cursive script that reads "Bari Talente".

Bari Talente, Esq.  
Executive Vice President, Advocacy and Healthcare Access  
National Multiple Sclerosis Society



March 15, 2024

Dr. Meena Seshamani, M.D., Ph.D  
Director, Center for Medicare  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

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

Dear Director Seshamani,

On behalf of the more than 30 million Americans living with one of the over 10,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks the Center for Medicare for the opportunity to provide comments on the “Medicare Prescription Payment Plan: Draft Part Two Guidance,” hereafter referred to as “MPPP.” Our comments are intended to serve as a companion piece to our response to the MPPP Part One Guidance, submitted September 2023.<sup>1</sup>

NORD is a unique federation of non-profits and health organizations dedicated to improving the health and well-being of people with rare diseases by driving advances in care, research, and policy. NORD was founded 40 years ago, after the passage of the Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing that landmark law. Since that time, NORD has been advancing rare disease research and funding to support the development of effective treatments and cures; raising awareness and addressing key knowledge gaps; and advocating for policies that support the availability of and access to safe and effective therapies.

The MPPP presents a tremendous opportunity to reduce out-of-pocket costs for rare disease patients who frequently are subject to significant financial burdens in order to obtain their medications. A 2019 NORD survey found that 76% of respondents had experienced financial challenges due to their own or their family member’s rare diagnosis.<sup>2</sup> According to data from the NIH’s National Center for Advancing Translational Sciences (NCATS), medical costs are 3-5 times greater for people with a rare disease than

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<sup>1</sup> *Part 2 of the Medicare Prescription Payment Plan Guidance*. MAPRx. (2024, March 15). <https://rarediseases.org/wp-content/uploads/2023/09/Medicare-Prescription-Payment-Plan-Sign-On-Letter-9.20.23.pdf>

<sup>2</sup> *Barriers to Rare Disease Diagnosis, Care and Treatment in the US*. National Organization for Rare Disorders. (2020, November 19). [https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report\\_FNL-2.pdf](https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report_FNL-2.pdf)

those who do not have a rare disease.<sup>3</sup> As of 2019, the average annual cost of an orphan therapy was \$32,000 per treated patient.<sup>4</sup>

Despite the direct, positive patient impacts envisioned by the Part D redesign provisions in the Inflation Reduction Act, awareness among the general public remains limited. A July 2023 survey found that only 34% of Medicare aged respondents knew about the forthcoming annual limit on out-of-pocket drug costs for individuals with Medicare.<sup>5</sup> Without increased public awareness of the MPPP, and given the statutory requirement for patients to opt into the program, we are concerned that many patients that would otherwise benefit from participation in the MPPP may not enroll, in particular during the first year of the program. We urge CMS to work with community serving organizations, such as organizations that provide health or other services to (parts of) the Medicare population, as well as health plans, community pharmacists, health care providers, and other key stakeholders, to raise awareness. NORD is pleased to provide more detailed recommendations below and agree with comments and recommendations submitted by the MAPRx coalition on this same guidance.<sup>6</sup>

**Recommendation 1: Ensure educational materials regarding the MPPP are consistent and avoid confusion about availability of or access to the MPPP among different health plans (see Section 30.1)**

NORD strongly believes that the MPPP will benefit rare disease patients, many of whom rely on high-cost medication for treatment, but health plans will be crucial to ensuring patients are aware of and can utilize this benefit. Therefore, NORD supports mandating Part D sponsors include educational materials on MPPP throughout the course of the year and as a part of annual mailings and explanation of benefits. However, to avoid confusion and potential unintended consequences such as inadvertently steering high-cost beneficiaries to some health plans that use certain educational materials about the MPPP, we recommend a multi-pronged approach:

1. CMS should increase current agency-led education and outreach efforts regarding the MPPP, and partner with community serving organizations and other key partners to raise awareness and educate beneficiaries about the MPPP, with particular focus on engaging beneficiaries from historically underserved communities.

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<sup>3</sup> *NIH Study Suggests People with Rare Diseases Face Significantly Higher Health Care Costs*. NCATS. (2021, October 22). <https://ncats.nih.gov/news-events/news/nih-study-suggests-people-with-rare-diseases-face-significantly-higher-health-care-costs#:~:text=According%20to%20the%20Eversana%20health,those%20without%20a%20rare%20disease>

<sup>4</sup> *The Next Generation of Rare Disease Drug Policy: Ensuring Both Innovation and Affordability*. Institute for Clinical and Economic Review. (2022, April 7). [https://icer.org/wp-content/uploads/2022/04/ICER-White-Paper\\_The-Next-Generation-of-Rare-Disease-Drug-Policy\\_040722.pdf](https://icer.org/wp-content/uploads/2022/04/ICER-White-Paper_The-Next-Generation-of-Rare-Disease-Drug-Policy_040722.pdf)

<sup>5</sup> *KFF Health Tracking Poll July 2023: The Public's Views of New Prescription Weight Loss Drugs and Prescription Drug Costs*. KFF. (2023, August 4). <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs/>

<sup>6</sup> *Part 2 of the Medicare Prescription Payment Plan Guidance*. MAPRx. (2024, March 15). <https://rarediseases.org/wp-content/uploads/2023/09/Medicare-Prescription-Payment-Plan-Sign-On-Letter-9.20.23.pdf>

2. CMS should take deliberate steps to ensure plan sponsors use consistent language and emphasize to patients that the program is not specific to any plan. This will help ensure patients choose the plan that works best for them based on unique plan characteristics, rather than out of a mistaken belief that the MPPP is only available through certain plans. Organizations that represent the health plan community, such as AHIP and other trade organizations, can play a key role in helping to standardize the use of materials and to raise awareness more broadly.
3. Data clearly suggest that beneficiaries' health as well as socio-demographic factors are influencing plan choices, including switches between Medicare Advantage (MA) and fee-for-service (FFS) plans. Specifically, patients with increased healthcare needs are overrepresented among beneficiaries electing to switch from MA to FFS plans, a trend that may be further exacerbated by the MPPP \$2,000 out-of-pocket cap.<sup>7</sup> We encourage CMS to increase educational efforts explicitly informing beneficiaries of potential post-deductible co-insurance requirements and Medigap pre-existing condition policies to ensure all beneficiaries can make appropriately informed decisions that can best meet their healthcare needs, both at the time they first become eligible for Medicare and with each subsequent plan choice.
4. Finally, it is vital for CMS to study health plan compliance and outreach effectiveness, in particular in the first year of the program, and to learn from and revise the approaches based on these learnings moving forward.

**Recommendation 2: Consider developing additional tools and approaches to better support patients in their decision whether to participate in the MPPP (see Section 30.1.5)**

We are broadly supportive of CMS' proposed educational efforts, including adding proposed detailed examples of calculations under multiple scenarios. Specifically, we are supportive of CMS' proposal to include numerous examples of when the MPPP would or would not be likely to benefit a patient who utilizes covered part D drugs. However, we remain concerned that generalized examples will be difficult for patients to navigate and may not provide sufficient information for patients to make appropriately informed decisions about their participation in MPPP.

Choosing whether to opt-into the MPPP requires consideration of numerous factors that are frequently patient specific, including the potential for the addition of expensive products later on in the plan year. As such, we recommend developing additional educational tools, such as the creation of a tool that will allow patients to calculate their potential monthly payments with or without opting into the MPPP under different scenarios, which are tailored to be as specific to their unique situation as appropriate. We urge CMS to carefully consider the needs of the patient community and to work with external partners that serve these communities to identify these needs and find ways to improve the education process.

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<sup>7</sup> *Medicare Switching: Patterns of Enrollment Growth In Medicare Advantage, 2006-22*. Health Affairs. (2023, September). <https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00224#:~:text=Exhibit%203%20shows%20the%20characteristics,Medicare%20it%20was%201.2%20percent>.

**Recommendation 3: Limit broad distribution of ‘likely to benefit’ notices to the beginning of the plan year and tailor their distribution later in the plan year to those individuals most likely to benefit (see Section 30.2.2.3)**

We support CMS’s plans to ensure the broad distribution of “likely to benefit” notices, provided by plans at the pharmacy counter, at the beginning of the plan year as described in Section 30.2.2.3. We also share CMS’ concerns that distribution of “likely to benefit” notices late in the plan year could inadvertently result in greater harm than good for many beneficiaries who at this time in the plan year may no longer benefit from the MPPP. For this reason, we recommend a staged approach:

1. **For the first quarter of the plan year:** We recommend limiting broad distribution of the likely to benefit notices to the first quarter of the plan year. Within the likely to benefit notice, we recommend including language cautioning that MPPP participation may provide limited or no benefits when initiated later in the plan year. Moreover, we recommend time-stamping the notice and/or otherwise signaling to beneficiaries that the benefit of participation is time-limited and likely to decrease as time elapses. We further recommend reassessing participation rates in nearly real-time and engaging with community facing partners before, during, and after the first quarter of the plan year to test the language in the notice to beneficiaries and to better understand and refine the need for additional promotion efforts.
2. **Following the first quarter of the plan year,** individuals most likely to benefit from new MPPP participation are likely those with high and unexpected medical costs, such as newly diagnosed rare disease patients or oncology patients who had been in remission but whose cancer now recurred. Identification of populations most likely to benefit later on in the plan year is an area where further data collection is necessary. We encourage CMS to refine the population identification process following learnings from the first year. To most effectively educate those individuals for whom the initial targeted outreach was not as relevant given their specific circumstances, we recommend partnering with patient and provider groups serving these patients to selectively distribute likely to benefit notices and increase tailored outreach and education strategies; again, we recommend assessing the usefulness of these strategies and to identify the strategies that may be most effective in increasing expedient enrollment for future plan years.
3. **In general,** we propose a cutoff for the broad distribution of likely to benefit notifications after the first quarter of the year; while education for future years remains important, the utility of opting into the program late in the year dwindles for most beneficiaries. Likely to benefit notifications could change to forward looking documents that may help beneficiaries opt into the program at the start of successive the plan year, rather than encouraging the beneficiary to consider opting into the program for the duration of the existing plan year.

Additionally, we continue to propose amending the likely to benefit threshold trigger from one drug to the cumulative out-of-pocket costs that a beneficiary may be responsible for across all drugs they take. More

than half of Medicare aged Americans take four or more prescription drugs.<sup>8</sup> Limiting the likely to benefit notifications to situations where a single drug triggers the out-of-pocket cap leaves out a significant number of beneficiaries who would otherwise benefit from the program.

**Recommendation 4: Build upon first year learnings through data driven growth strategies (see Section 30.2.2.1)**

We applaud CMS' proposal to mandate that targeting strategies found to be effective by a plan sponsor will subsequently be applied evenly across the covered population. We recognize that equitable access and marketing across populations is a concern and believe that this proposed solution will be an important step to address this issue. To build on these successes and ensure that maximum benefit can be granted to enrollees, we encourage CMS and plan sponsors to partner to learn from the broader landscape beyond outreach and engagement initiated by plan sponsors. To achieve maximum impacts in future years, we need appropriate data; as such, we recommend CMS monitor trends in a variety of areas, including state and national lines, and plan sponsors. Following the collection of successes and failures from the first year of the program, CMS could use the collected information to require additional successful strategies in future iterations of guidance.

**Recommendation 5: Purposefully partner with healthcare providers, community-serving organizations, community pharmacists and other trusted voices to improve equitable access to the MPPP (see Section 30.2.3)**

We are supportive of CMS' proposal to encourage distribution of educational materials to in-network providers. Health care providers are trusted care partners and play a crucial role in educating patients about their conditions, the importance of medication adherence, and potential associated costs. Moreover, health care providers already often play a key role in helping patients navigate health insurance challenges from prior authorization requests to other utilization management tools. Data consistently shows that patients who have received greater levels of education from their providers have reduced hospitalizations, lower emergency room utilization, and overall health care costs.<sup>9</sup>

Lack of education can lead to negative consequences resulting from worse health outcomes and increased utilization that can be more expensive for the patient, the Part D sponsor, and the health system writ large. A 2022 survey of Medicare-aged respondents found that over 20% had not filled a prescription due to cost, with nearly 90% indicating their interest in their physician using a real time prescription benefit tool to discuss access and cost requirements.<sup>10</sup> Medication non-adherence due to cost is frequently associated

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<sup>8</sup> *Data Note: Prescription Drugs and Older Adults*. KFF. (2019, August 9). <https://www.kff.org/affordable-care-act/issue-brief/data-note-prescription-drugs-and-older-adults/>

<sup>9</sup> *Better Patient Education Can Lead to Lower Medical Costs*. Relias Media. (2020, December 1). <https://www.reliasmedia.com/articles/147129-better-patient-education-can-lead-to-lower-medical-costs>

<sup>10</sup> *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*. JAMA. (2023, May 18). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012>

with worse general health status, functional limits and higher counts of total conditions.<sup>11</sup> Health care providers therefore have a vested interest in educating their patients about the MPPP.

In addition to instructing health plans to work with health care providers to distribute information about the MPPP, we encourage CMS to directly engage health care providers more broadly to distribute educational materials on the MPPP program to covered out-of-network specialists that a patient may need to see. Rare disease patients frequently must endure a diagnostic odyssey before finally receiving a correct diagnosis. The typical rare disease patient takes 5-7 years before receiving an accurate diagnosis for their condition, including an average of six physicians prior to receiving a diagnosis from the expert.<sup>12</sup> Often, there are only one or two centers across the country with the requisite knowledge to treat the patient's rare disease, which may or may not be in network with the patient's plan. Further, specialists are more likely to prescribe high-cost, specialty medications. Indeed, despite accounting for only 2% of total prescribing volume in 2021, specialty drugs accounted for over 50% of total spending on prescription drugs.<sup>13</sup>

It is crucial that all points of contact that a patient is engaged with in the health system be informed about the benefits of participation in MPPP. A patient's health care coverage can change for a variety of reasons during the plan year and not everyone in the family may have the same health coverage. Distributing information about the MPPP through health care providers more broadly will help ensure the broadest distribution to the eligible beneficiary population. Additional educational materials distributed through community pharmacists and other public facing organizations will increase outreach capacity. Through NORD's Rare Disease Centers of Excellence program, NORD has access to a national network of clinicians at major academic medical centers, and through our patient assistance, education, and community engagement programs, we regularly engage with a large and diverse cross-section of the rare disease community and would be happy to help CMS navigate the outreach to the rare disease patient and provider community.

**Recommendation 6: NORD recommends automatically re-enrolling patients who opted into the MPPP for future plan years (Section 30.3.5)**

Generally, we support CMS' efforts to generate an easy-to-understand notice of voluntary termination, as well as guidelines for ensuring that beneficiaries are not required to pay the entirety of their outstanding balance at once following termination from the program. However, we are concerned that CMS will require beneficiaries to opt into the MPPP prior to the beginning of each plan year, even if the patient remains in the same plan. Academic literature consistently shows that opt-in mechanisms result in lower

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<sup>11</sup> *Cost-Related Medication Nonadherence and its Risk Factors among Medicare Beneficiaries*. Medical Care. (2021, January). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7735208/>

<sup>12</sup> *Rare diseases: why is a rapid referral to an expert center so important?* BMC Health Services Research. (2023). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10463573/>

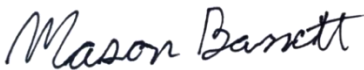
<sup>13</sup> *Trends in Prescription Drug Spending, 2016-2021*. Assistant Secretary for Planning and Evaluation. (2022, September). <https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf>



enrollment rates compared to opt-out mechanisms.<sup>14,15</sup> Absent a submission of voluntary termination during the plan year, we strongly suggest keeping beneficiaries opted-in to the MPPP as a default during the start of a new plan year with a grace period to allow the patient to opt out shortly after the beginning of the new plan year. Around 80% of Part D beneficiaries maintain the same plan year over year.<sup>16</sup> Requiring patients to continue re-enrolling in the MPPP year after year could result in increased mid-year enrollment (with noted fewer benefits), lower overall program enrollment, and additional operational challenges for plan sponsors.

We thank CMS for the opportunity to comment on this draft guidance. We look forward to partnering with the agency to ensure that MPPP implementation is maximally effective for the rare disease community. With any questions or comments, please contact Karin Hoelzer ([khoelzer@rarediseases.org](mailto:khoelzer@rarediseases.org)) or Mason Barrett ([mbarrett@rarediseases.org](mailto:mbarrett@rarediseases.org)).

Thank you for your consideration,



Mason Barrett  
Policy Analyst  
National Organization for Rare Disorders



Karin Hoelzer, DVM, PhD  
Director, Policy and Regulatory Affairs  
National Organization for Rare Disorders

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<sup>14</sup> *A Randomized Controlled Trial of Opt-in Versus Opt-Out Colorectal Cancer Screening Outreach*. American Journal of Gastroenterology. (2018, December).  
[https://journals.lww.com/ajg/Abstract/2018/12000/A\\_Randomized\\_Controlled\\_Trial\\_of\\_Opt\\_in\\_Versus.22.aspx](https://journals.lww.com/ajg/Abstract/2018/12000/A_Randomized_Controlled_Trial_of_Opt_in_Versus.22.aspx)

<sup>15</sup> *Effect of Opt-In vs Opt-Out Framing on Enrollment in a COVID-19 Surveillance Testing Program*. JAMA. (2021).  
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780574>

<sup>16</sup> *Medicare Beneficiaries Rarely Change Their Coverage During Open Enrollment*. KFF. (2022, November 1).  
<https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-rarely-change-their-coverage-during-open-enrollment/>



March 13, 2024

Administrator Chiquita Brooks-LaSure  
Centers for Medicare and Medicaid Services  
7500 Security Blvd  
Baltimore, MD 21244

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

Submitted electronically via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

Dear Administrator Brooks-LaSure,

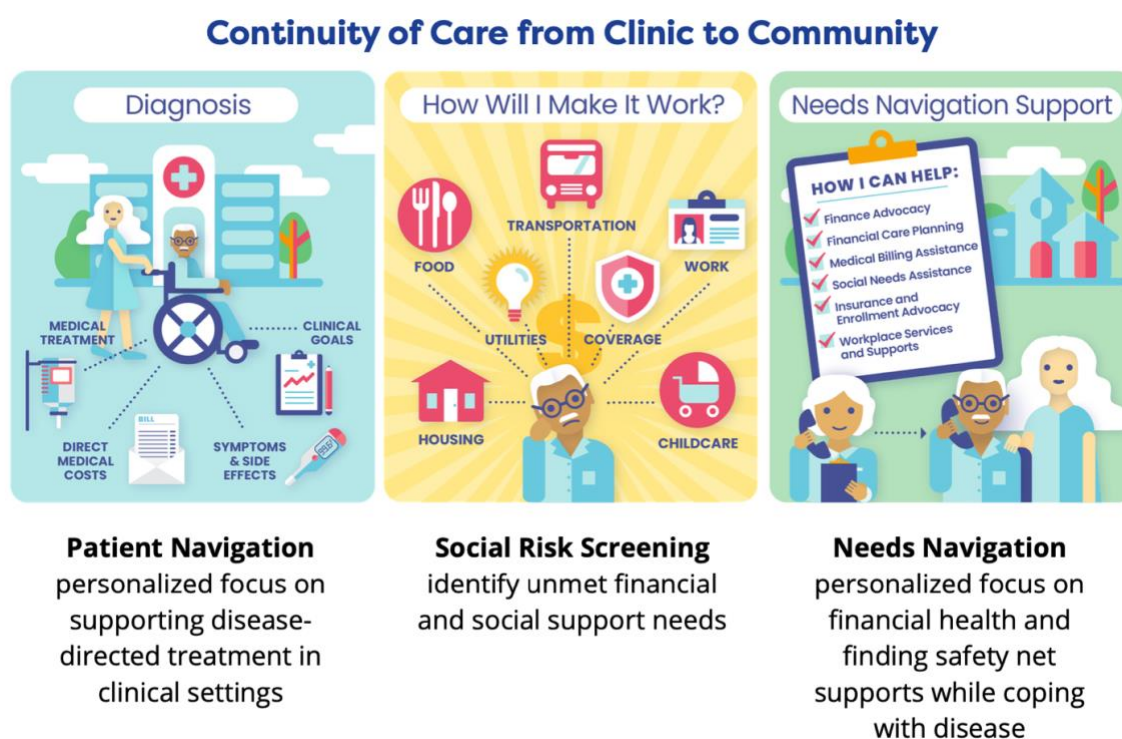
National Patient Advocate Foundation (NPAF) appreciates the opportunity to submit comments on this guidance as the proper implementation of this new Part D program should help the people we serve.

**Background**

NPAF advocates for inclusive policies that elevate and integrate patient and caregiver perspectives as critical parts of healthcare reform. Advancing equitable and affordable healthcare is the core of our person-centered agenda, in which financial and social stability are key components of quality healthcare. Our direct patient services counterpart, Patient Advocate Foundation (PAF), delivers a skilled needs navigation model specifically supporting social and financial well-being for thousands of limited-resourced patients and families. In 2022, PAF served 187,359 patients, a 22% increase versus the previous year, across all 50 states, two U.S. territories and Washington D.C. Our professional case managers provided essential services to 18,838 patients in 2022 to help those diagnosed with chronic and life-threatening conditions navigate equitable access to healthcare and safety net programs. Their direct interventions resulted in \$26,392,098 in debt relief secured on behalf of case management patients, 92% of whom would recommend PAF services to others. The patients we serve come from all walks of life, with one shared experience that unites them - an inability to obtain needed medical care or afford necessities such as food, housing, utilities, and transportation.

Needs Navigation is an innovative model of care to address patients' top of mind financial and social concerns in the context of coping with their illness. This model is provided by people skilled in person-centered communication and resources coordination who serve as a key contact in helping find and access safety net support for patients and families experiencing financial hardship because of their medical conditions. Navigation models have evolved over the past two and a half decades as a critical component of person-centered care to address those patients' needs necessary for making ends meet and maintaining their financial health while coping with disease and [we applauded their inclusion](#) in the final 2024 Physician Fee Schedule and the new CMMI GUIDE Dementia model.

This needs navigation model should now be expanded and integrated across all Medicare programs to provide real-time relief and practical help for limited-resourced patients and families confronted with medical debt, household financial hardships, or other financial and social strains that contribute to poorer health outcomes. The figure below shows how it could be integrated into existing healthcare and how it builds on the social risk screening that CMS is adding to Medicare programs:



It is with this perspective that we make two recommendations on this guidance:

Enrollee-vetted language- Our first recommendation is to make sure that the outlined process and outreach materials are clear to all who may benefit from this new Part D Payment program. The guidance says, “CMS will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates—including State Health Insurance Assistance Program (SHIP) counselors—have sufficient support

and materials needed to effectively communicate the availability and nuances of this program to individuals” (#40.3 on page 22). To that end we offer PAF’s [Patient Insight Institute](#) as a resource to get enrollee input. The Institute brings together policymakers, researchers and underrepresented patient voices so they can be heard, understood and, ideally, influence policy. In this case the direct input of potential enrollees will provide essential information on how to ensure that those who could benefit from this program become aware of it as an option. We would be honored to be an interested party assisting the agency in confirming that materials are effective with the intended audience.

Needs navigation- Our second recommendation is prompted by our concern that these materials be clear about the financial implications for the enrollee of participating in the program. We therefore recommend including needs navigation to help enrollees identify whether they are likely to benefit from this program or not. Choosing a Part D plan was already complicated before this new option and this new program makes it potentially more so. Having a knowledgeable navigator guide potentially enrollees to make the right decision for them would ensure access to needed medications while helping with finances. Such assistance could include helping potential enrollees know that the program is available, free to join without fees or interest charged, and that the program does not reduce the amount of cost-sharing a participant owes for their Part D prescriptions. Needs navigators could also underscore program materials noting the importance of paying the monthly bills, and the implications of not paying those bills. Finally, navigators could reinforce information about the Low-Income Subsidy (LIS) program, including information on recent the LIS expansion of eligibility, and how to apply and enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs). This would be important as LIS enrollment, for those who qualify, is likely to be more advantageous than participation in this new Medicare Prescription Payment Plan. With our long experience with needs navigation, we are available to discuss this further.

## Conclusion

NPAF appreciates CMS’ intent to improve access to more equitable healthcare for all. Providing a needs navigation model directly to patients and caregivers is a hallmark of PAF’s two and a half decades of organizational experience, expertise, and history. We are happy to share lessons learned and welcome the opportunity to meet directly with agency staff to discuss these recommendations to scale needs navigation as part of efforts to achieve equitable and affordable healthcare reform. Please contact me at [Rebecca.kirch@npaf.org](mailto:Rebecca.kirch@npaf.org) if NPAF can provide further details.

Respectfully submitted,



Rebecca A. Kirch  
Executive Vice President, Policy and Programs



March 15, 2024

Dr. Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director of the Center for Medicare  
Center for Medicare and Medicaid Services  
Sent via Electronic Mail

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

Dear Dr. Seshamani,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP submits the following comments in response to *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*, released February 15, 2024.

#### **Section 50. Pharmacy Processes**

*Pharmacies play an important role in operationalizing the Medicare Prescription Payment Plan. Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program. Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Given this statutory requirement, Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees.*

*In this section, CMS provides additional information around pharmacy processes related to the Medicare Prescription Payment Plan. Except as otherwise required in this guidance or under other applicable requirements, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including but not limited to, mail order, home infusion, specialty, and long-term care pharmacies.*

**NCPDP Comment:** NCPDP recommends providing standardized information by utilizing the NCPDP Approved Message Code (548-6F) values applicable to the Medicare Prescription Payment Plan program.



### **Section 50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount**

*In the draft part one guidance for the Medicare Prescription Payment Plan, CMS stated that the likely to benefit notification required at the pharmacy POS will be based on the OOP costs incurred for a single prescription. Part D sponsors will be responsible for notifying the pharmacy when OOP prescription costs equal or exceed the determined threshold that will be finalized in the final part one guidance. This notification will be returned to the pharmacy on the primary Part D claim response from the Part D sponsor or pharmacy benefit manager (PBM). CMS is aware, however, that a small portion of Part D enrollees will have supplemental coverage, such as through a State Pharmaceutical Assistance Program (SPAP), charity, or other health insurance (OHI). In these cases, the final patient pay amount on a covered Part D prescription drug claim may then be reduced below the required notification threshold because of the contributions of a supplemental payer. CMS intends to provide language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” that recommends enrollees with supplemental coverage seek advice related to their specific situation prior to opting into the Medicare Prescription Payment Plan.*

**NCPDP Comment:** From a pharmacy perspective the notification process outlined in the draft guidance is very general. NCPDP recommends CMS specifically call out the use of the NCPDP Approved Message Codes (548-6F) in the final guidance.

There is no mention in the guidance of Medicare Secondary Payers (MSP); the guidance only discusses Medicare Part D as a primary payer. NCPDP requests clarification on MSP.

NCPDP requests the word “primary” be removed from the sentence, “*This notification will be returned to the pharmacy on the primary Part D claim response*”.

If the Medicare Prescription Payment Plan Coordination of Benefits (COB) claim indicates a supplemental payer returned a greater dollar amount in the Patient Pay Amount (505-F5) than what was in the original Medicare Part D primary claim’s Patient Pay Amount (505-F5), should plans apply more than the Medicare Patient Pay amount to the beneficiary’s Medicare Prescription Payment Plan invoice? If the greater amount is applied, then the plan sponsor would have to pay the pharmacy that supplemental payer Patient Pay amount, and this could result in a beneficiary paying more than \$2,000 through their payment plan. If plan sponsors can only apply to the invoice amount up to the original Medicare Part D primary Patient Pay amount, the plan sponsor would need to process the COB claim to reflect the plan will only pay the pharmacy the original Medicare Part D Patient Pay amount and the beneficiary must be responsible to pay the difference in order for the claim to adhere to NCPDP standards for claim balancing.

### **Section 50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies**

*As noted above, in general, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including, but not limited to, mail order, home infusion, specialty, and long-term care pharmacies. In pharmacy settings in which there is direct contact with enrollees (e.g., community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. This includes pharmacies with a drive through or curbside pick-up option. However, CMS is aware that some pharmacy types may not have direct contact with Part D enrollees and/or may lack a practical means for providing a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” directly to the Part D enrollee. CMS is providing additional guidance below related to these settings.*





*In addition, CMS notes that regardless of the setting, if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the Part D sponsor must ensure that the pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee. For example, if a Part D enrollee visits a retail pharmacy to pick up their prescription but then declines to complete the transaction because of the cost, the Part D sponsor must still ensure that the pharmacy provides the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” to that Part D enrollee.*

*Pharmacies may also choose to develop additional strategies to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to enrollees identified as likely to benefit. For example, pharmacies with disease management or medication management programs may choose to include Medicare Prescription Payment Plan information as a component of those processes. In addition to providing a hard copy, pharmacies may also choose to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in other modes of communication with enrollees identified as likely to benefit, such as through a patient portal or secure email.*

**NCPDP Comment:** NCPDP requests clarification on the expectation that the pharmacy is required to always provide a paper hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the beneficiary. There are many reasons a hard copy may not be provided, and alternatives to hard copies should be available. Alternative examples include, but are not limited to, SMS text messaging, email, QR codes, QR codes within text messages, etc.

NCPDP requests CMS change the language within the sentence, “*the Part D sponsor must still ensure that the pharmacy provides the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” to that Part D enrollee*” from “ensure” to “encourage”. Medicare Part D sponsors cannot ensure pharmacies provide the notice to the beneficiary and pharmacies cannot be held liable if the notice is not able to be provided to the beneficiary (e.g., the beneficiary does not come to the pharmacy to pick up the medication).

### **Section 50.3.1 Long-Term Care Pharmacies**

*Long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident). In these cases, the pharmacy delivers medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee). As such, when the POS notification is received by a long-term care pharmacy, the plan sponsor is not required to ensure that the long-term care pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to dispensing the medication. Instead, the plan sponsor can require the long-term care pharmacy to provide the notice to the Part D enrollee at the time of its typical billing process.*

**NCPDP Comment:** CMS states, “the plan sponsor is not required to ensure...” and “the plan sponsor can require...” Does this mean the long-term care (LTC) pharmacy requirement to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” at point of service is at the plan’s discretion?

Is “time of its typical billing process” referring to when the online claim is submitted or when the pharmacy sends out monthly out of pocket billing statements? If CMS is anticipating the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to the enrollee at the time of online claim submission, the same challenges will be incurred because LTC pharmacies do not have personal contact with enrollees. If CMS is anticipating the “Medicare



Prescription Payment Plan Likely to Benefit Notice” will be included in the pharmacies out of pocket billing to the enrollee, this would be cumbersome for pharmacies distributing thousands of statements. In either case, the pharmacy will have already billed the enrollee. How long is the pharmacy expected to wait for the enrollee’s decision on election into the program?

The suggested changes in this section of the guidance do not adequately address the challenges arising from the fact that LTC pharmacies do not have personal contact with enrollees.

### **Section 50.3.2 Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacies**

*I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost-sharing, as defined by their plan’s benefit structure, is not collected at the POS. As such, if a high-cost prescription drug claim for an IHS-eligible Part D enrollee is submitted to a Part D sponsor from an I/T/U pharmacy, the Part D sponsor is not required to return the pharmacy notification indicating the enrollee is likely to benefit from the program.*

**NCPDP Comment:** Plans do not have visibility into which beneficiaries are IHS eligible. Assuming I/T/U pharmacies only provide services to IHS eligible beneficiaries, NCPDP requests CMS clarify this section to indicate that the plans are not required to send the pharmacy notification to any I/T/U pharmacy.

### **Section 50.3.3 Other Pharmacy Types**

*For other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. This requirement should not, however, be interpreted as a requirement to delay dispensing the medication. Pharmacies are encouraged to utilize existing touchpoints with Part D enrollees, such as outreach to review medication instructions or collect a method of payment, to convey the content of the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to processing payment for the prescription that triggered the notice. CMS encourages Part D sponsors to work with pharmacies to establish and maintain reasonable 26 procedures related to the timing and number of attempts for prompt notification of identified Part D enrollees.*

**NCPDP Comment:** NCPDP requests clarification on the following:

- Will the language for the telephone script be provided by CMS or should enrollees be directed to the letter?
- Is proof required from the pharmacy that the patient was given the “Medicare Prescription Payment Plan Likely to Benefit Notice”?
- The process for patients who continue to receive notice of being likely to benefit but do not notify their Part D sponsor they do not wish to enroll into the program.

### **Section 50.4 Readjudication of Prescription Drug Claims for New Program Participants**

*Part D enrollees who opt into the Medicare Prescription Payment Plan will pay \$0 at the POS for a covered Part D drug instead of the OOP cost-sharing they would normally pay when filling a prescription. For claims to be processed appropriately using the Medicare Prescription Payment Plan BIN/PCN methodology, the date of service on the primary Part D claim and the additional program-specific transaction must be on or after the date of program effectuation.*





*When a Part D enrollee receives the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription. As such, when the Part D enrollee returns to the pharmacy to pick up their prescription(s) after successfully opting into the program, all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary must be readjudicated to allow for appropriate processing by the Part D sponsor and/or PBM. This includes unpaid claims for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification.*

*For example, a Part D enrollee is prescribed a new medication with an OOP cost that is above the POS notification threshold. The plan would notify the pharmacy that the enrollee is likely to benefit from the Medicare Prescription Payment Plan. The pharmacy would then provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee. The enrollee decides to leave the pharmacy without paying for their high-cost prescription, so they can contact their plan and opt into the program. However, the pharmacy also has two other covered Part D prescriptions filled for the Part D enrollee from prior dates of service, for which the Part D enrollee also decided to leave the pharmacy without picking up and paying. When the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess all three claims, so the program participant pays \$0 at the pharmacy for all three drugs. Alternatively, the Part D enrollee could choose to pick up and pay for the two other covered Part D prescriptions at the initial pharmacy visit and only return for the high-cost prescription that triggered the notification once their election into the Medicare Prescription Payment Plan has been effectuated. The pharmacy must then reverse and reprocess only the claim for the high-cost prescription that is being billed under the program, so that the program participant pays \$0 at the pharmacy for that prescription. This same process applies when the Part D enrollee has prescriptions that have not yet been picked up and paid for at multiple pharmacies.*

*In the case of same-day program effectuation (when the Part D claim date of service is the same as the date of program effectuation), the pharmacy is not required to reverse and resubmit the Part D claim, provided that they otherwise obtain the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.*

*CMS notes that, in general, plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for by the Part D enrollee. As noted in section 70.3.8 of the draft part one guidance, Part D sponsors must have processes in place to reimburse enrollee cost-sharing for urgent prescriptions when an enrollee has met the conditions for a retroactive election into the Medicare Prescription Payment Plan.*

**NCPDP Comment:** NCPDP requests standardization of the identification of the effectuation date and suggests pharmacies utilize the date of service of the claim that triggered the “Medicare Prescription Payment Plan Likely to Benefit Notice”.

This section seems to assume that picking up the prescription and paying the out of pocket expense occur at the same time. For LTC, the dispensing and delivery is considered picking up the prescription while the payment of the out-of-pocket expense occurs upon the enrollee’s receipt of a monthly invoice from the pharmacy.

If an LTC pharmacy has out of pocket expenses yet to be billed for medications already dispensed and delivered when an enrollee elects into the program, is the LTC pharmacy expected to reverse and rebill these prescriptions? LTC pharmacies are unable to change the date of service because medications have already been delivered.



### **Section 50.5.1 Long-Term Care Pharmacies**

*CMS is aware that there are multiple types of payment arrangements between long-term care pharmacies and long-term care facilities and/or Part D enrollees. In some situations, long-term care pharmacies do not collect Part D cost-sharing from the enrollee but instead bill the long-term care facility for the final patient OOP responsibility. When such an arrangement is in place between a long-term care pharmacy and a long-term care facility, and an enrollee in a long-term care facility is participating in the Medicare Prescription Payment Plan, billing the participant's Part D plan's Medicare Prescription Payment Plan BIN/PCN for the participant's OOP costs (when the pharmacy would not have otherwise directly billed the enrollee) may result in additional financial burden on that participant. In such cases, CMS encourages Part D sponsors to take the participant's particular circumstances into account when considering Medicare Prescription Payment Plan billing practices and to work with the participant, their authorized representative, and the long-term care pharmacy to understand the best billing approach for the participant.*

**NCPDP Comment:** There is a concern with the LTC requirements, as CMS is encouraging Part D sponsors to adopt a high-touch, individual approach and outreach for each LTC beneficiary, rather than a systematic approach.

### **Section 50.5.2 I/T/U Pharmacies**

*As noted in section 50.3.2, I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost-sharing, as defined by their plan's benefit structure, is not collected at the POS. Given that, if an IHS-eligible Part D enrollee is also participating in the Medicare Prescription Payment Plan, the I/T/U pharmacy cannot bill the Part D plan's Medicare Prescription Payment Plan BIN/PCN. Instead, the I/T/U pharmacy must process the claim as if the IHS-eligible enrollee were not participating in the Medicare Prescription Payment Plan. If a Part D sponsor receives a claim from an I/T/U pharmacy for an IHS-eligible enrollee that was submitted to the Medicare Prescription Payment Plan-specific BIN/PCN, the Part D sponsor must reject the claim. To help prevent this situation from occurring, Part D sponsors must also put in place processes to prevent Medicare Prescription Payment Plan BIN/PCNs from being returned on paid claim responses to I/T/U pharmacies.*

*These requirements apply only with respect to I/T/U pharmacies that dispense prescriptions at no cost to the IHS enrollee. The plan sponsor must ensure other network pharmacies providing services to IHS-eligible Part D enrollees process claims in accordance with the Medicare Prescription Payment Plan requirements, as outlined in the draft part one guidance and elsewhere in this draft part two guidance.*

*Part D sponsors should also ensure that their customer service representatives are aware of this situation regarding I/T/U pharmacies when receiving inquiries from Part D enrollees regarding 28 program election. In discussing a Part D enrollee's prescription drug costs, customer service representatives may need to review the primary pharmacy type used by the Part D enrollee. Part D enrollees who use solely I/T/U pharmacies, and thus have \$0 in OOP costs for covered Part D drugs, may not benefit from participation in the Medicare Prescription Payment Plan.*

**NCPDP Comment:** Plans do not have visibility into which beneficiaries are IHS eligible or which I/T/U pharmacies dispense prescriptions at no cost to IHS enrollees. Assuming that all I/T/U pharmacies dispense at no cost to IHS-eligible beneficiaries, NCPDP requests CMS to clarify this section to indicate the claim rejection should apply to all beneficiaries that utilize I/T/U pharmacies. If this is not the case, CMS needs to provide further information, such as a list of I/T/U pharmacies, to plans so the reject can be implemented.



NCPDP thanks CMS for the opportunity to comment on the *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* and for the consideration of our comments. NCPDP looks forward to continuing its work with CMS.

**For direct inquiries or questions related to this letter, please contact:**

Alaina Clark  
Standards Specialist, Standards Development  
NCPDP  
[standards@ncdp.org](mailto:standards@ncdp.org)

Respectfully,

A handwritten signature in black ink, reading 'Lee Ann C. Stember'.

Lee Ann C. Stember  
President & CEO  
National Council for Prescription Drug Programs (NCPDP)

Hello,

I'm seeking clarification regarding the timeframe for when termination notices are to be sent.

Section 80.2.1 Notice Requirement of Final Part 1 guidance on pg. 77 states "...within 3 business days following the end of the grace period...."

The discussion in section C, in response to comments, on pg. 37 states "...within 3 calendar days after the end of the grace period...." This aligns with the Draft Part 1 guidance issued in August 2023.

Is it 3 business or calendar days?

Respectfully,

Shannon

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Shannon Schuster, Director Regulatory Affairs

1570 Midway Place | Menasha, WI 54952

920-628-7267 office | 920-660-4049 cell | [sschuste@networkhealth.com](mailto:sschuste@networkhealth.com)



To: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

Subject: Medicare Prescription Payment Plan Guidance – Part Two

## Submitted Electronically

Dear Director Seshamani:

Otsuka America Pharmaceutical, Inc. (Otsuka) appreciates the opportunity to comment on the Medicare Prescription Payment Plan (MPPP) part two guidance.

Otsuka and its affiliates oversee research and development (R&D) and commercialization activities for innovative products in North America. At Otsuka, we are dedicated to providing patients with the right therapy to treat their health needs, including serious mental illness, agitation associated with dementia due to Alzheimer's disease, and complex kidney disease. Otsuka is proud to be at the forefront of the R&D of new therapies in these disease areas.

Otsuka believes the MPPP represents a significant opportunity to increase affordability adherence for patients with high drug spending, which could improve adherence to their treatment regimens. Robust education and outreach to beneficiaries and their caregivers on the MPPP will be key to successful program implementation and will ensure that the patients most likely to benefit from the MPPP understand their opportunity to elect into the program.

### Plan Education and Outreach Requirements

Otsuka supports CMS's proposal to require general plan outreach and education to enrollees as part of the Annual Election Period, including as part of the Annual Notice of Change (ANOC), Evidence of Coverage (EOC), and membership ID card mailings. For enrollees identified as likely to benefit prior to the start of the plan year, **Otsuka urges CMS to require that Part D plans provide the "Medicare Prescription Payment Plan Likely to Benefit Notice" earlier in the Annual Election period** rather than by the end of the Annual Election Period. Providing this notice as early as possible will provide enrollees who are "likely to benefit" from the MPPP the information they need to make informed plan choices and would enable them to elect into the MPPP at the same time they are making a plan selection during the Annual Election Period. Making election into the MPPP as seamless as possible during the plan selection process would increase the likelihood that enrollees most likely to benefit from the MPPP participate in the program.

While outreach prior to the start of the plan year will be critical to enrollee education on the program, we recommend that CMS balance Annual Election outreach requirements with other plan requirements for outreach and education during the plan year as new prescriptions come in. Given that CMS recently finalized the point-of-sale (POS) pharmacy notification threshold in part one final guidance on the higher end of per prescription incurred costs (\$600), **Otsuka strongly urges CMS to consider other plan requirements for enrollee outreach and education on the MPPP during the plan year.** A beneficiary's out of pocket (OOP) cost burden can vary widely depending on the mix of drugs they take and their plan's benefit design. For example, a beneficiary with multiple, complex health conditions may take many medications, with no single prescription that would meet the pharmacy POS notification

threshold. However, when filled together: multiple, moderate, or even lower cost medications may result in a high OOP cost burden. Similar to the requirement for plans to assess 3 quarters of claims data to identify enrollees “likely to benefit” prior to the start of the plan year, **we request that CMS implement additional requirements for plans to consider cumulative OOP cost burden throughout the plan year, particularly for OOP costs incurred for multiple prescriptions in a short period of time.**

CMS has previously referenced the development of a calculator tool for beneficiaries and their caregivers to understand what monthly costs may look like under the MPPP. **Otsuka believes this type of tool will be critical for beneficiaries to make informed decisions on the MPPP and urges CMS to release more information about this tool as soon as possible, including tool functionalities and capabilities as well as the timeline for its release.** As CMS is aware, some enrollees may not benefit from election into the MPPP, particularly beneficiaries in plans with lower cost sharing requirements (e.g., copays instead of coinsurance). If these beneficiaries elect into the MPPP, they may have more minimal OOP costs earlier in the calendar year, but monthly costs under the MPPP will accumulate later in the year, potentially resulting in MPPP payments that exceed the beneficiary’s original copay amount. **We therefore recommend that CMS consider opportunities to incorporate notifications or other functionalities into the calculator tool that can clearly alert users to when an enrollee would or would not benefit from the MPPP.** This should include links or clear directions on next steps of how to opt in or out of the program based on whether the enrollee is likely to benefit from the MPPP.

Otsuka also supports including language on the MPPP, including a breakdown of what a patient’s OOP costs would look like with and without the MPPP in the Explanation of Benefit (EOB) documents sent throughout the year. It is also imperative that the breakdown of costs is designed to be concise and easy to understand for the beneficiary and/or the caregiver. We also encourage CMS to make the calculator tool previously referenced in part one guidance widely available and easily accessible to all beneficiaries, including **requirements for plans to link to this calculator tool in the EOB, on their websites, and in any other educational and outreach materials.** This tool will be critical to helping beneficiaries and their caregivers understand how the MPPP could impact their costs, particularly as their OOP costs change throughout the year with new prescriptions.

#### Education and Outreach to Additional Stakeholders: Caregivers and Healthcare Professionals (HCPs)

Patients with complex medical conditions such as Alzheimer’s disease often rely on caregivers to help them make informed decisions about their care. Otsuka appreciates the ability for an enrollee’s representative to receive the POS pharmacy “likely to benefit” notification and for the representative to be able to elect into the MPPP on an enrollee’s behalf. However, given the critical role caregivers play for beneficiaries with serious mental illness, **Otsuka encourages CMS to and its’ contracted Part D plans to explore opportunities that allow caregivers to opt in to receive relevant communications on the MPPP, particularly for patients with certain conditions,** such as Alzheimer’s, where caregivers are likely to play a more central role in a beneficiary’s care and potentially their finances. **We also encourage CMS to consider the development of targeted outreach materials that are specific to a caregiver audience.** Targeted materials for caregivers can ensure that they understand the MPPP and its potential implications on OOP costs, as well as the actions needed for the election process.

Additionally, HCPs and their staff represent a critical component of the patient’s care team. HCPs, their staff, and other members of a patient’s care team are often closely involved in navigating insurance



related issues – including dealing with ramifications from a high OOP. Therefore, **Otsuka encourages CMS and plans to consider additional opportunities to educate HCPs and their staff on the MPPP.** For example, CMS should consider developing provider-focused materials on the MPPP and educating HCPs and their staff on the program through CMS’s existing provider communication channels. This will help ensure that beneficiaries, their caregiver(s) and providers driving their treatment decisions are also considering how MPPP could help alleviate cost burden.

Otsuka appreciates the opportunity to comment on the draft part two MPPP guidance given the importance of the program in increasing beneficiary affordability under Part D redesign. If you have specific questions about the content of this letter, please contact: Molly Burich – Senior Director, Public Policy at [molly.burich@otsuka-us.com](mailto:molly.burich@otsuka-us.com).

Sincerely,

Adam Brand  
Vice President, Government Affairs and Public Policy  
Otsuka America Pharmaceutical, Inc.  
2440 Research Boulevard  
Rockville, MD 20850

March 15, 2023

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

Via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

On behalf of the undersigned patient and healthcare provider organizations, we appreciate the opportunity to provide feedback on CMS's Medicare Prescription Payment Plan (MPPP) Part 2 Guidance issued February 15, 2024.

We greatly appreciate that CMS has been open to meeting with patient groups over the past several months about MPPP. We welcome the opportunity to continue to work with CMS to not only shape MPPP guidance implementation to best meet the needs of enrollees, but also look forward to working with CMS to better educate enrollees, their families, and other stakeholders about this important option.

We would like to underscore that the Medicare Part D cap of \$2,000, combined with the MPPP, provides significant opportunities for Medicare beneficiaries to lower and better predict their out-of-pocket prescription medication costs. These are impactful changes to the Medicare program for beneficiaries and therefore the smooth roll out of MPPP along with education about the program is critical, especially for those who will benefit the most from participation.

Please find our comments on the MPPP Guidance below:

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

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

We support that the guidance requires Part D plans to provide education and information about the MPPP to enrollees via membership ID cards, the Annual Notice of Change (ANOC), the Evidence of Coverage (EOC), the Explanation of Benefits (EOB), and plan sponsor websites. All communications should be easy-to-understand and in multiple languages. It will be important for those enrolled in prescription drug plans (PDP) to be informed through a variety of communications about MPPP and the need to opt into the program should they determine it will be beneficial for them. As CMS notes proactive notification of Part D enrollees prior to their interaction at the point of sale (POS) will streamline the program election process and help to prevent drug dispensing delays. It will be important to make clear that this is a new government-mandated program that will help enrollees manage their monthly OOP costs.

- ***Section 30.1.1 Required Mailings with Membership ID Card Issuance***



We support the requirement that Part D sponsors must include with the membership ID information regarding the MPPP along with the MPPP election request form. We look forward to reviewing the CMS-developed educational products that plans have the option of using or developing their own materials that are compliant with CMS requirements. We urge CMS to be as prescriptive with plans as possible, rather than allowing flexibility.

- ***Section 30.1.5 Part D Sponsor Websites***

We support the requirement that plan websites must have robust information about MPPP. This information should be in an easy and obvious place to find on plan websites. CMS should consider specifying where on the plan website these educational resources must appear to promote consistency for PDP enrollees. CMS should also consider providing model language for websites that incorporates the CMS-developed education products on MPPP and other CMS-developed resources. The website should also have the ability for Part D participants to easily verify if they have been enrolled in MPPP.

Information about how to elect into the program should be front and center on the plan websites and the mechanism used to enroll into MPPP must be easy to use. Enrollment should be via online form, and not through a PDF submitted to plans. Additionally, websites should have mechanisms in place so that patients can easily verify if they have enrolled into MPPP.

Further the plan websites should make clear that is a free Medicare program, not a new plan. The websites should also prominently display low-income subsidy (LIS) eligibility information as prospective LIS enrollees will benefit more in LIS than MPPP.

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

- ***Section 30.2.1 Notice for Part D Enrollees Likely to Benefit***

The guidance requires that Part D plan sponsors provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to Part D enrollees likely to benefit via mail or electronically (based on individual enrollee’s preferred and authorized communication methods). We support sending the notice based on enrollee’s preferred communication methods when outreach occurs outside of the pharmacy POS notification process. Targeted enrollment outreach is important; however, we support broad outreach and education to all Part D beneficiaries regardless of their previous OOP experience. Outreach is particularly critical for the year-one roll out and must coincide with education about the \$2,000 cap in OOP expenses.

- ***Section 30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year***

The guidance defines those “likely to benefit” Part D enrollees as those who would have to incur some level of substantial OOP costs meaning that their highest monthly OOP cost is greater than their monthly OOP cost under the MPPP. In the final guidance Part 1, CMS sets an OOP threshold of \$600 for a single prescription to identify enrollees that are likely to benefit from MPPP and therefore must receive the “MPPP Likely to Benefit Notice.” We believe the threshold should be based on cumulative costs rather than a single prescription. For the PDP enrollee, the \$600 OOP expense is the same regardless of it being one prescription copay or a combination of five drug copays. This may inadvertently exclude those who

would benefit from the program. Approaching costs from a cumulative perspective we believe, is more aligned with Congressional intent when the law was passed.

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

The guidance requires Part D plans to assess current enrollees' costs and conduct outreach prior to the plan year if that enrollee has costs greater than \$2,000 through September of the previous year. Outreach by the plan must occur in October, November, or early December (no later than December 7, 2024). We urge outreach with Part D enrollees to occur a few months prior to open enrollment so prospective participants have time to determine if they will benefit and are prepared to opt into MPPP at the earliest opportunity.

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

The guidance requires plans to do outreach during the 2025 plan year if the plan becomes aware of a new high-cost prescription that would trigger the pharmacy POS notification process and if they're likely to benefit from opting into the program. We support continued outreach during the 2025 plan year and believe plans should be required to continually send information on MPPP to beneficiaries, even if beneficiaries initially opt against enrollment.

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

The guidance requires plans to notify the pharmacy when an enrollee incurs OOP costs exceeding a set threshold. Pharmacists must inform enrollees they may benefit from the MPPP and provide the CMS-drafted notice. As noted above, we believe the single prescription \$600 OOP threshold is too limiting and could be potentially burdensome for the pharmacist.

Pharmacies are encouraged but not required to provide additional counseling or education. To make this education as burdenless as possible, we encourage CMS to provide model language for pharmacists to use when educating or counselling. We understand that CMS has no authority to require plans to reimburse pharmacists for such services but we support such reimbursement. Additionally, CMS should provide educational collateral to display at pharmacies, including QR codes for patients to enroll/learn more, and encourage pharmacists to direct patients to contact plans based on the contact information on membership ID card for more information or to opt into MPPP.

- ***Section 30.2.3 Communications with Contracted Providers and Pharmacies***

The guidance encourages Part D sponsors to communicate MPPP information with providers and network pharmacies as they "play a key role in cost-of-care conversations with their patients that can include discussions about potential prescription drug costs." We believe this should be a requirement to increase beneficiary engagement at the pharmacy POS and help create an additional access point for beneficiaries to evaluate the benefits of enrolling in the MPPP.

The guidance also encourages Part D sponsors to target communication to subgroups of providers based on provider specialty and likelihood of prescribing high cost covered drugs. While this is important, we believe this could leave out providers that Part D enrollees trust for drug related information. Therefore, we encourage CMS to consider communication about MPPP to the broad healthcare provider community.

## **Section 30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors**

- ***Section 30.3.1 Overview of Election Requirements***

- ***Section 30.3.1.1 Request to Participate in the Medicare Prescription Payment Plan***

The guidance requires Part D sponsors to allow enrollees to opt into the MPPP during Part D plan annual enrollment periods, initial Part D enrollment periods, and special Part D enrollment periods. We support this requirement. The plans must also offer a toll-free telephone number, website application, fax or mail option. Plans should also include an ability to enroll on the plan's smart phone applications.

We also support the requirement that Part D plans must send the "Medicare Prescription Payment Plan Participation Request Form" with the membership ID card provided to new Part D enrollees and that Part D sponsors must accept election requests they receive regardless of the format of the request.

The guidance requires that when a Part D sponsor receives an election request in an alternate format and required information is missing, they must contact the Part D enrollee telephonically or electronically to collect all necessary information and document the Part D enrollee's and/or their legal representative's agreement to the Part D sponsor's terms and conditions. We support this requirement and urge a 72-hour timeframe for seeking such information. Further, plans should be required to submit enrollment data to pharmacies following enrollment and correspondingly termination status.

- ***Section 30.3.1.2 Paper Election Requests***

We also support the guidance directive that Part D sponsors ensure that paper election requests sent to enrollees include all the information, including terms and conditions, needed to enroll the patient. If the request is incomplete or missing information, the sponsor must contact the enrollee by phone or email to collect the missing information. Again, we urge a 72-hour timeframe for seeking such information. We also support that paper election requests can either be filled out electronically and printed or filled out by hand by a Part D enrollee or their representative and that there will be an option for either a signed or electronic signature.

- ***Section 30.3.1.3 Telephonic Election Requests***

We support that the guidance requires calls received by the plan sponsor be recorded and follow a script previously approved by the Part D sponsor to ensure the information listed in the CMS model request form is obtained during the phone call with the enrollee. We urge CMS to draft and provide a model script to plans for such calls. CMS should also require plans to conduct outreach several times before giving up in contacting the beneficiary.

We support CMS' expectation that Part D sponsors complete the entire MPPP election process in that single telephone interaction if the Part D enrollee wishes to participate in the program. We recommend that compliance with this expectation should be a factor in MPPP audits of plan sponsors.

- ***Section 30.3.1.4 Website Election Requests***

The guidance notes that enrollees should be able to complete the entire election request process,

including documenting the individual's agreement to the Part D sponsor's terms and conditions, through the website. Further, the guidance requires that the election request systems must include a distinct step that requires the Part D enrollee to read and agree with the Part D sponsor's terms and conditions.

We support the requirement that Part D plans have an election request mechanism so prospective participants can enroll online. The election mechanism must be front and center on a plan sponsor's Medicare pages. The mechanism for enrollment into MPPP must be easy to use, similar to enrollment into the prescription drug plan itself. We also urge CMS to require an online election option to "pop-up" following online plan enrollment. It is also imperative that plan websites have real online enrollment, not simply completing a printable PDF that is then submitted to the plan. This could potentially delay enrollment in MPPP.

- ***Section 30.3.2 Notice of Acceptance of Election***

We support the requirement that the Part D sponsor must communicate that the request to participate in the payment plan has been accepted and effectuated via written notice. The plan sponsor must inform the enrollee by phone of their acceptance and follow up within 3 days via email or mail with a written notification.

- ***Section 30.3.3 Notice of Failure to Pay***

We support the guidance requirement that plan sponsors send enrollees notification of a failed payment within 15 days of the payment due date. We recommend aligning the timing notification on missed premium payment in Part D. There must be more than just one notice from the plan. Further, after notification the plan should send a link to the beneficiary via email to facilitate prompt payment and once paid send a verification of acceptance of payment.

- ***Section 30.3.4 Notice of Termination of Election Following End of Grace Period***

We support the requirement that Part D sponsors must provide a notice of termination within three calendar days after the end of the two-month grace period.

- ***Section 30.3.5 Notice of Voluntary Termination***

We support the requirement that Part D sponsors work with enrollees voluntarily terminating their participation in MPPP to determine how they will pay their outstanding balance. We agree that sponsors cannot require full and immediate payment and that the plan sponsor must process the voluntary termination request and send notification confirming the termination within 10 calendar days of receipt of the request. We urge that the termination forms be very clear and state that termination does not affect an enrollee's Part D status, just their MPPP status. The forms should also highlight how termination does not inhibit eligibility and participation in MPPP in future plan years. In terms of the payment plan, we urge CMS require plan sponsors to follow a calculation with prorated payments after termination.

The draft guidance states that disenrollment from a plan includes switching plans during the coverage year or for a subsequent coverage year. To lessen the burden on beneficiaries, we urge CMS to consider ways, including targeted educational materials, to ensure that changing plans does not lead to an unwanted disenrollment from the program and maintains the ability to opt-in to the new plan.

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

We support the requirement that plans must provide outreach materials and communication in a culturally competent manner that can be translated and made available in markets with a significant population with limited English proficiency (LEP). We urge the plan sponsors and CMS to have a plan to get information out to underserved and LEP communities in particular.

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

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

The guidance requires CMS to develop and provide an educational product for Part D enrollees on the Medicare.gov website and through other communication channels that Part D sponsors, pharmacies, providers, beneficiary advocates, and others are encouraged to use for education. We appreciate that CMS has been very intentional in thinking through education options, but we remain concerned that the proposed resources are not prescriptive enough for patient groups to truly gauge if they will be effective for their populations. Patient advocacy organizations are well positioned to help review MPPP resources as they are developed, and we encourage CMS to leverage these resources. Going further, we request that CMS provide the patient advocacy community and independent charitable foundations with model language or a script for how to discuss the MPPP with Part D beneficiaries. We also recommend that CMS utilize health literacy experts in the development of the educational product.

Without articulated specificity on what the educational product will comprise, we recommend the inclusion of the following key pieces:

- Overview of OOP cap and MPPP, including that all Part D plans must allow MPPP participation
- Emphasis on the \$2,000 Part D cap; despite monthly payment fluctuations with MPPP, Medicare beneficiaries will not pay more than \$2,000 annually.
- Enrollment options and processes, including that enrollment is required annually
- Easy-to-understand calculation examples
- Who is likely to benefit
- Implications for failing to pay
- Monthly billing statement information
- Information on LIS
- Complaints and grievances process
- How to obtain additional information
- How to get in touch with local State Health Insurance Assistance Program (SHIP) counselors
- Adaptable script for patient education

The guidance encourages Part D plans to provide additional information that pharmacists can give to those likely to benefit, communicate details of the educational material to contracted providers and other parties, and describe the MPPP in other materials (e.g., educational materials, communications, marketing materials). We urge CMS that this be a requirement for Part D plans. In particular, there is a significant need to communicate broadly with the health care provider community.

We also urge CMS to send a new colored letter specifically focusing on MPPP that is not a part of the Annual Notice of Change communication pieces and highlight this further in the Medicare & You handbook. It is critical that this information stand out amongst the many letters a Medicare enrollee

receives highlighting the option to participate, how to determine if they will benefit from the program, and how to enroll.

It will also be critical that the monthly billing statements offer clear information for the enrollee, so that these statements stand out from other Explanation of Benefits. The billing statement should also clearly outline how much is remaining in terms of payment before reaching the \$2,000 cap.

We also urge CMS to use social media, television commercials, public service announcements for waiting rooms at physician offices, federally qualified health centers, and other appropriate locations to educate about MPPP.

CMS should also conduct regular focus groups with Part D beneficiaries to ensure program and educational outreach are meeting their assigned objectives.

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

The guidance notes that CMS will make applicable changes regarding MPPP to the CMS provided materials (e.g., Medicare Part D documents, website content, tools) before the plan year begins. CMS intends to work with interested parties to make sure that Part D sponsors, pharmacies, providers, and beneficiary advocates will have what they need to inform individuals about the details of the MPPP. We urge CMS to include navigators and SHIPs in this group.

We laud CMS for thinking through education options but remain concerned that the proposed resources are not prescriptive enough for patient groups to truly gauge if they will be effective for their populations. We urge CMS to hold meetings with patient advocacy groups to gain insight on necessary content for adaptability by patient groups. provide specific guidance on the necessary education.

For the Medicare & You handbook, we urge that CMS provide a clear and concise section focused on MPPP. This should include pop-up images and language on the cover and in the table of contents to drive readers to the new section.

For Medicare Plan Finder, there should be a similar enrollment mechanism for MPPP as for a Part D PDP. We urge offering a clear and obvious enrollment option after a Part D beneficiary enrolls into a PDP such as a pop-up box so patients can enroll following their plan selection. Ideally this would be a simple Yes/No selection. Additional pop-up options for enrollment into the MPPP should be created if a prospective enrollee inputs drugs costs during Plan Finder searches in the enrollment process. We also urge CMS to explore offering an online calculator to help patients understand whether they will benefit from MPPP.

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

The guidance acknowledges the important role that SHIP counselors will play in educating Medicare beneficiaries in PDPs about the option to participate in MPPP. SHIPs should be well resourced to educate beneficiaries on the MPPP and be provided with sample scrips and tip sheets with key information that can be used at events and on SHIP websites.

We also urge that agents and brokers be required to educate beneficiaries on MPPP and undergo mandatory training on the MPPP benefit.

## **Section 50. Pharmacy Processes**

### **Section 50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount**

The guidance acknowledges that a small portion of Part D enrollees will have supplemental coverage, such as through a State Pharmaceutical Assistance Program, charity (e.g., charitable foundation), or other health insurance. CMS notes that for these enrollees, the final patient pay amount on a covered Part D prescription drug claim could be reduced below the required notification threshold because of the contributions of a supplemental payer. Therefore, CMS intends to provide language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” that recommends enrollees with supplemental coverage seek advice related to their specific situation prior to opting into MPPP. We are concerned that this is overly complicated and puts the burden on the Part D enrollee to factor this into their calculation of whether they are likely to benefit from MPPP. It is also unclear how supplemental coverage, including assistance provided by independent charitable foundations, will be accounted for by the plans.

### **Section 50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies**

Per the guidance, all pharmacies will be required to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” at POS. Hard-copy notification is required by pharmacies with in-person pick-up options. We support this proposal given the important notification role of pharmacies and pharmacists.

For non-POS pharmacy interaction, email or patient portal notification complies with the requirement when the method of communication is established with the patient (e.g., pharmacies with medication management programs). Phone or another established method is required when in-person patient counseling is not an option (e.g., mail-order and specialty pharmacies). We support these requirements.

### **Section 50.4 Readjudication of Prescription Drug Claims for New Program Participants**

CMS requires pharmacies to reprocess claims for Part D covered prescriptions if the patient enrolls after receiving the Likely to Benefit Notification (triggered by a high-cost Part D covered prescription drug). If the patient leaves the pharmacy to enroll in the plan and returns with MPPP BIN/PCN, the pharmacy must reprocess the claims and the enrollee then pays \$0 at POS. All processed Part D claims that have not been paid, and the prescriptions have not been picked up by the enrollee, must be reprocessed based on the enrollee’s enrollment in the MPPP. We support these proposal requirements.

## **Section 60 Part D Sponsor Operation Requirements**

The guidance discusses the various operational requirement that Part D sponsors should be aware of and must comply with in implementation of MPPP. We support the expectation that sponsors incorporate the MPPP into compliance programs to meet program requirements.

### **Section 60.1 Part D Bidding Guidance for CY2025**

We urge CMS to incorporate MPPP details into plan bid submissions for CMS to review.

### **Section 60.4 Audits**

The guidance says that CMS and/or its contractors *may* conduct plan audits of MPPP implementation. We believe audits are a critical piece of compliance and should be made publicly available.

## **Additional Comments**

### **Program Name**

The nomenclature “Medicare Prescription Payment Plan” could be confusing for Part D enrollees in a prescription drug plan – it’s a plan within a plan. The name is also not clearly associated with Part D, which could also be confusing for potential participants. Although the terminology “Medicare Prescription Payment Plan” has been used for some time, we wonder if there is more descriptive language that could be used that better describes the intent of the program. While we do not propose a specific name for the program, we believe CMS should shift the nomenclature from MPPP closer to a “budgeting” benefit, given that this may resonate more with beneficiary populations as they are generally savvy with living off a fixed income.” Regardless, CMS should use standard terminology across all promotional materials to mitigate confusion among enrollees and ensure consistency across educational resources developed and disseminated by other interested parties, such as advocacy groups.

### **POS Enrollment**

While we understand the challenges for 2025, we continue to urge CMS to identify and develop infrastructure to allow for enrollment at the point of sale. Allowing patients to opt-in at the point of sale will ensure that patients receive medications on time while mitigating financial burden.

### **MPPP Model Documents**

We are reviewing CMS’ information collection request (ICR) referenced in the Draft Part 2 Guidance and released on February 29 and look forward to providing comments by the April 29 deadline.

We appreciate your leadership to increase equitable access to and affordability of health care for more Americans. Thank you for your consideration of our comments. MPPP is a critically important Medicare reform, and we welcome the opportunity to provide perspectives regarding its successful implementation.

If you have questions about the issues raised, please contact Amy Niles, Chief Mission Officer, Patient Access Network Foundation at [aniles@panfoundation.org](mailto:aniles@panfoundation.org).

Sincerely,

Alliance for Aging Research  
Alliance for Patient Access  
American Liver Foundation  
Bone Health and Osteoporosis Foundation  
Colorectal Cancer Alliance  
Crohn's & Colitis Foundation  
Depression and Bipolar Support Alliance (DBSA)  
Gaucher Community Alliance  
Hemophilia Federation of America  
HIV+Hepatitis Policy Institute  
International Pemphigus & Pemphigoid Foundation  
International Waldenström's Macroglobulinemia Foundation  
Melanoma Research Foundation



MPN Advocacy & Education International  
MPN Advocacy and Education International  
Multiple Sclerosis Association of America  
Myasthenia Gravis Foundation of America (MGFA)  
National Council on Aging  
National Eczema Association  
NCODA  
Patient Access Network (PAN) Foundation  
Pink Fund  
Prevent Blindness  
The AIDS Institute  
The Mended Hearts, Inc.  
The NaVectis Group  
The Sumaira Foundation  
University of Michigan Center for Value-Based Insurance Design

# PATIENTS FOR AFFORDABLE DRUGS™

**March 14, 2024**

The Honorable Meena Seshamani  
Deputy Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

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

Patients For Affordable Drugs (P4AD) is the only national patient organization focused exclusively on system-changing policies to lower drug prices. We are bipartisan and independent. We do not accept funding from any entities that profit from the development or distribution of prescription drugs. Since we launched seven years ago, we have collected over 34,000 stories<sup>1</sup> from patients, across all 50 states, struggling to afford their drugs because of high prices. And we have built a community of over three-quarters of a million patients and allies supporting policies to lower drug prices.

The new requirement mandating Part D sponsors provide all Part D enrollees the option to pay their out-of-pocket (OOP) costs in monthly, interest-free installments over the course of the plan year, instead of paying OOP costs as they are incurred at the point of sale is a significant advancement. This change will deliver upfront financial relief and ensure long-term predictability for Part D enrollees, especially benefiting patients reliant on some of the costliest prescription medications.

We appreciate the efforts by the Centers for Medicare and Medicaid Services (CMS) to invite feedback and the opportunity to comment on the draft part two guidance related to the Medicare Prescription Payment Plan. The success of the Medicare Prescription Payment Plan depends on patient-centered implementation. P4AD specifically commends CMS for its enhanced emphasis and specificity on targeted outreach in this revised guidance. We also applaud CMS for the detailed and patient-focused thinking included in the program implementation, and we acknowledge the challenges inherent in implementing such a complex program, particularly given the *opt-in* nature of the program for Part D enrollees.

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<sup>1</sup> (2024, February 26). *Patients For Affordable Drugs Map*. Patients For Affordable Drugs.  
<https://map.patientsforaffordabledrugs.org/>

## **Outreach, Education, and Communications Requirements for Part D sponsors (section 30)**

### **1. General Outreach and Education (section 30.1)**

- P4AD strongly supports requiring Part D plan sponsors to notify prospective Part D enrollees prior to the plan year as well as using existing plan materials that are already furnished to Part D enrollees or updating materials where necessary. We also support the decision to ensure that Part D sponsor websites include anti-discrimination provisions and comply with language access and accessibility requirements.
- We strongly support the inclusion of “easy-to-understand explanations”, a description of who is likely to benefit, and the emphasis on the program being free to join and devoid of any fees or interest. These measures will be critical in ensuring patients understand how the program will benefit them in a manner that is best tailored to their needs and may help reduce real or perceived barriers to access.

### **2. Targeted Outreach and Education Requirements for Part D Sponsors (section 30.2)**

- We applaud CMS’ decision to identify Part D enrollees likely to benefit in advance of the plan year, and the requirement for Part D sponsors to assess their current enrollees who incurred \$2,000 in out-of-pocket (OOP) costs for covered drugs through September of that year. Further, we commend the targeted outreach approach to inform those Part D enrollees of the program. As an additional step, we recommend further outreach to patients taking specific higher-cost medications and/or living with specific conditions known to require expensive drugs.
- We also support the outlined approach as the minimum requirements for Part D sponsors to be put into place to ensure ongoing identification of Part D enrollees likely to benefit during the year in order to increase awareness and understanding of the benefits of the program to patients.
- We support CMS in its encouragement of Part D sponsors to provide pharmacies with education and resources related to the Medicare Prescription Payment Plan (MPPP). However, we urge CMS to also expand outreach to other community health centers, senior centers, and other points of contact that are typically tailored to serving diverse populations.

### **3. Communications with Program Participants and Model Materials Requirements for Part D Sponsors (section 30.3)**

- P4AD strongly supports the initiative for outreach to be made in various formats (electronically, paper, and/or phone, etc.) in order to provide tailored support to the potential participant’s specific situation, especially when they are less likely to benefit and/or it would be more advantageous to apply for the Low Income Subsidy (LIS) program rather than the MPPP program.
- P4AD supports the requirement by CMS for Part D sponsors to allow enrollees to voluntarily opt-out or unenroll from the MPPP program.

- P4AD urges CMS to ensure the process and financial OOP implications of voluntarily unenrolling are clear to the patient upfront and before termination.
- 4. Language Access and Accessibility Requirements (section 30.4)**
  - P4AD strongly supports CMS' requirement to provide outreach materials and communications in a culturally competent manner to all Part D enrollees, including those with Limited English Proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds. This is especially important given that communities of color are disproportionately harmed by high drug prices and Black and Latino adults over age 65 and older were more likely to report difficulty affording prescription medications than white adults. Black and Latino adults age 65 and older reported this difficulty at rates roughly 1.5 to 2 times higher than White adults.<sup>2</sup>
  - P4AD strongly supports the requirement for Part D sponsors to provide translated materials in an accessible format to Part D enrollees in languages spoken by at least 5 percent of the individuals within a plan benefit package service area.

### **CMS Part D Enrollee Education and Outreach (section 40)**

#### **1. Modifications to Existing Part D Resources (section 40.2)**

- P4AD supports CMS' commitment to developing new Part D educational resources and updating existing resources including web content, and tools to ensure information is updated and available in advance for patients before the plan year begins.

#### **2. National Outreach and Education Efforts (section 40.3)**

- P4AD supports CMS' commitment to ensuring that consumers have all the resources and assistance they need to learn about the availability of the MPPP.

### **Pharmacy Processes (section 50)**

Broadly, P4AD encourages outreach to patients who purchase their prescription drugs through specialty pharmacies. Specialty pharmacies already engage in individualized work with patients using expensive prescription drugs, making them an ideal vehicle and source for educating and informing patients about the program. By leveraging the existing informational infrastructure of specialty pharmacies, we can effectively reach many of the individuals who are most likely to benefit from the program's offerings.

#### **1. Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount (section 50.1)**

- P4AD supports the understanding that Part D plan sponsors should ensure that their customer service representatives are aware of the possibility that a small portion of Part D patients enrolled will have supplemental coverage such as through State Pharmaceutical Assistance Program (SPAP), charity, or other health insurance.

#### **2. Pharmacy POS Notifications Late in the Plan Year (section 50.2)**

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<sup>2</sup> Tarazi, W. et al. *Prescription Drug Affordability among Medicare Beneficiaries*. ASPE Office Of Health Policy. (2022, January 19).

<https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efec9c6f96f0/prescription-drug-affordability.pdf>

- P4AD supports the expectation that Part D plan sponsors should ensure that their customer service representatives are informed about the possibility that late in the year Part D enrollees *may* be alerted that they would be “likely to benefit” based on their OOP costs even if their costs fall below the maximum monthly cap and could then be required to pay the full amount as part of their first month’s bill. We urge CMS to encourage Plan D sponsors to not only understand the financial implications of late enrollment into MPPP but also proactively communicate this nuance upfront to patients through their customer service representatives, in order to prevent misunderstanding.

**3. Pharmacy POS Notifications in Retail and Non-Retail Pharmacies (section 50.3)**

- P4AD applauds CMS for ensuring all MPPP requirements are identical for every pharmacy type.
- P4AD supports the requirement that the Part D sponsor must ensure a hardcopy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to enrollees at the time they physically collect their prescription if they are identified as likely to benefit. However, P4AD remains concerned that it is unrealistic to assume that long, complex conversations will be successfully held at the pharmacy counter.

P4AD thanks CMS for ensuring patients are informed about the process of implementing all the provisions of the Inflation Reduction Act, and looks forward to continued engagement in the process in the coming months.

Sincerely,

Patients For Affordable Drugs

March 14, 2024

Meena Seshamani, M.D., Ph.D.,  
CMS Deputy Administrator, Director of the Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

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

Dear Dr. Seshamani:

Paytient Technologies would like to thank you for the opportunity to share our comments and suggestions on the draft Part Two guidance for the implementation of the Medicare Prescription Payment Plan (M3P).

**About Paytient**

Paytient is a Missouri-based company that is committed to building payment solutions that deliver value to employers, payers, and health systems by ensuring people can access and afford the care they need to live healthier lives. Since 2018, we have been working with employer and payer partners to put health payment accounts into the hands of Americans to help them more equitably access and afford healthcare, especially when they have high deductible health plans and low or empty health savings accounts. In January 2024, 92 percent of participants in Paytient's employer plans reported being more satisfied with their health benefits and two-thirds reported improved health for them and their family.

Paytient has been collaborating with government payers since 2021, particularly ACA marketplace plans, to help smooth high prescription costs for their enrollees. We are currently working with three of these payers reaching enrollees in eight states. Our work offers a unique perspective on which to build our feedback on the Part Two draft guidance, particularly in the areas of Part D enrollee outreach and education. Throughout 2024, Paytient will be partnering with plan sponsors and pharmacy benefit managers to coordinate this type of outreach and contact for the M3P.

**Multiple touchpoints will be important for enrollee education**

We support the requirement for Part D plan sponsors to incorporate education about the M3P program into several communication tools that are already required by Medicare regulations. In our experience this kind of repeated outreach is necessary to ensure robust enrollment in the payment plan because individuals need to have heard about the M3P option before and during their plan year and well before they are approached to opt into it. With that approach, CMS can be more confident that individuals will not hear about this program for the first time as they are being asked by a pharmacist at the point of sale (POS) to opt in. This helps ensure informed decision making and long-term participation.

We have found that when Paytient's plan partners offer only a few communications via email about their payment plan options, the insurers often see fewer enrollees than expected enter the program. Instead, plans find higher rates of participation when both Paytient and the plan – a name the enrollee knows and trusts - communicate about our payment plan option often and in multiple communication channels (i.e., mail, email).

### **Plans and enrollees will benefit from model language and example scenarios**

We appreciate CMS's commitment to offering plans model language for M3P outreach materials as well as the agency's efforts to publish this information through its own channels. We are grateful that this model language has already been released ahead of the initial summer timeline and we are reviewing the model notices to offer our specific feedback.

As CMS did in the Part One guidance, we recommend the Part Two guidance offer Part D sponsors scenario-based examples of how to use the educational materials to best serve their enrollees. Over the next few months ahead of the 2025 plan year, plan sponsors and their partners including software vendors and marketing contractors will be closely focused on operationalizing the M3P program and amending the technical communications that will need to include M3P information such as the Explanation of Benefits and Notice of Plan Changes. We suggest that CMS focus during this time on offering best practices for other types of communications with Part D enrollees given CMS's long standing experience of successfully reaching seniors where they are.

### **Web-based resources for additional information will relieve administrative burden**

In today's digital age, consumers expect to find reliable information online and we support CMS's plan to include education about M3P on its and the Part D sponsors' public facing websites. This effort will cut down on customer service calls to the plan sponsors and to CMS and may help alleviate the burden on potential M3P enrollees who want to learn more, especially after learning of the program through word of mouth.

We also support the option for enrollees to receive communications via email if they have chosen that delivery method. This aligns with Medicare rules and Paytient's best practice to use mailed communications at the outset of an enrollee's experience in our program until that individual opts to receive their notices in a different format.

### **Communication plan adheres to best practices for payment plans**

The recommended M3P notices follow what we believe to be best practices for operating this kind of payment plan. When individuals opt into a program they expect to receive confirmation of their enrollment and likewise if they choose to terminate their participation they will expect a notice to confirm that they have exited the program. When it comes to making payments, individuals expect to be able to enroll in automated payments, to enjoy some amount of grace period to make up for overdue balances, and to receive clear notice of termination for continued non-payment. We applaud these aspects of the communications guidelines and we are confident that this is the best way to support M3P participants given our experience in other insurance markets.

### **Pharmacy opt in will require careful consideration given the no-cost nature of the visit**

We understand the value of individuals being able to opt into M3P at the POS in their pharmacy because it is the best moment to pinpoint those individuals that can benefit from payment smoothing for the remainder of their plan year, but we are concerned that participants will leave the pharmacy without a full understanding of their payment obligations in the following month since in the moment they were able to have their medications at zero cost. The statute requires this visit comes at no cost to the participant, however without very careful explanation and consideration, it will be easy for some individuals to be induced to enter M3P to avoid paying the high cost of the medications awaiting pickup. They may later feel unprepared to make their monthly installment payments leading to churn within the M3P and unresolved debt for the Part D sponsors.

One way to work toward that balance is for CMS to offer in the final guidance additional examples of circumstances when it *does not* make sense for individuals to opt into M3P and specific advice for pharmacy staff on how to estimate when and how much the individual will be billed for the medications they will leave with that day. We believe this additional information will assist individuals' understanding and ensure they are fully informed about their responsibilities when they opt in at POS.

### **Clarification needed on incurred cost during the opt-out period**

Additional guidance from CMS related to circumstances when a member opts in the M3P program, then opts out, only to return through another opt-in would assist market uncertainty. Part D sponsors are in need of clarification on how to treat prescription claims that the member incurs during their transitional opt-out period in this scenario.

We suggest that CMS allow Part D sponsors to create a new payment schedule in this scenario that will reflect any claims incurred during the member's opt-out period that would have contributed to their total OOP cost. The plan sponsor should sum any claims from the previous opt-in period with the month in which the member has opted back into M3P and generate a new payment schedule and a new monthly bill. This consideration allows the "first month" calculation of the latest opt-in period to be a reflective change in true out-of-pocket costs (TrOOP). Under this approach, M3P members would receive a new bill that reflects a sum of the months and presents only one payment amount to eliminate confusion and the plan sponsor will reconcile its records internally to capture the first and subsequent opt-in periods.

### **Comment related to enforcement discretion**

CMS has stated that it is sympathetic to the overwhelming administrative work that will be required this summer to program M3P information and processes into the Part D sponsors' work flows ahead of October 1. Based on market feedback, we suggest CMS consider giving plans a glidepath toward compliance with the M3P program requirements, especially for changes that must be made to electronically delivered notices, like the explanation of benefits and notice of plan changes. In speaking with Part D sponsors, we have learned that most are hesitant to begin software programming in earnest until the final notice language is released this summer to avoid



the risk of needing to reprogram items if the draft and final versions are not identical. We appreciate CMS offering the model notices earlier this month, but concerns remain that plans may hesitate to begin work based on drafts, which could risk their ability to be in full compliance by October despite best efforts from all involved. To that end, we suggest CMS finalize the model notices by July 2024 if it does not plan to offer any period of enforcement discretion.

### **Clarification of consumer credit**

In the final Part One guidance, CMS stated that:

*“...plan sponsors (and any third parties Part D sponsors contract with) are expected to follow all applicable federal and state laws and requirements, including those related to payment plans, credit reporting, and debt collection, when collecting any unpaid balances related to the program”*

The classification of a product as a regulated consumer credit product carries significant legal and regulatory implications and sponsors need express clarification from CMS about whether the M3P will be classified as a regulated consumer credit product. This classification could result in additional considerations specific to product design and requirements in servicing the product. Some of these considerations include:

- Truth in Lending Act (TILA/Regulation Z)
- Equal Credit Opportunity Act (ECOA/Regulation B)
- Servicemembers Civil Relief Act (SCRA) and Military Lending Act (MLA)
- Bank Secrecy Act (BSA)/Anti-Money Laundering Provisions (BSA/AML)
- Unfair, Deceptive, and Abusive Acts and Practices (UDAAP)
- Fair Credit Reporting Act (FCRA/Regulation V)
- Fair Debt Collection Practices Act (FDCPA/Regulation F)

It is essential to understand if the M3P product will be defined as a “credit” product by federal and state regulators. Without this knowledge, it will be difficult for Part D sponsors to comply with CMS’s direction to follow all applicable laws and regulations and to mitigate risks and protect consumers’ interests.

### **Conclusion**

Paytient looks forward to serving the implementation of M3P because we believe in its promise to Medicare beneficiaries: ensuring equitable access to high-cost prescription medications for older adults that rely on Medicare to remain physically and financially healthy as they age. Our company was built on this idea. We are hopeful that our previous experience in this arena will help CMS improve on the draft Part Two guidance and we remain available to discuss that experience with you as appropriate and any questions you have about the views we have presented here.

Please contact David Smith, Senior Director of Partnerships, with any questions at david@paytient.com or (573) 424-2122.





**March 15, 2024**

*Submitted via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov) with the subject line "Medicare Prescription Payment Plan Guidance"*

Dr. Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator & Director of the Center for Medicare  
U.S. Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

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

Dear Dr. Seshamani:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the U.S. Centers for Medicare & Medicaid Services' (CMS) part two guidance regarding the Maximum Monthly Cap on Cost-Sharing Payments Program established by section 11202 of the Inflation Reduction Act (IRA).<sup>1</sup> We thank CMS for the timely issuance of this important guidance.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and through the exchanges established by the Affordable Care Act. Our members are committed to increasing affordability of drugs and work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

PCMA appreciates the timely issuance of additional guidance for the Medicare Prescription Payment Plan (referred to as M3P) for year one of the program. We also appreciate the opportunity to provide comments as both CMS and the industry work to bridge the application divide between congressional intent and successful program implementation. We would like to also thank the agency for the recently released final part one guidance and the issuance of draft model materials for beneficiary identification, notification and termination addressed in this

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<sup>1</sup> CMS. "Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025." February 15, 2024. Available at [Medicare Prescription Payment Plan Draft Part Two Guidance \(cms.gov\)](https://www.cms.gov/medicare/prescription-drug-payment-plan/draft-part-two-guidance)



guidance. We are commenting on the actual model materials separately under the Paperwork Reduction Act process CMS has initiated.

PCMA would like to highlight some general concerns focusing on time constraints given the volume of novel model documents and processes needed. In recognition of the burden of these new administrative processes, we request that CMS allow for flexibility as the industry prepares for the launch of the M3P program by the end of the year. Given the need for time and resource allocation, we recommend that the model materials be expedited to the greatest extent possible and be finalized by late June. With regards to program implementation, we request maximum flexibility and ask for a grace period and enforcement discretion, especially since there will be beneficiary confusion, administrative hurdles, and an overall increase in complaints.

PCMA is also concerned that the final part one M3P guidance, released by CMS on February 29, 2024, includes references to many proposed part two M3P requirements not yet finalized. These references from a final guidance to a proposed guidance appear to indicate that CMS has seemingly assumed that some of its proposed requirements will be finalized even before considering stakeholder's feedback. We recommend that CMS consider all stakeholder's feedback in earnest before finalizing this part two guidance.

Our specific comments on CMS's part two guidance on M3P can be summarized as follows:

- **Required materials:**

- Given the need for time and resource allocation, we recommend that the model materials be expedited to the greatest extent possible and be finalized by late June, or as soon as possible under the Paperwork Reduction Act's timeline for approval.

- **Likely to benefit:**

- *Likely to Benefit Definition*: CMS should use True Out-of-Pocket costs (TrOOP) rather than out-of-pocket costs (OOPC) for likely to benefit threshold calculations.
- *Likely to Benefit Communication*: CMS should provide clarifications with regards to the questions posed regarding beneficiary focused communication related to likely to benefit.
- *Likely to Benefit Information Dissemination*: CMS should exclude the M3P election request form with the Member ID card to prevent beneficiary's submission of the election form when they may not be likely to benefit. CMS should consider not including M3P information in Explanation of Benefits (EOBs) and simply referring beneficiaries to a robust source. Finally, CMS should clarify which state and federal consumer financial

protection laws, if any, are applicable for the M3P program.

- **Language Access and Accessibility**

- **Elections:** CMS should allow plan-sponsors to decide whether to allow beneficiaries in good standing to remain enrolled in their plan's M3P program yearly. CMS should provide guidance on how to disenroll members with delinquent balances due to the 60-day grace period if an auto-renew option is added.
- **Multi-Language Insert (MLI):** CMS should provide all pharmacies with materials either for top-5 languages or 5% languages as proposed during the M3P guidance-related briefing and discussion on March 7, 2024.
- **CMS Enrollee Education and Outreach:** All beneficiary-facing communication needs to be easy to understand and be provided through easy-to-access modes such as websites, YouTube, Facebook, and community settings.
- **Pharmacy Process:** CMS should provide guidance on how to address difficulty in identifying populations likely to benefit. CMS should allow for flexibility in providing point-of-sale (POS) notification for those who may not benefit from the M3P program.
- **Part D Sponsor Operational Requirements:** CMS should allow for a grace period when addressing M3P program-related complaints and grievances.

## **I. Required materials and content for beneficiary**

The IRA requires Part D sponsors to notify prospective enrollees prior to the plan year through promotional materials of the option to participate in the M3P. In addition, Part D sponsors must provide educational materials to current enrollees. To facilitate this communication, CMS is requiring Part D sponsors to use existing Part D required materials to inform and educate enrollees about the program. Draft materials have been posted by CMS and are not the subject of these specific comments. Part D sponsors may also include information about the M3P in their own marketing materials.

In general, we do not have any concerns with most of the proposed required communications, and request that the model materials be finalized as soon as feasible. From a beneficiary, plan and PBM perspective, it would be helpful if CMS provided a website that housed all this information along with beneficiary focused educational materials and videos.

**PCMA Recommendation: Given the need for time and resource allocation, we recommend that the model materials be expedited to the greatest extent possible and be**

***finalized by late June, or as soon as possible under the Paperwork Reduction Act's timeline for approval.***

## **II. Likely to Benefit**

### **a. "Likely to Benefit" Definition**

PCMA recognizes that one of the most important aspects of the M3P program is to identify beneficiaries who are most "likely to benefit." The success of the M3P program depends on reaching these individuals as early as possible and in as many ways as possible. The \$600 single claim threshold for identifying these individuals was finalized in part one of the guidance. We thank CMS for incorporating public comments in finalizing this number. In addition to the threshold value, CMS specifies that sponsors must assess current enrollees' costs from the current year based on their out-of-pocket costs (OOPC). We recommend that threshold calculations use True Out-of-Pocket (TrOOP) costs rather than OOPC. M3P should initially only be targeted to those likely to hit their maximum out-of-pocket costs.

**PCMA Recommendation: CMS should use TrOOP rather than OOPC for likely to benefit threshold calculations.**

### **b. Likely to Benefit Identification and Communication**

From an administrative standpoint, CMS should note that PBMs cannot produce ad hoc notices along with coverage decision letters, so the "likely to benefit" notice would have to be coded into all client decision templates.

For communications related to "likely to benefit" status, we ask CMS for clarity on the following:

- Does CMS expect that the identification of "likely to benefit" beneficiaries be limited to those with favorable coverage determinations? Would that also include partially favorable decisions?
- How do we address a member requesting a Tier Exception? It is our concern that there would be compounded risk if, in an untimely coverage determination, the notice was also not delivered timely to the beneficiary.
- CMS should note that during a coverage review, it may not be known what quantity will be prescribed and what the day supply will be, whether 30 or 90 days. This will make it difficult to determine whether a member's cost share will be above the threshold of \$600. Members who are not likely to benefit may receive a notification. How do we address this issue and mitigate it?
- Most importantly, if beneficiary expresses concern about the price of a drug, what should take priority: offering a coverage determination or tiering exception to get a lower price, versus offering the M3P "likely to benefit" information?

- Does the information need to be sent separately from the coverage determination notification or can it be included as an attachment with the decision? We recommend this requirement be applicable only for approved coverage determinations or appeals since sending the M3P information and election form when the request results in a denial would not benefit the beneficiary and may, in fact, lead to the submission of an election form when the request is denied. We also request CMS to provide instructions if the appeal is approved at the Independent Review Entity (IRE) stage.
- Does CMS envision a hierarchy of administrative steps from formulary tiering to exceptions processes and M3P program enrollment?
- CMS should clarify that members precluded from M3P, such as involuntary terminated members who have not paid, should not be sent a likely to benefit notice by pharmacies or by the plan.

**PCMA Recommendation: CMS should provide clarifications with regards to the questions above when finalizing part two of the guidance.**

c. “Likely to Benefit” Information Dissemination

For CY 2025, CMS will require Part D sponsors to include the following M3P materials with the membership ID card hard copy mailing: information regarding the M3P and a M3P election request form. We would like to note that not all beneficiaries receive a new ID card each year. Is CMS comfortable with this mailing only going to members who are receiving an ID card? If not, CMS should clarify the requirement for plans to provide M3P information with the ID card mailing, given that not all beneficiaries are likely to benefit. If CMS prefers that all members receive M3P related information, it might be better to have it sent with a confirmation of enrollment communication or something similar.

PCMA also has concerns about including information about the M3P in the EOB document. EOBs are sent to enrollees multiple times throughout the coverage year, including late in the year, when M3P enrollment would be less beneficial. This requirement would also mean that members who are not likely to benefit from M3P enrollment would receive this information on multiple occasions. We recommend that CMS modify this proposal to require the inclusion of high-level information about the M3P in the EOB, and direct members to where they can learn more about M3P if they are interested.

In addition, PCMA urges CMS to work with federal consumer financial protection agencies to clarify that federal and state consumer financial protection laws and regulations do not apply to the M3P. In the M3P Final Part One Guidance, CMS alludes to the applicability of federal and state laws in the context of collection of unpaid balances, however, the final part one guidance is vague as to which specific laws and regulations apply. We are concerned that full applicability of consumer financial protection laws and regulations associated with consumer credit and

lending will undermine the goals of the M3P by confusing consumers and creating a barrier to access.

**PCMA Recommendation: CMS should exclude the M3P election request form with the Member ID card to prevent beneficiary submission of the election form when they may not be likely to benefit. CMS should consider not including M3P information in EOBs and simply referring beneficiaries to a robust source. Finally, CMS should clarify which state and federal consumer financial protection laws, if any, are applicable for the M3P program.**

### **III. Language Access and Accessibility**

#### **a. Elections**

CMS is developing a model “M3P Participation Request Form” for Part D sponsors that enrollees can use to initiate the request to opt into the program. Part D sponsors must accept an election request regardless of the format of the request and must contact the enrollee to collect all necessary information and to document their agreement to the M3P terms and conditions. Once the program election request is accepted by the Part D sponsors, the sponsor must communicate that the election request to participate in the M3P has been accepted and effectuated via written notice, according to the time frames in the final part one guidance.

PCMA realizes that the initial setup and enrollment will be time and resource intensive given the newness of the program. However, once elections are made, CMS should consider administrative simplifications and automation of some processes such as auto-renewal. Auto-renewal should be a choice for plan sponsors to offer to beneficiaries. There also needs to be a disenrollment process for those who may have opted into auto-renewal but are in the 60-day delinquency grace period or have been terminated from the program due to delinquency.

**PCMA Recommendation: CMS should allow plan sponsors to decide whether to allow beneficiaries in good standing to remain enrolled in their plan’s M3P program yearly. CMS should provide guidance on how to disenroll members with delinquent balances due to the 60-day grace period if an auto-renew option is added.**

#### **b. Multi-Language Insert (MLI)**

CMS should note that pharmacies do not have visibility into beneficiary language preference and needs. This information resides with the plan sponsor. Hence, the proposed requirement will be operationally difficult and require plans to create processes for providing pharmacies with the 5% language threshold specific notices based on beneficiary demographics and language needs at each pharmacy. However, beneficiaries can go to different pharmacies at various



points in time or at the same time with multiple prescriptions, which will add administrative complexity and lead to pharmacy level communication issues.

***PCMA Recommendation: CMS should provide all pharmacies with materials either for top-5 languages or 5% languages as proposed during the M3P guidance-related briefing and discussion on March 7, 2024.***

#### **IV. CMS Enrollee Education and Outreach**

To facilitate broad education about the M3P, CMS will develop new Part D educational resources and will update existing Part D resources that provide individuals with information on Medicare Part D (“CMS-developed educational product”). Part D sponsors will be permitted to use this product to satisfy their requirements to provide information on: (1) their website; (2) alongside the election request form in the ID card mailing; and (3) alongside the Likely to Benefit Notice when sent prior to or during the plan year. Other interested parties (namely pharmacies and providers) are also encouraged to use this product to educate enrollees.

CMS should consider alternative ways for Part D enrollees to receive information in an easy-to-understand manner such as YouTube and Facebook videos. All educational materials, written/videos/websites) should be targeted to all literacy levels and should be focus group tested for ease of comprehension. Additionally, CMS should provide more information on how they plan to include M3P updates in the Medicare Plan Finder. Will they include static messaging, or will they be detailed based on beneficiary inputs? Another consideration is that Employer Waiver Group Plans (EGWPs) are waived from providing information on websites due to the nature of these plan types. Therefore, EGWPs, due to the waiver for websites, should not be required to post information on websites.

***PCMA Recommendation: All beneficiary facing communication needs to be easy to understand and be provided through easy to access modes such as website, YouTube, Facebook, and community settings.***

#### **V. Pharmacy Process**

In the proposed guidance, CMS asks Part D sponsors to ensure that network pharmacies disseminate education and resources related to the M3P. We are concerned that network pharmacies may object to further requirements without contractual changes to add enforcement mechanisms for pharmacies to provide any information to a Part D enrollee at the (POS). It is important for CMS clarify to that a contractual provision compelling pharmacies to conduct this action is sufficient to satisfy the proposed “ensure” requirement. It is unrealistic and burdensome to require pharmacies to track and report this information to plan sponsors. Therefore, the contractual provision compelling the pharmacies to provide the information when appropriate should be enough.

PCMA asks that CMS elaborate on how the communication requirements will be applied to mail-order pharmacies and specialty pharmacies. CMS specifically calls out considerations for long-term care pharmacies and Indian Health Service (IHS) pharmacies but offers little on how POS notifications would work when the enrollee isn't in a physical pharmacy setting. Specifically, for IHS, Tribe and Tribal Organization, and Urban Indian Organization (ITU) pharmacies, the process for identifying ITU members is not visible to the pharmacy industry. The claim adjudication process can identify the ITU pharmacies, but there is not a systematic way to identify members. Moreover, ITU members do not pay a copay; however, this is accomplished through a pharmacy process that is a backend process, and ITU claim still returns a copay on the claim transaction for a Part D claim.

PCMA asks that CMS clarify M3P billing processes if members with supplemental coverage opt to enroll in M3P. Supplemental coverage changes patient's liability (less than or greater than the Part D copay). This necessitates CMS's guidance on how to counsel these beneficiaries for both the sponsor and pharmacy. We also encourage CMS and sponsors to consider suppression of POS notification to the pharmacy, when the program is not truly beneficial to avoid member dissatisfaction with their sponsor and/or pharmacy. In addition, if there are other scenarios where offering the program is not ideal due to possible member abrasion, CMS should clarify how sponsors should maintain rules and suppress pharmacy notification, such as member obtaining multiple qualifying prescriptions from multiple pharmacies in a short period of time.

**PCMA Recommendation: CMS should provide guidance on how to address difficulty in identifying populations likely to benefit. CMS should allow for flexibility in providing POS notification for those who may not benefit from the M3P program.**

## **VI. Part D Sponsor Operational Requirements**

CMS proposes to monitor and collect data about beneficiary complaints and grievances reported via the Medicare Claims Tracking Module (CTM) to assess compliance with the M3P requirements. CMS is assessing whether an additional CTM category or subcategory for the program is appropriate for future years. CMS also states that the agency may conduct specific audits of Part D sponsors' implementation of the program as well.

PCMA requests clarity about the type of audits CMS proposes to use in monitoring plan compliance on M3P. We request that plans have some flexibility during the first couple years of the program, and this allows for CMS to consider how best to address initial M3P program related complaints and grievances.

**PCMA Recommendation: CMS should allow for a grace period when addressing M3P program related complaints and grievances.**



## **VII. Conclusion**

We appreciate the opportunity to provide this feedback to CMS on ways to address M3P implementation for the first year. Our concerns and discussion focus on timing constraints, administrative complexities and the risk of beneficiary confusion mostly. If you need any additional information, please reach out to me at [tdube@pcmanet.org](mailto:tdube@pcmanet.org).

Sincerely,

*Tim Dube*

Tim Dube  
Senior Vice President, Policy and Regulatory Insights

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs

**March 15, 2023**

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

Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-8016

**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.

\* \* \* \*

## **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.igvia.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/pa-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.

\* \* \* \*

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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Meiti Negari

Senior Director, Policy & Research



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Kristin Williams

Senior Manager, Policy & Research



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**Submitted Electronically to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)**

March 16, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
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Meena Seshamani, M.D., Ph.D.  
Deputy Administrator  
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**RE: Medicare Prescription Payment Plan Guidance Part Two**

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

The Protecting Innovation in Rare Cancers (PIRC) coalition appreciates the opportunity to provide feedback and recommendations on the Centers for Medicare & Medicaid Services' (CMS') draft part two guidance proposing policies and mechanisms for implementing the Medicare Prescription Payment Plan program created under Section 11202 of the Inflation Reduction Act (Social Security Act Section 1860D-2(b)(2)(E) (the Program).

PIRC is a collaborative, multi-stakeholder, patient advocacy coalition focused on improving access to and affordability of existing treatments while preserving the incentives required to advance future innovations in rare cancers. The coalition seeks to fulfill an important role in exchanging information and collaborating toward educating both our rare cancer communities



Protecting Innovation In Rare Cancer  
[www.rarecancerira.org](http://www.rarecancerira.org)

and policymakers on the impact the Inflation Reduction Act (IRA) might have on access to existing Part D drugs and development of new therapeutic options.

Cancer patients can face significant challenges in affording their prescribed treatments. Since rare cancer patients typically have fewer effective therapeutic options, unaffordable out-of-pocket costs can be catastrophic. The IRA's enactment of a more affordable Part D out-of-pocket cap, combined with an available option for Part D enrollees to participate in a payment plan will make a real difference for Medicare beneficiaries and their families as they fight cancer. We look forward to working with the Agency in educating our rare cancer communities about these changes.

We appreciate that CMS' draft guidance seeks to strike a balance between timely outreach and participation election for beneficiaries and manageable implementation of this new Program for Part D plans and sponsors. We focus our comments and recommendations on refinements that align with the real-world experience of rare cancer patients and the Program's intended goal of ensuring that all Medicare patients and their families can base treatment decisions on their needs rather than their financial resources.

We look forward to working with CMS to ensure that all rare cancer patients who might benefit from the Program have the information they need to decide whether and when to opt in.

#### **General Outreach, Education, and Communication Requirements for Part D Sponsors**

PIRC appreciates that CMS has emphasized the need for informational uniformity and clarity through multiple messaging channels in crafting Part D plan outreach and education requirements. We agree that CMS-created model notices, forms, and beneficiary communications will be crucial to effective outreach and urge CMS to publish these resources in draft to enable stakeholder feedback.

We also support CMS' requirement that plans provide their enrollees with Program information on their websites as well as within the Part D materials currently furnished to enrollees, including mailings of membership ID cards, explanation of benefits (EOB), Annual Notice of Change (ANOC), and Evidence of Coverage (EOC) documents. We are concerned, however, that the routine nature of these mailings might increase the likelihood that enrollees will overlook important information on Program availability and opt-in mechanisms. We strongly recommend that CMS require plans to make this "new" information conspicuous by including notification

language on the envelope where it can easily be seen as well as on the first page of any document(s).

We also urge CMS to require plans to include:

- A clear explanation of each mechanism for opting into the Program, with steps clearly outlined. Potential participants should, for example, be informed of the timeline for receipt and processing of their request when submitted online, by telephone, or by mail.
- Availability of a real-time opt-in mechanism through which participants can fully complete all participation requirements and receive a unique confirmation number that can be used at the pharmacy counter or in communications with their plan.
- A calculator tool in addition to examples of how the Program works so that Medicare beneficiaries can have an estimate of their monthly costs under the Program based on their prescribed medications.

We similarly urge CMS to:

- Include Program information on the plan finder tool that beneficiaries and their families are accustomed to using when selecting their Part D plan.
- Append the “Medicare & You” handbook to include educational content related to the program and provide a phone number and website that beneficiaries can use to learn more about the program.
- Consider broadcasting Public Service Announcements similar to those used to inform individuals about availability of Affordable Care Act coverage and enrollment deadlines.
- Include prescribers within outreach and education initiatives so that physician offices have the resources they need to discuss the program with their patients.
- Develop a set of informational materials tailored for use by pharmacies to educate beneficiaries about the program in advance of the 2025 plan year so that beneficiaries can make a timely decision on whether to opt-in and initiate their participation at the start of the plan year when it is of greatest benefit.

### ***Requirements for Targeted Outreach***

PIRC agrees that increased outreach and education efforts targeted toward individuals most likely to benefit from the Program will be essential to Program success, especially in its initial years. We appreciate that CMS seeks to provide these individuals with multiple, meaningful opportunities to review Program materials and opt into participation. We support CMS' requirement that plans review enrollee prescription drug expenditures for previous plan years and target outreach to their enrollees with historically high out-of-pocket costs.

We also agree that the later a beneficiary opts into the Program, the less likely they are to benefit from participation. These individuals may, however, benefit from opting in for the next plan year and, for beneficiaries meeting "likely to benefit" criteria in the fourth quarter, we urge CMS to require that plans give these individuals an opportunity to opt in for either/both the current and next plan year.

Similarly, we support targeted outreach during the plan year based on prior authorization requests for costly treatments. Unfortunately, Program information and participation forms delivered by mail are unlikely to reach the enrollee by the time their prescription is ready for pickup. We believe these individuals need to understand that there is an alternative to paying the full out-of-pocket costs or declining to pick up the prescription. While the ability to pay at the pharmacy counter and ask for a refund based on retroactive participation in the Program may be helpful for some individuals, far too many patients will be unable to do so. We strongly urge CMS to require that plans use a notification mechanism such as telephone contact to provide Program information and enable a real-time opt-in mechanism.

We also urge CMS to require that plan efforts to identify enrollees likely to benefit from the program focus beyond costs associated with a single prescription. Medicare beneficiaries with rare cancers often fill multiple prescriptions each month – to treat their cancer, manage side effects or treat other chronic conditions. It is common for a patient to reach their out-of-pocket maximum during the first quarter of a plan year without receiving any medications that have exceptionally high out-of-pocket costs. We were disappointed that CMS' final Part One Guidance contained a single-fill threshold of \$600 and ask that that plans calculate the costs of all prescriptions presented or filled on a single day toward the single-fill threshold.

PIRC similarly believes that pharmacies may be the most critical point of contact for Medicare beneficiaries as they can provide real-time information on the out-of-pocket costs associated with a pending prescription and give patients the information they need to opt into the Program when participation is likely to convey a meaningful benefit. Ideally, a beneficiary would

have an opportunity to opt in through online or telephone participation mechanisms, receive a confirmation number from their plan, and pick up their prescription(s) without paying at the pharmacy counter.

### ***Election Requirements***

PIRC understands that the recently finalized Part One guidance contains election process requirements that intersect with the draft Part Two guidance. We strongly urge CMS to reconsider its decision to delay implementation of a point of service (pharmacy counter) election mechanism and, at a minimum, enable real-time 2025 plan year elections with participation effective as of the date and time the election is made. As you know, access to prescribed medications is particularly critical for cancer patients and too many individuals with rare cancers have been unable to afford the treatment that best suits their needs. For our patients, the ability to spread costs over the year can make the difference between knowing that they can start and stay on their prescribed treatment and having to choose between paying for life-extending treatments and being able to afford their housing, transportation, and food. Any uncertainties, delays, or requirements for multiple interactions within the opt-in process that result in delayed access to treatment will perpetuate the financial stressors the program seeks to avoid. We expect that these delays, requirements that beneficiaries pay at the pharmacy counter after opting in, and uncertainties in when enrollment is effective will reduce confidence in the benefits of participation in future years.

We understand that the IRA requires plans to make the program available to all their enrollees and appreciate that CMS has declined to adopt stakeholder recommendations to delay or limit the Program. With the exception of nonpayment of a prior year's monthly payment obligations, there is no clear statutory basis for any plan to decline any enrollee's opt-in request. This does not apply during the 2025 plan year. Although plans may require a period of time to process requests and update their systems, the time to perform these ministerial tasks should not impact the patient or their ability to receive their medications at the pharmacy counter and be billed on a monthly basis for their out-of-pocket costs. We applaud CMS' for the proposal that plans issue a confirmation number to enrollees completing their Program election and urge the Agency to outline a simple mechanism through which beneficiaries can present their member ID and Program election confirmation number to the pharmacy counter when they pick up their medications.

We similarly believe that offering a point of sale (POS) opt-in process will ensure that patients facing prohibitive costs when filling their prescription can immediately elect to participate in



the program and fill their prescriptions without delays related to financial burdens. The processes outlined in CMS' Part One guidance for plans to determine whether a prescription is urgent create additional layers of Program complexity and will burden clinicians with additional paperwork beyond the prior authorization documentation hurdles they currently navigate. Rare cancer patients urgently need all of their prescribed treatments and a streamlined election process with real-time effect would alleviate the burden on clinicians and plans associated with determining whether a particular treatment is "urgent" for a particular patient.

Finally, we expect that a POS election option would be particularly helpful in streamlining elections for future years. For example, a pharmacy filling a prescription for a Program participant during the last quarter of the plan year could prompt the patient on whether they intend to opt into the Program for the next calendar year and offer real-time election to opt-in or terminate participation as well as information on the election process if the beneficiary has not yet decided. This would streamline the process for Medicare beneficiaries who may assume that both their plan enrollment and program participation continue from year-to-year.

***Program details on which our patient communities have requested additional information.***

PIRC's rare cancer communities have expressed an interest in having greater clarity from CMS on:

- How drug "returns" due to intolerable side effects or lack of response to treatment would impact the monthly payment amount. This is particularly important within the context of rare cancer patients since the out-of-pocket costs associated with a single prescription could quickly reach the \$2,000 cap, and treatment alternatives may be limited to Part B drugs.
  - o Would participants be issued a refund for returned product?
  - o Could patients be required to continue paying for a drug they stopped using?
  - o How would this work within the context of a 3-month mail order fill, versus a single prescription purchased at the pharmacy counter?
- How participants can avoid termination during the grace period if they become current on payments.
  - o Will CMS encourage plans to spread the past-due amount(s) over remaining plan months rather than allow them to require a larger lump sum payment?
  - o We urge CMS to encourage that plans provide participants with at least one opportunity per plan year to catch up on missed payments by requesting a

recalculation that evenly distributes their missed monthly payments over the remaining months of the plan year.

## **Conclusion**

Once again, the undersigned organizations appreciate the opportunity to comment on CMS' part two guidance outlining CMS intended implementation of the Medicare Prescription Payment Plan. We look forward to continuing to work with you in ensuring that all Medicare beneficiaries, including those with rare cancers, can receive the treatments they need without financial hardships associated with high out-of-pocket costs. Please contact us at [info@rarecancerira.org](mailto:info@rarecancerira.org) or our policy advisor, Saira Sultan, JD, at [ssultan@cillsociety.org](mailto:ssultan@cillsociety.org) with any questions.

Sincerely,

Biomarker Collaborative  
CancerCare  
Cancer Support Community  
Chondrosarcoma Foundation  
CLL Society  
Cutaneous Lymphoma Foundation  
Desmoid Tumor Research Foundation  
Exon 20 Group  
Hope For Stomach Cancer  
ICAN, International Cancer Advocacy Network  
MET Crusaders  
No Stomach for Cancer  
Ovarian Cancer Research Alliance (OCRA)  
PD-L1 Amplifieds  
PTEN Foundation (Hamartoma Tumor Syndrome Foundation)  
The Healing NET Foundation  
The Life Raft Group

March 15, 2024

Meena Seshamani, M.D., Ph.D.  
Director, Center for Medicare  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**Re: Medicare Prescription Payment Plan (M3P) Draft Part Two Guidance**

Dear Dr. Seshamani,

Point32Health welcomes the opportunity to provide insights on the Medicare Prescription Payment Plan (M3P) Part Two Guidance. The Inflation Reduction Act of 2022 included many important provisions impacting Medicare Advantage and Part D members. We are committed to collaborating with CMS to optimize these benefits for our members and to assure implementation is as smooth and seamless as possible.

**Who We Are**

Point32Health is a leading health and well-being organization, delivering an ever-better healthcare experience to everyone in our communities. Building on the quality, nonprofit heritage of our founding organizations, Tufts Health Plan and Harvard Pilgrim Health Care, we leverage our experience and expertise to help people find their version of healthier living through a broad range of health plans and tools that make navigating health and wellbeing easier.

Our programs take a 360-degree view of health for our members -- no matter their age, health, identity, or income. Our Foundation works with communities to support, advocate, and advance healthier lives for everyone and our Institute works to improve population health. We use empathy to understand what is important to those we serve, always making their priorities our own. We work to guide and empower people by bringing together wide-ranging partners and perspectives to create new approaches that make a real difference for both our industry and our 2.1 million members across the United States. We are proud that Harvard Pilgrim Health Care Commercial (HMO, POS, PPO, Exchange – HMO) plans in Massachusetts and Maine, and Tufts Health Public Plans Medicaid and Exchange HMO plans were the first plans in New England to achieve the National Committee for Quality Assurance (NCQA) Health Equity Accreditation. And we are consistently a highly rated Medicare Advantage plan. For eight years, from Star Year 2016 to Star Year 2023, our Tufts Medicare Preferred HMO plan received a 5-star rating from the Centers for Medicare & Medicaid Services, the highest rating possible.

We are proud that Point32Health was recently recognized for the second year in a row as one of the 50 most community-minded companies in the nation by Points of Light, the world's largest nonprofit dedicated to volunteer service. A national standard for corporate citizenship, the Civic 50 showcases

how leading companies are incorporating social impact, civic engagement, and community integration into their practices and values.

### The Value of Medicare Advantage and Part D Plans to Beneficiaries

We are proud to cover over 144,000 Medicare Advantage and Dual Eligible Plan members. Most of our products integrate critical Part D benefits seamlessly with Medicare coverage for our members. This simplifies the health care system for our members as they only need to carry one card to access both medical and pharmacy benefits. They also benefit because our case management and other quality management programs incorporate both medical and pharmacy needs. Our high quality ratings historically allow us to use a portion of our bonus rebate dollars to keep Part D premiums affordable.

Our two dual eligible plans are uniquely designed so that our Senior Care Options (SCO) plan serves individuals 65 and over whereas our OneCare plan serves individuals who qualify for Medicare based on disability. In Connecticut, our joint venture harnesses the expertise of Hartford HealthCare and Tufts Health Plan, aligning physicians, hospitals, and a health plan together to improve quality and care coordination through a Medicare Advantage plan entitled CarePartners of Connecticut.

Our beneficiaries enjoy a wide range of innovative benefits and services. For instance, this year our members in CarePartners as well as those in our Massachusetts Medicare Advantage and Dual Eligible plans enjoy a unique Behavioral Health Service Navigation program. This program helps members navigate the complex mental healthcare system through enhanced personalized interactions. When members call into the customer service line with a need for mental health care help, they are provided a warm connection to our specialty Behavioral Health Service Navigation team. There, we help members obtain timely behavioral health appointments. We also educate members about other services, such as our innovative digital tools that support behavioral health. Our team's goal is to ensure our members receive the right behavioral health service at the right time. All these efforts support the advancement of health equity. The feedback we have received on the program is phenomenal. Members feel the program has changed their lives and matched them with providers with whom they can connect. About 90% of the members involved in the program are seeking help to locate a provider. Typically, our service navigators, on average, execute 12 calls for each navigation episode.

For specific assistance in navigating pharmacy needs, our behavioral health care management and pharmacy teams work hand-in-hand to assist members who encounter obstacles. Our members struggling with mental health or substance use have access to peer specialists, who can help them navigate their complex health needs and access care. Members are matched with peer specialists with similar lived experiences to help guide them to resources in the community. Our behavioral health team also features a dedicated nurse practitioner specializing in behavioral health, who can collaborate with other care management teams and provide consults for patients with behavioral health needs, including accessing medication and pharmacy needs.

### Our Comments on the Advance Notice

In 2025, several important Part D changes will take effect and we are committed to optimizing our members' experience accessing these new benefits and programs. The Medicare Prescription Payment Plan (M3P) is an important one of these programs. However, we also recognize that the breadth and complexity of some changes may confuse members. We urge CMS to keep this in mind and to partner with health plans to mitigate confusion and maximize understanding and appreciation of the new benefits.

## I. Election Mechanisms

The draft Part Two Guidance says "Part D sponsors must accept election requests they receive regardless of the format of the request (e.g. a letter or email.) If required information is missing, sponsors must contact the enrollee to collect all necessary information and document their agreement to the Part D sponsor's terms and conditions. The Part One Guidance requires Part D sponsors to allow Part D enrollees to opt into the M3P through several mechanisms, including: a form as part of the member ID card issuance, a paper option that can be mailed, a toll-free telephone number, and a website.

Given the M3P program is new and unfamiliar to many individuals, we encourage CMS to construct first year enrollment mechanisms that will further member satisfaction and program success. We caution CMS against setting consumer expectations that they can enroll "any way" into the M3P program. Instead, we recommend limiting first year enrollment to: 1) as part of their annual MA/Part D enrollment or through a triggered special enrollment period; 2) via a toll-free number or, 3) through a website. If all beneficiaries are directed to these specific mechanisms, it will allow Part D sponsors to create uniform, positive experiences with the new program. If beneficiaries are told they can enroll "any way" and submit paper requests, emails, or other random communications, they are likely to be disappointed with the results. For instance, paper submissions or emails are at a high risk of missing critical information. While Part D sponsors would be responsible for telephonic outreach, the reality is that it is increasingly difficult to reach members on their telephones. In addition, members may fail to receive or understand the messages left, or may be frustrated by the follow-up necessary. On the other hand, if CMS sends a clear message to beneficiaries that they have very specific avenues to opt in to M3P -- their initial enrollment process, a call into a toll-free line, or a website -- those mechanisms contain built-in quality controls to assure that all necessary information is collected at the same time. This will expedite enrollment and increase the likelihood that members will view the new program positively.

- **Recommendation:** To optimize beneficiary enrollment experience into M3P, we recommend limiting election mechanisms to:
  - As part of their initial annual enrollment (or through a triggered special enrollment period)
  - Through a toll-free telephone number

- Via a website

**II. “Likely to Benefit” Members:** Prior to Plan Year: CMS applies responsibilities on Part D sponsors to identify individuals who are “likely to benefit” from the M3P prior to enrollment for 2025 as well as throughout the plan year.

**Prior To Plan Year:** To identify Part D enrollees likely to benefit in advance of the plan year, Part D sponsors are required to assess their current Part D enrollees’ prescription drug costs from the current year and conduct outreach to Part D enrollees who incurred \$2,000 in out of pocket (OOP) costs for covered drugs through September of that year. During the fourth quarter, Part D sponsors must review their Part D claims history from the first three quarters of the year to identify Part D enrollees likely to benefit in the upcoming year. Sponsors must notify each such Part D enrollee in writing that they are likely to benefit from the M3P, using the standardized Likely to Benefit Notice and additional information about the program no later than the end of the Annual Election Period. The initial notice may be provided via telephone, so long as the written notice and additional information are sent within three calendar days of the telephone notification.

- **Recommendation:** Point32Health recommends that CMS grant flexibility to plans in terms of how and when they communicate information to members. There are numerous changes that members will face in 2025. In order to maximize understanding and minimize confusion, plans must carefully craft and orchestrate communications in an integrated manner. For instance, for the first time in 2025, annual out of pocket costs will be capped at \$2,000 for Part D members. Rather than require one-off notices, we urge CMS to allow and encourage plans to construct communications that explain new benefits and programs in a coordinated manner. Multiple, disconnected notices are likely to be ignored by members, trigger confusion or be viewed with annoyance. We urge CMS to collaborate with plans to build a foundation where members will be introduced to M3P – and other new benefits – in a positive manner.

**Throughout the Plan Year:** If Part D sponsors have prior authorization or other utilization management edits in place for a drug that, based on their benefit structure, would result in out of pocket costs above the pharmacy point of service notification threshold, then the Part D sponsor must undertake outreach to the Part D enrollee, informing them of the M3P and of the opportunity to opt into the program. Part D sponsors must provide the “Likely to Benefit Notice” within the same timeframe that applies to the coverage determination for the associated utilization management requirement, in writing either by mail or electronically, as well as information about the M3P. Initial notice may be provided via telephone, so long as the written “Medicare Prescription Payment Plan Likely to Benefit Notice” and additional information are sent within three calendar days of the telephone notification.

- **Recommendation:** When plans generate an approval in response to a prior authorization request, it will be beneficial for members to also receive information on the M3P program and how to enroll. We support requirements that plan sponsors bundle their approval notification with M3P information. However, if the prior authorization review results in a denial, we recommend against the inclusion of information on the M3P. In that scenario, inclusion of the

information is likely to confuse the member and potentially lead them to think they have financial protections when they do not.

**Pharmacies:** Part D Sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs Out of Pocket (OOP) costs with respect to covered Part D drugs that make it likely they would benefit from participating in the M3P program. Part D sponsors must ensure that a pharmacy, after receiving such a notification, provides the member with the standard “Likely to Benefit Notice.” In pharmacy settings that have direct contact with enrollees, the Part D sponsor must ensure that *a hard copy* of the Likely to Benefit Notice is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. Regardless of the setting, if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the Part D sponsor must ensure that the pharmacy provides the Likely to Benefit Notice to the Part D enrollee.

- **Recommendation:** The objective of point of service interactions with patients should be to assure they understand how to enroll in the M3P program of *their* health plan. We are concerned that the distribution of paper information by pharmacies could result in confusion for patients (since they need information specific to their health plan) as well as a significant waste of paper. Individuals have become accustomed to receiving point of service notifications as part of a computer payment screen for HIPAA and similar notifications. We recommend that M3P enrollment information be incorporated into a HIPAA-like screen. The messaging should be fairly simple such as: “You May Be Eligible to Pay Your Pharmacy Costs Gradually Throughout the Year. Call the toll-free number on your membership card to obtain more information from your insurer or enroll in the program.” Individuals could be prompted to click that they have read the notification.

**III. The Timing of Specific Required Notices:** CMS will require Plan Sponsors to provide a series of new notifications to members as a result of M3P. CMS provides unique timing requirements for different notifications and scenarios.

**Notice of Acceptance of Election (30.3.2):** Within 10 calendar days of receiving an individual’s request to participate in M3P, the plan must communicate to the member one of the following: 1) an acceptance with an effective date; 2) a request for additional information; or, 3) denial of the request with a reason specified. CMS is developing a model notice of acceptance, to be released in summer 2024. If additional information is requested, individuals have 21 calendar days to submit the information before the application can be denied.

- **Recommendation:** As mentioned above, we urge CMS to direct beneficiaries to enroll for 2025 through 1) their initial annual enrollment process (or a triggered special enrollment period); 2) a toll-free number or 3) a website. Expansion beyond these specific avenues is likely to lead to frustrated beneficiaries. From a practical standpoint, it will be difficult for Part D sponsors to meet a 10-day calendar timeline for requests that are sent through problematic mechanisms such as random emails or paper submissions. Separately, we are concerned that CMS has not

submitted to a specific date for release of the standard notice. We ask CMS recognize that plans need to know the content of this notice by May 6 in order to have it operational by the time that open enrollment begins in a reasonably efficient manner.

**Notice of Failure to Pay /Notice of Termination:** If a Part D sponsor determines that a participant has failed to pay a monthly billed M3P amount, the Part D sponsor must send the individual an initial notice explaining that the individual has failed to pay the M3P billed amount within 15 calendar days of the payment due date. CMS is developing a “Failure to Pay” model notice, to be released in summer 2024. Individuals will have a two-month grace period during which they will continue to be actively part of the M3P program. Following the end of the grace period, Part D sponsors may terminate the individual from the M3P program. However, the draft guidance would require a termination notice be sent within three calendar days after the end of the grace period. CMS is developing a model termination notice, to be released in summer 2024.

- **Recommendation:** If an individual fails to make their M3P payments throughout their two-month grace period, they would receive two “Failure to Pay” notices during that time period. Presumably, the CMS model notice will specifically warn individuals that they will be disenrolled from the program if they do not meet specified payment deadlines. This is reasonable to give individuals more than one notice to explain the repercussions of nonpayment. However, CMS proposes that the actual termination notice be sent within *three* calendar days of the end of the grace period. This short of a timespan will create significant administrative burdens for the health plan when the individual already has received two prior notices regarding the gravity of the situation. We recommend that health plans have a minimum of seven calendar days to generate the ultimate notice of termination.

**IV. Non-Retail Pharmacies:** CMS outlines several pharmacy scenarios and associated Part D Sponsor responsibilities. Because long-term care pharmacies typically do not have a point of service (POS) encounter between the pharmacy and the enrollee and instead often engage in retrospective or post-consumption billing, Part D sponsors can require the long-term care pharmacy to provide the notice to the Part D enrollee at the time of its typical billing process. For pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. CMS encourages Part D sponsors to work with pharmacies to establish and maintain reasonable procedures related to the timing and number of attempts for prompt notification of identified Part D enrollees

- **Recommendation:** We recommend that mail-order pharmacies also be required to include written information on the M3P as part of their shipments to individuals that have not yet enrolled in the program. The written information should include specific details regarding the appropriate telephone number and website avenues for enrollment specific to the individual’s plan.



## V. Financial Impacts

**Part D Bidding Guidance for CY2025 (60.1):** Any unsettled balances with respect to amounts owed by participants under the MPPP are treated as plan losses. Only uncompensated unsettled balances can be included in the bid; if a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells an unsettled balance as a debt, it cannot treat the amount as a loss and cannot include it in its bid. The Part D bid pricing tool will be modified to reflect projected losses associated with the MPPP.

- **Recommendations:** Given the unprecedented nature of the M3P program for insurers, it will be difficult to accurately predict future unsettled balances in the 2025 bid process. We encourage CMS to partner with plans to develop options to mitigate potential financial volatility that may occur as a result of numerous unknown variables such as: How many individuals will enroll in the program? How many will fail to make their M3P payments? Will some individuals attempt to “game” the system by switching health plans in order to restart the M3P process? Plan sponsors lack data on many of the variables associated with this new program. Therefore, predictions may or may not be accurate or significantly off from final experience. We encourage CMS to consider reconciliation options, risk corridor options or other policy options to mitigate the impact of this uncertainty.

**Medical Loss Ratio Instructions (MLR):** Consistent with the inclusion of plan losses in the administrative expense portion of the Part D bid, unsettled balances will be considered administrative costs for the purposes of the MLR calculation and therefore be excluded from the MLR numerator.”

- **Recommendation:** Regarding the Medical Loss Ratio Instructions, we urge CMS to allow these losses to be reflected in the benefit portion of the MLR. These dollars reflect payments made to cover pharmaceuticals, which are clearly medically related services. These dollars should be considered as part of the MLR numerator.

## VI. Standard Forms

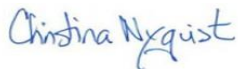
**Notice for Part D Enrollees Likely to Benefit:** CMS is developing a standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” that Part D sponsors must send to members likely to benefit. When performed outside the pharmacy POS notification process, the notice may be sent via mail or electronically. The notice will be developed through the OMB ICR process and will be released in summer 2024 ahead of the 2025 AEP.

- **Recommendation:** Point32Health recommends that CMS grant flexibility to plans in terms of how and when they communicate information to members. There are numerous changes that members will face in 2025. In order to maximize understanding and minimize confusion, plans must carefully craft and orchestrate communications in an integrated manner. For instance, for the first time in 2025, annual out of pocket costs will be capped at \$2,000 for Part D members. Rather than require one-off notices, we urge CMS to allow and encourage plans to construct communications that explain new benefits and programs in a coordinated manner. Multiple, disconnected notices are likely to be ignored by members, trigger confusion or be viewed with

annoyance. We urge CMS to collaborate with plans to build a foundation where members will be introduced to M3P – and other new benefits – in a positive manner. Importantly, we also urge CMS to release this form by May 6. There are numerous steps involved in preparing for open enrollment, and it is critical for plans to have this information by May 6 in order to assure member communications are ready for open enrollment in a reasonably efficient manner.

We appreciate the opportunity to comment on these important proposals by CMS. Please let us know if we can provide any additional support as you move forward with your objective of improving the Medicare Advantage program for the enrollees that we serve. For additional information, please contact me at [Christina.Nyquist@point32health.org](mailto:Christina.Nyquist@point32health.org)

Sincerely,



Christina Nyquist

Vice President, Federal Affairs

Good afternoon,

Please find questions/comments that Priority Health/Corewell Health has compiled surrounding the Medicare Prescription Payment Plan Guidance (Part 2):

- Medicare Prescription Payment Plan Participation Request Form
  - o Will this be used in addition to addition to the Part D Member Enrollment Form, or will we only use the M3P Participation Request Form?
- MARx
  - o Can you provide additional clarification around what we will need to submit to MARx as “transmitting election information,” and what it will be used for?
- Unpaid Balance
  - o Will plans be made aware of members who have left a different plan with an unpaid balance from the Medicare Prescription Payment Plan Program?
- Appeals
  - o Can you please give some examples around what would be an appeal and the process for handling these appeals? How is this different than Good Cause for re-entry or participation in the program?

Thank you,

Candice Niesen, JD

Senior Compliance Liaison

1231 East Beltline Ave. NE

Grand Rapids, MI 49525

(M) 616.295.5076

March 15, 2024

Dr. Meena Seshamani  
Deputy Administrator and Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

*Submitted via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)*

**RE: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part Two  
Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025**

**Dear Dr. Seshamani:**

Sanford Health Plan – a Midwest-based integrated health plan a part of the Sanford Health family – offers our members a broad array of products, including commercial health insurance products on and off the ACA exchange, third-party administrator services, and a recently launched Medicare Advantage plan. Sanford Health Plan’s Medicare Advantage plan – Align powered by Sanford Health Plan – recently received a 4.5-star rating from the Centers for Medicare and Medicaid Services (CMS) for the 2024 plan year for its plans available in North Dakota, South Dakota and Iowa, placing them among the highest-rated in the region as well as the nation. Apart from our nearly unheard of first ever 4.5 MA Star rating, our Medicare Advantage plan is committed to being nimble, adaptive, and responsive to the unique needs of our members – many of whom live in rural areas.

People living in rural America face unique challenges. They are more likely to have fewer resources to access care and experience higher rates of poverty, food insecurity and chronic disease – which often lead to poorer health outcomes. At Sanford Health, two-thirds of our patients live in rural communities across America’s heartland, and five out of the top 25 poorest counties in the U.S. are also located in our footprint. Our promise to those we have the privilege of serving is that their care won’t be limited by their zip code. We’re committed to removing barriers to access, addressing health disparities, serving our communities and investing in the people and places of our region to improve quality of life for all – no matter where people live or the health challenges they face.

Sanford Health Plan is encouraged and applauds the efforts of CMS to address the rising costs of prescription drugs and the challenges those costs bring to the Medicare population. However, Sanford Health Plan continues to have concerns about implementing and operationalizing the requirements of the Inflation Reduction Act as it relates to the Medicare Prescription Payment Plan. In particular, challenges and questions remain on how Medicare Advantage plans will obtain payment from members and feels that this will place such plans in a position similar to debt collectors. To be clear, Sanford Health Plan supports ways that allow our members access to needed medications, but the reality is that implementing the requirements to comply with the Inflation Reduction Act and guidance while also maintaining high levels of member satisfaction will be extremely challenging.

Below, please find Sanford Health Plan's comments in response to the Draft Part Two Guidance on the Medicare Prescription Payment plan.

### **Education, Outreach, and Communication With Members Likely to Benefit**

Sanford Health Plan appreciates that CMS is actively developing model documents for Medicare Advantage plans to use to inform, educate and communicate with plan members. These materials and their development are critical for health plans to comply with and implement the requirements of the Inflation Reduction Act, along with guidance of CMS. With these documents under development, the timing in which they are made available, along with upcoming product development will be key to successful implementation. Sanford Health Plan, along with other Medicare Advantage Plans, are currently developing products for the 2025 plan year – this includes collateral such as education materials and other marketing items. Under the draft guidance, CMS indicates that the primary method of sending the model Medicare Prescription Drug Payment Plan notice will be through the ID card issuance mailing. However, Sanford Health Plan requests additional flexibility with this requirement. Health plans may not reissue new ID cards each plan year and to require health plans to mail each existing member a new card and information on the program would be operationally burdensome and increase spending. Specifically, if CMS is to proceed with the ID card mailing as the primary method of notification and communication, that requirement should be deferred until 2026. In alignment with the stated objective of CMS to ensure members are notified of program eligibility prior to going to the pharmacy counter, health plans should also be afforded the opportunity to send materials prior to the ID card issuance. Sometimes, ID cards are not reissued every year and may not be sent until immediately prior to the start of the plan year. By affording additional flexibility to plans to send materials, health plans and members will be better equipped to inform, educate, and communicate with members.

### **Communication With Pharmacies, Pharmacists, and Plan Members**

Sanford Health Plan agrees with CMS that pharmacists and pharmacies play a critical role – not only in implementing the requirements of the Inflation Reduction Act and guidance – but also every day that they assist members with questions, provide information and deliver much needed services. Rural health care delivery and coverage raises unique questions. For example, not all pharmacists or pharmacies may be operating on the same electronic platforms for the purposes of communication or notification. With this nuance, health plans will need to adapt and be nimble in notifying and communicating with pharmacies in administering the Medicare Prescription Payment Plan. Sanford Health Plan stands ready to work with our pharmacy partners; however, we also wanted to express the unique challenge that rural health care brings to this new coverage requirement.

### **General Comments and Feedback**

Sanford Health Plan again wants to highlight our commitment to provide high-quality coverage and access to care – especially in a primarily rural footprint. This extends to prescription drug coverage and ensuring members are able to obtain needed medication. The Biden Administration, CMS and others are pressing the pharmaceutical industry to address the rising costs of prescription drugs. The Medicare Prescription Payment Plan, in its entirety, presents unique challenges for health plans to comply and meet the objective of CMS to lower monthly out of pocket costs for plan members. Looking ahead, we stand ready to implement the coverage requirements, but also acknowledge that it will take time to understand member

engagement in this program, utilization and effect on administrative expenses for this program. With this uncertainty, Sanford Health Plan would request additional projections and estimates that may be used in the calculation of bids and MLR for the initial program year. In addition, Sanford Health Plan requests that CMS consider soliciting additional feedback from health plans, pharmacies and members after the initial plan year to consider revisiting previously issued guidance and whether changes may need to be made.

In conclusion, Sanford Health Plan appreciates the opportunity to provide comments on the draft guidance. We stand ready to help CMS, our members and other stakeholders to work towards an efficient and member-centric Medicare Advantage plan – including the Medicare Prescription Payment Plan. Should CMS have additional questions or wish to discuss our comments in detail, please reach out to Dylan Wheeler, Head of Government Affairs, at [dylan.wheeler@sanfordhealth.org](mailto:dylan.wheeler@sanfordhealth.org).

Respectfully Submitted,

Sanford Health Plan



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VIA ELECTRONIC SUBMISSION: [Regulations.gov](https://www.regulations.gov)

March 15, 2024

Department of Health & Human Services (HHS)  
Centers for Medicare & Medicaid Services (CMS)  
7500 Security Boulevard, Mail Stop C4-26-05  
Baltimore, MD 21244-1850

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

Dear Reviewer:

SCAN Health Plan (SCAN) is pleased to submit comments in response to the Medicare Prescription Payment Plan (MPPP) Draft Part Two Guidance. The Inflation Reduction Act (IRA) makes the most substantial changes to the Part D program since the creation of the benefit. SCAN appreciates CMS' efforts to solicit stakeholder feedback as the agency implements various parts of this law, including the MPPP. SCAN also appreciates CMS' efforts to develop model language and documents that allows Part D sponsors to comply with several of the requirements included in this guidance. SCAN urges CMS to publish such language and documents as soon as possible to ensure plans incorporate these materials into applicable beneficiary communications. Further, SCAN thanks CMS for its efforts to target MPPP toward enrollees who are most likely to benefit. We recognize the challenge of administering a program that allows for all enrollees to opt-in to the program. SCAN urges Congress to modify MPPP to limit enrollment to non-LIS Part D enrollees and encourages CMS to continue to evolve the program to ensure only enrollees most likely to benefit opt-in.

The following includes background on SCAN and comments on selected provisions in the Draft Program Instructions.

**I. SCAN Background**

SCAN Health Plan, one of the nation's foremost not-for-profit MA plans, serves over 280,000 members in California. SCAN Desert Health Plan and SCAN Health Plan also provide MA coverage to Medicare beneficiaries in Arizona, Nevada, New Mexico, and Texas. Independence at Home, a SCAN community service, provides vitally needed services and support to seniors and their caregivers free of charge and regardless of plan membership. Additionally, SCAN and Commonwealth Care Alliance have partnered to launch myPlace Health, an integrated care delivery organization that will specialize in providing personalized care to older adults who wish to remain living in their homes and communities for as long as possible. A risk-bearing care delivery platform, myPlace Health will deliver services to vulnerable older adults through the Program for All-Inclusive Care for the Elderly (PACE) model and as a value-based provider working in partnership with local health plans.

**II. Comments on Selected Provisions**

**Section 30.1.1 Required Mailings with Membership ID Card Issuance**

**CMS Proposal:** CMS will require Part D sponsors to include with the membership ID card hard copy mailing information regarding the Medicare Prescription Payment Plan and a Medicare Prescription Payment Plan election request form.

**SCAN Response:** SCAN urges CMS to reconsider this requirement to reduce confusion among enrollees, especially Low-Income Subsidy (LIS)-eligible enrollees. SCAN believes the other requirements in Section 30 of this guidance that provide additional avenues for enrollees to become familiar with MPPP (e.g., sections 30.1.2, 30.1.3, 30.1.4) are adequate. Requiring plans to include information alongside membership ID cards is burdensome and costly for plans. More importantly, it may confuse LIS enrollees and runs counter to CMS' goals of steering low-income enrollees toward LIS and away from MPPP. As CMS knows, the information provided when an enrollee receives his/her ID card does not include any information on LIS. If members receive information on MPPP (but not LIS), a low-income member may be inclined to enroll in MPPP even though this member is not likely to benefit from the program.

### **Section 30.1.5 Part D Sponsor Website**

**CMS Proposal:** CMS will require Part D sponsors to include information on the Medicare Prescription Payment Plan on their websites, including an itemized list of ten categories of information.

**SCAN Response:** SCAN appreciates CMS' efforts to provide standardized and/or sample language to assist plans in meeting other requirements described in this guidance. Similar to those provisions, SCAN urges CMS to provide standardized language to plan sponsors that could be used to meet the requirements of this section.

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

**CMS Proposal:** CMS will require Part D sponsors to review their Part D claims history from the first three quarters of the year to identify Part D enrollees likely to benefit in the upcoming year. Plan sponsors will be required to send notifications to enrollees identified as likely to benefit no later than the end of the Annual Election Period (open enrollment), which is December 7 of each year.

**SCAN Response:** SCAN supports this general policy and process outlined by CMS. However, SCAN urges CMS to provide plan sponsors flexibility in the first year of implementation. Specifically, SCAN urges CMS to extend this notification deadline to December 31<sup>st</sup> (rather than December 7<sup>th</sup>). We believe this will still allow enrollees who are likely to benefit from MPPP to enroll in the program in time for the new plan year and for prescriptions filled in January 2025 and provide plans to finalize the necessary communication and other requirements for the first year of implementation.

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

**CMS Proposal:** CMS will require Part D sponsors, if they have prior authorization or other utilization management edits in place for a drug that, based on their benefit structure, would result in OOP costs above the pharmacy POS notification threshold, then the Part D sponsor must undertake outreach to the Part D enrollee, informing them of the Medicare Prescription Payment Plan and of the opportunity to opt into the program.



**SCAN Response:** SCAN is concerned about the potential confusion this requirement may cause enrollees. Specifically, CMS may be requiring a plan to provide conflicting information to an enrollee simultaneously: 1) a denial of a coverage determination/appeal and 2) an alternative way to pay for such drug through MPPP. In place of this requirement, SCAN urges CMS to consider adding language related to MPPP enrollment to the standard coverage determinations and/or appeal approval letter templates. In this circumstance, enrollees receive clearer information about plan coverage of a drug and the options provided by MPPP.

### **Section 30.3.1 Overview of Election Requirements**

**CMS Proposal:** CMS will encourage Part D sponsors to provide support tailored to the potential participant's unique situation and clearly communicate to enrollees when it appears that they are less likely to benefit from the program (e.g., enrollees with low-to-moderate recurring OOP drug costs).

**SCAN Response:** SCAN appreciates CMS' efforts to provide standardized and/or sample language to assist plans in meeting other requirements described in this guidance. SCAN urges CMS to provide plans with standardized language for enrollees that are unlikely to benefit from opting into the program.

### **Section 30.3.5 Notice of Voluntary Termination**

**CMS Proposal:** CMS will require Part D sponsors to allow enrollees who have opted-in to MPPP to voluntarily disenroll. Enrollees who disenroll have the option of continuing their monthly payments or providing the plan a lump sum payment. However, CMS will prohibit plans from requiring a lump sum payment upon voluntary disenrollment.

**SCAN Response:** SCAN supports enrollees' ability to voluntarily disenroll from MPPP. However, SCAN is concerned that allowing for continued monthly payments, even though the enrollee has disenrolled, will lead to an increase in enrollees failing to pay all expected monthly payments. Higher rates of non-payment will lead to an accumulation of bad debt by the plans. SCAN urges CMS to allow enrollees to voluntarily disenroll from MPPP but, if done so, require enrollees to make a lump sum payment for any remaining payments that would otherwise be paid in monthly amounts.

### **Section 50.4 Readjudication of Prescription Drug Claims for New Program Participants**

**CMS Proposal:** CMS indicates that for claims to be processed appropriately using the MPPP BIN/PCN methodology, the date of service on the primary Part D claim and the additional program-specific transaction must be on or after the date of program effectuation. As such, when a Part D enrollee leaves the pharmacy without their prescription(s) after receiving the "Medicare Prescription Payment Plan Likely to Benefit Notice", and returns after successfully signing up for the program, CMS will require the pharmacy to readjudicate all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary to allow for appropriate processing by the Part D sponsor and/or PBM.

**SCAN Response:** SCAN is concerned with this policy and urges CMS to reconsider this requirement. While Part D sponsors would be aware of which claims have been adjudicated, for plan oversight purposes, they would not have insight into which prescriptions have been picked up and paid for by the Part D enrollee. In addition, the requirement to readjudicate all claims from prior dates of service that

have not yet been picked up and paid for by the enrollee has the potential to be extremely burdensome for pharmacies.

### **Section 50.5.1 Long-Term Care Pharmacies**

**CMS Proposal:** CMS will encourage Part D sponsors to work with an enrollee who has opted-in to MPPP, their authorized representative, and the long-term care pharmacy to understand the best billing approach for the enrollee.

**SCAN Response:** SCAN appreciates CMS' discussion of operationalizing MPPP in various pharmacy settings. SCAN encourages CMS to analyze the implementation of MPPP in the LTC setting during and after the first year of the program to understand if there is a high rate of uncollected amounts. If so, SCAN encourages CMS to provide specific policy guidance for future years of the program.

### **Section 60.1 Part D Bidding Guidance for CY 2025**

**CMS Proposal:** CMS indicates that the Part D bid pricing tool (BPT) will be modified to reflect projected losses associated with the MPPP. The Agency specifies that these losses must be reflected as administrative costs in the Part D BPT.

**SCAN Response:** SCAN is very concerned about the level of uncertainty related to the overall costs associated with MPPP and the bad debt due to non-payment from enrollees who opt-in to the program. SCAN encourages CMS to provide plans with estimates from the Office of the Actuary on the expected bad debt to be input in the CY 2025 plan bids. Further, SCAN encourages CMS to publish information related to bad debt during CY 2025 that could inform CY 2026 plan bids.

### **Section 60.2 Medical Loss Ratio (MLR) Instructions**

**CMS Proposal:** CMS will require that any plan losses due to unsettled balances from MPPP will be considered administrative costs for purposes of the MLR calculation and will be excluded from the numerator.

**SCAN Response:** SCAN urges CMS to reconsider this policy and allow for plan losses to be included in the numerator of the MLR calculations. Unlike other administrative costs excluded from the numerator of the MLR calculation, plan losses are outside the control of the plan. Plans have limited ability to aggressively pursue unpaid monthly payments from enrollees, and SCAN is not in favor of such an approach. Given that all Part D enrollees are permitted to enroll in MPPP, it is unfair to potentially penalize plans due to circumstances outside of their control. SCAN urges CMS to treat unsettled balances like other claims for MLR purposes and reevaluate this policy once CMS and plans have more certainty regarding the percent of monthly payments owed that go unpaid under MPPP.

### **Section 60.4 Audits**

**CMS Proposal:** CMS indicates that the agency and/or its contractors may conduct audits of Part D sponsors' implementation of the MPPP.

**SCAN Response:** SCAN appreciates CMS' efforts to ensure program integrity. SCAN urges CMS to take into account the novelty and complexity of the MPPP implementation and any forego any audit activities



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to assess the first year MPPP implementation, but rather publish the MPPP best implementation practices for the plans.

Thank you for the opportunity to submit comments on the Draft Guidance. SCAN truly appreciates your commitment to improving the health of older adults and vulnerable populations and hopes you will take our comments into consideration. Please do not hesitate to contact me at [sjhawar@scanhealthplan.com](mailto:sjhawar@scanhealthplan.com) if you would like additional information.

Sincerely,

A handwritten signature in black ink that reads "Sharon K. Jhawar". The signature is written in a cursive, flowing style.

Sharon K. Jhawar, PharmD, MBA, BCGP  
Chief Pharmacy Officer  
SCAN Health Plan

To Whom It May Concern:

After reading the Part Two Guidance we have one comment regarding Identifying Part D Enrollees Likely to Benefit During the Plan Year (30.2.2.2). In this section it states that a Part D plan is required to perform targeted outreach to a beneficiary if they become aware of a new high-cost prescription. The guidance then mentions if a Part D plan receives a PA or Exception request the plan should perform this outreach.

Outreach to any beneficiary that puts in a request for coverage would likely cause a lot of confusion and even encourage beneficiaries to elect into the Medicare Prescription Payment Plan when it will not be in their best interest. For example, if a beneficiary puts in a request for a high-cost drug, but is denied due to not meeting criteria, it will not be helpful to them to receive information on the Program or to elect into the Program. Especially where many prior authorization and formulary exception requests are denied due to failure of the beneficiary to try a lower cost drug first. As such, could this guidance be modified to state that a Part D plan is required to perform targeted outreach to a beneficiary that is *approved* for a high-cost drug? This would then encourage a beneficiary to elect the Program only when they are able to fill a high-cost drug. This would also give the Part D plan an opportunity to educate the beneficiary with a phone call to state since their medication was approved and will have a high out of pocket cost, they will likely benefit from election into the Program.

Thank you for your consideration.

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**Mike Eaton, PharmD**

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March 15, 2024

**Submitted via Electronic Filing: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)**

Meena Seshamani, M.D., Ph.D.  
CMS Deputy Administrator and Director of the Center for Medicare  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-8016  
Attn: PO Box 8016

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

Dear Dr. Seshamani:

The Senior Care Pharmacy Coalition (“SCPC”) appreciates the opportunity to provide comments on the February 15, 2024 memorandum issued by the Centers for Medicare & Medicaid Services (“CMS”), entitled *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* (the “Draft Guidance”), and particularly Sections 50.3.1 and 50.4 of the Draft Guidance. While we appreciate that the Draft Guidance recognizes there is no “point of sale” for long-term care (LTC) pharmacy, the Draft still does not properly account either for how LTC pharmacies dispense first and collect co-pays later, or the process by which LTC pharmacies adjudicate claims.

For these reasons, more fully explained below, **we urge CMS to revise Sections 50.3.1 to clarify that Plans should not require LTC pharmacies to provide beneficiary notices.** The Draft Guidance’s proposals for LTC pharmacies remain unnecessarily complex and costly, and will not benefit beneficiaries, pharmacies, or the Medicare program. Rather, it is likely to cause significant more work for LTC pharmacies that at a minimum will need to re-adjudicate claims and will cause beneficiary confusion.

**About SCPC:** SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 75% of all independent LTC pharmacies. Our members serve one million residents daily in skilled nursing facilities and assisted living communities across the country. Given the distinct characteristics of the LTC patient population and the enhanced clinical responsibilities of LTC pharmacies, we offer unique perspectives on CMS' initiatives and proposals, particularly how Medicare Prescription Drug Benefit (Part D) policies and requirements impact Part D enrollees with institutional level of care needs and the LTC pharmacies that serve them.

**Full Benefit Dual Eligible ("FBDE") Residents of LTC Facilities Should be Categorically Exempt from the Guidance's Proposed Pharmacy Requirements:** Before addressing the specifics of the Proposed Guidance, we again urge CMS to recognize and acknowledge that residents of long-term care facilities, including both residents of skilled nursing facilities and assisted living facilities, typically are dually-eligible for both Medicare and Medicaid, and as such *do not pay co-pays* on their medications. Consequently, many of the proposals in the Draft Guidance are not relevant to the LTC patient population or to LTC pharmacies. **We urge CMS to clarify the final guidance will not apply to FBDEs residing in LTC facilities.**

Since LTC pharmacies also serve Part D beneficiaries residing in assisted living facilities and other community-based settings, including at home, we address other concerns about the Draft Guidance below.

**Section 50.3.1 – LTC Pharmacy Notice Requirements:** SCPC appreciates the agency's acknowledgement of its prior comments that there is no "point of sale" in most LTC pharmacy transactions, and is grateful for the agency's statement that: "[l]ong-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident)." We also appreciate that CMS recognizes that "the pharmacy delivers medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee)." We thank the agency for its conclusion that, as regards LTC pharmacy, "the plan sponsor is not required to ensure that the long-term care pharmacy provides the "Medicare Prescription Payment Plan Likely to Benefit Notice" prior to dispensing the medication," urge the agency to finalize that conclusion, and urge the agency to clarify that the conclusion applies to all types of long-term care facilities including assisted living facilities and other congregate living facilities as well as patients residing at home but requiring LTC pharmacy services.

We are, however, still concerned about the Draft Guidance statement that the "the plan sponsor can require the long-term care pharmacy to provide the notice to the Part D enrollee at the time of its typical billing process" and the confusing use of "not require" and "can require." Further, it is unclear what CMS means by "the typical billing process." The draft could be read as meaning either the billing to the plan or the typical billing of co-payments to beneficiaries. Further, there remain many instances where even during the billing process there is no direct communication with the beneficiary.

For these reasons, we urge the agency to rewrite the last two sentences of the paragraph as follows (redlined text shown):

Long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident). In these cases, the pharmacy delivers medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee). As such, ~~when the POS notification is received by a long-term care pharmacy,~~ the plan sponsor ~~should not require~~ is not required to ensure that the long-term care pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” or any other related notification prior to dispensing the medication. Instead, the plan sponsor can ~~require request~~ the long-term care pharmacy attempt to provide the notice to the Part D enrollee (or their representative) at the time of its typical co-payment billing process.

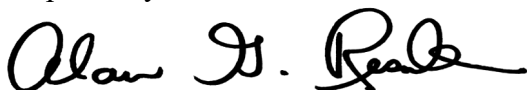
We believe these changes will more accurately reflect how LTC pharmacies operate and interact with beneficiaries, and will more appropriately guide all stakeholders on whether and how the “Likely to Benefit” notice should be circulated.

**Section 50.4 -- Readjudication:** The proposed guidance also includes a readjudication section pertaining to cases where a beneficiary presents a prescription at a retail setting but declines to purchase the drug and then later makes a Payment Plan election. Because this scenario never occurs in the LTC pharmacy context given that LTC pharmacies dispense first and bill later, we urge the agency to address LTC pharmacy in Section 50.4 and to clarify that no readjudication is required of LTC pharmacies.

\*\*\*\*\*

Thank you for your consideration. If you have questions or wish to discuss our comments, please feel free to contact me at [arosenbloom@seniorcarepharmacies.org](mailto:arosenbloom@seniorcarepharmacies.org) or (717) 503-0516.

Respectfully submitted,



Alan G. Rosenbloom  
President & CEO  
Senior Care Pharmacy Coalition

# Special Needs ——— ——— Plan Alliance

Via Electronic Submission: [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

March 15, 2024

Meena Seshamani, M.D., Ph.D.,  
CMS Deputy Administrator and Director of the Center for Medicare  
DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

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

Dear Dr. Seshamani,

The Special Needs Plan (SNP) Alliance is a national, non-profit leadership association addressing the needs of high-risk and high-cost populations through specialized managed care. We represent 26 health plans offering over 550 plan benefit packages (PBPs) and 175 contracts through special needs plans (SNPs) and Medicare-Medicaid demonstration plans (MMPs). These plans have over 3 million beneficiaries enrolled in 47 states and the District of Columbia— totaling more than 55% of the national SNP and MMP (Medicare Medicaid Plan) enrollment. Our primary goals are to improve the quality of service and care outcomes for complex populations and to advance integration for those dually eligible for Medicare and Medicaid.

As SNP plans continue to grow throughout the country, the SNP Alliance stands ready to work closely with CMS on strategies to clearly explain options to low-income vulnerable populations with complex care needs. The SNP Alliance would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on Part One of the Medicare Prescription Payment Plan (MP3) guidance. In Part One, the SNP Alliance highlighted the crucial importance of the outreach and education process for Part D enrollees about the program. We want to continue our efforts to accentuate how the MP3 program will be detrimental to special needs plan (SNP) beneficiaries.

Specifically, the SNP Alliance would like to articulate the impacts that the MP3 Program will have on dual-eligible beneficiaries, or D-SNP beneficiaries. D-SNPs enrollees have complex medical, pharmacological, and social needs. They are also low-income individuals. Due to their socio-economic status, almost all D-SNP enrollees utilize Low Income Subsidy (LIS) which helps people with Medicare pay for prescription drugs and lowers the costs of Medicare prescription drug coverage. Most Medicare members with LIS pay \$0 for prescription drugs.

Many D-SNP enrollees lack the financial resources to pay for their prescriptions now. In fact, lots of D-SNP members may be unaware they are already enrolled in an LIS program—they are enrolled automatically based on meeting existing eligibility. They assume that their health plan's Part D coverage has \$0 prescription drug costs. The SNP Alliance is concerned about the current language within the MP3 program which offers Medicare enrollees already utilizing Low Income Subsidy (LIS) the opportunity to switch to the MP3



# Special Needs ——— ——— Plan Alliance

program. CMS has stated in Parts One and Two of this guidance that the MP3 program will not be the best choice for most of those eligible for LIS programs. Individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the MP3 program even if they do have nominal copays for prescription drugs. It is anticipated that few D-SNP beneficiaries will be able to receive help from the MP3 program.

However, this knowledge may not trickle down. The current language does not account for unique situations and policies for special needs plans, particularly dual-eligible special needs plans (D-SNPs). The SNP Alliance is concerned that outreach, education, and communications that do not address D-SNP beneficiaries will lead to chaos and confusion for the plans we represent and the enrollees we serve. CMS is asking D-SNPs to pay to implement a program that none of our members will ever use. In the comments of the rule the last sentence says, “Part D sponsors must identify Part D enrollees likely to benefit from the program and educate those enrollees on the impacts of potentially participating in the Medicare Prescription Payment Plan.” Since none of D-SNP members would benefit from the MP3 program, we take this language to mean health plans with D-SNPs will be implementing a program their beneficiaries will never use.

We urge CMS to clarify that MP3 program is not applicable to D-SNPs when there is no Part D cost-share. Without truly explicit guidance from CMS concerning the beneficiaries that will benefit from the program and those beneficiaries that should be excluded from the program, implementation of the MP3 program will elicit beneficiary complaints and confusion in the first year (2025) not programmatic success nor beneficiary prescription cost savings. The SNP Alliance is concerned that inclusion of D-SNP members when there is no practical applicability to them will cause significant confusion.

Support and assistance with our comments, please contact Regan Hunt, SNP Alliance Associate Director of Health Policy, at [rhunt@snpalliance.org](mailto:rhunt@snpalliance.org).

Sincerely,

*Michael Cheek*

Michael W. Cheek  
President & CEO

# Special Needs ——— ——— Plan Alliance

The SNP Alliance has outlined our comments and concerns below.

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

The SNP Alliance commends CMS for its efforts to consistent communication strategy and consistent language about the Medicare Prescription Payment Plan publicized in all CMS model documents. The education and outreach requirements aim to integrate the new MP3 program into current Part D education, outreach, and enrollment processes to create a seamless experience for Part D enrollees. Additionally, the SNP Alliance would like to suggest that if CMS does not explicitly clarify that MP3 program does not include D-SNP enrollees, CMS may need to allow separate but consistent materials targeted to these D-SNP members, especially for those enrolled in integrated Medicare-Medicaid plans.

The SNP Alliance continues to request that model documents and newly developed materials outline the similarities and differences between the LIS program and the MP3 program. Clearly delineating both programs' eligibility criteria and programmatic benefits. Additionally, we urge CMS to clarify that MP3 does not apply if the individual's cost-sharing will always be minimums (i.e., LIS beneficiaries, certain duals). This would prevent confusion and potentially improper enrollment by these individuals.

Likewise, we urge the development of an out-of-pocket calculator for Medicare beneficiaries to use as a comparison for participation in Medicare Prescription Payment Plan program with other programs (particularly LIS). A calculator would allow Medicare beneficiaries the chance to see if their medication costs, cost-sharing amounts calculations, and monthly amount billed meet the MP3 threshold for participation. Whether this calculator is crafted by CMS or by each Plan D sponsor, the SNP Alliance feels a that proposed calculator would be a great resource and tool, not just for Medicare beneficiaries to see month by month "Does the MP3 Program Benefit Participant This Month?", but also for other stakeholders who may be assisting an individual to assess if the MP3 program is appropriate.

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

### **D-SNPs**

If CMS does not explicitly clarify that MP3 program does not include D-SNP enrollees, then CMS needs to provide additional, detailed outreach and educational materials for the D-SNP population. The SNP Alliance really wants to emphasize and reiterate the need for ongoing and extensive education. Determining the best fit program is paramount and crucial for D-SNP members, especially to the large number of LIS members including dually eligible individuals for whom the new MPPP program may not be appropriate.

Low education levels<sup>1</sup> and low health literacy comprehension is likely to create potential confusion about the MP3 program option. There is and will continue to be a lack of understanding from D-SNP LIS eligible enrollees about which option is best for them. As previously mentioned, many D-SNP members may already be enrolled in LIS and may not even be aware that they are already enrolled. At Open Enrollment or any other valid enrollment period for special needs plans, enrollees may be encouraged to try the MP3 program from an enrollment entity, not realizing the prescription drug coverage and programmatic loss

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<sup>1</sup> [Differences in care between Special Needs Plans and other Medicare coverage for dual-eligibles - PMC \(nih.gov\)](#)

# Special Needs ——— Plan Alliance

they will experience in leaving LIS.

Education on the MP3 program needs to be simple. Education needs to address the intent of MP3, programmatic requirements, and other CMS program options available such as Low-Income Subsidy (LIS) and should be developed for enrollees, community education groups such as Area Agencies on Aging (AAAs) and State Health Insurance Programs (SHIPs), and insurance brokers who enrollee individuals.

These materials need to:

1. provide robust communication tools to support the dually eligible population in their decision-making.
2. assess the impacts to LIS/dual eligible beneficiaries, including information that LIS is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.
3. addresses the loss of coverage—dual eligible, LIS, or MA—and how the health plans could screen and educate only those losing eligibility status to determine whether they are still eligible for LIS or could benefit from the MP3 program.

## **C-SNPs**

Chronic Condition Special Needs Plans (C-SNPs) are SNPs that restrict enrollment to special needs individuals with specific severe or disabling chronic conditions, defined in 42 CFR 422.2. Section 1859(b)(6)(B)(iii) of the Act and 42 CFR 422.2 define special needs individuals with severe or disabling chronic conditions as special needs individuals “who have one or more co-morbid and medically complex chronic conditions that are substantially disabling or life threatening; have a high risk of hospitalization or other significant adverse health outcomes; and require specialized delivery systems across domains of care.” Currently there are fifteen (15) SNP-specific chronic conditions that health plans structure a C-SNP around.<sup>2</sup> Additionally, health plans can build and group multi-condition C-SNPs (more than one chronic condition together) or develop their own multi-condition C-SNP.

Due to their chronic conditions, C-SNP enrollees may have recurring medication and prescription drug costs that could benefit from the Medicare Prescription Payment Plan. C-SNP beneficiaries will accumulate costs throughout the year. Those out of pocket (OOP) costs will add up and possibly meet the annual OOP cost threshold (\$2,000) amount for a calendar year in earlier in the remaining months.

As of March 2024, there are over 682,000 C-SNP beneficiaries enrolled in C-SNP plans in the United States.<sup>3</sup> There should be concerted efforts to connect with Chronic Condition Special Needs Plans (C-SNPs) and C-SNP members not on LIS regarding the MP3 program.

Education and materials should be provided on LIS, for those who qualify, and on the MP3 program. Information on recent the LIS expansion of eligibility, how to apply and enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs), and participation in the Medicare Prescription Payment Plan (MP3).

Associations that support those chronic conditions such as such the American Diabetes Association or American Heart Association are good conduits for outreach and education opportunities.

## **50. Pharmacy Processes**

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<sup>2</sup> [Chronic Condition Special Needs Plans \(C-SNPs\) | CMS](#)

<sup>3</sup> [SNP Comprehensive Report 2024 03 | CMS](#)

# Special Needs ——— ——— Plan Alliance

Pharmacies play a crucial role in operationalizing the Medicare Prescription Payment Plan. Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs out of pocket (OOP) costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program.

In the draft part one guidance for the Medicare Prescription Payment Plan, CMS stated that the likely to benefit notification required at the pharmacy point of sale (POS) will be based on the OOP costs incurred for a single prescription. The SNP Alliance encourages CMS to produce standardized language for pharmacies to notify patients at the point of sale on MP3 enrollment. We want to ensure that all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including, but not limited to, mail order, home infusion, specialty, and long-term care pharmacies.

## **50.3.1 Long-Term Care Pharmacies and 50.5.1 Long-Term Care Pharmacies**

In addition to serving D-SNP and C-SNP populations, the SNP Alliance also represents institutional and institutional-equivalent (I-/IE-SNP) beneficiaries. I-SNP beneficiaries reside in long-term care settings and often receive their medications from on-site pharmacies. Long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident).

The SNP Alliance asks that CMS provide clear information to Part D sponsors, health plans, facilities, I-SNP beneficiaries (and their authorized representatives), and the long-term care pharmacy when devising MP3 program billing practices and policies.



March 16, 2024

The Honorable Meena Seshamani, M.D., Ph.D.,  
Deputy Administrator and Director of the Center for Medicare  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Deputy Administrator Seshamani,

I am writing on behalf of Susan G. Komen (Komen) to comment on the Centers for Medicare and Medicaid Services' (CMS) Draft Part Two Guidance on the Medicare Prescription Payment Plan (MPPP). We appreciate the opportunity to comment on behalf of the breast cancer community. Komen is the world's leading nonprofit breast cancer organization representing the millions of people who have been diagnosed with breast cancer. Komen has an unmatched, comprehensive 360-degree approach to fighting this disease across all fronts—we advocate for patients, drive research breakthroughs, improve access to high quality care, offer direct patient support and empower people with trustworthy information. Komen is committed to supporting those affected by breast cancer today, while tirelessly searching for tomorrow's cures. We advocate on behalf of the estimated 313,510 people in the United States who will be diagnosed with breast cancer and the almost 43,000 who will die from the disease in 2024 alone.

Komen and the millions of breast cancer patients, survivors and co-survivors that we represent, are extremely supportive of the MPPP as well as the \$2,000 cap on out-of-pocket (OOP) spending under Medicare Part D. This long has been a policy priority for Komen and the broader breast cancer community. The costs of cancer treatment in the U.S. are astronomically high and expected to rise, increasing the burden for patients. More and more stakeholders in the cancer community are recognizing the financial toxicity associated with adhering to treatment as prescribed, which can not only expose patients to financial ruin but also can negatively affect their health if they are forced to delay or stop treatment or make suboptimal treatment decisions due to cost. Komen is grateful for the creation of the MPPP to help address the financial challenges associated with breast cancer care, and we know that CMS shares our goal to ensure that patients benefit as much as possible from the new law. Please find Komen's comments on the Draft Part Two MPPP Guidance below.

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

Under General Outreach and Education, CMS outlines a long list of documents that will be used to educate enrollees on the MPPP as well as numerous ways that these documents will be shared with enrollees. The guidance, in many places, gives plans the option of using CMS-developed resources to meet the requirements around outreach and education or allows the plans to develop and use alternative informational materials. If plans choose to develop their own materials, CMS states that they

must accurately convey the program information and be compliant with the existing Part D requirements.

Komen is concerned that a lack of standardized language and/or materials could lead to confusion and inconsistencies and urges CMS to require that plans use the CMS-developed materials. Further, we are concerned that the compliance monitoring of individual plans' documents regarding the MPPP could pose a significant administrative burden.

If, however, it is finalized that plans are able to develop their own materials, CMS should outline a process by which these materials will be reviewed periodically to ensure that they accurately convey the program information and meet the language access and accessibility requirements outlined in this guidance.

### **Identifying Part D Enrollees Likely to Benefit**

Because of the structure of the MPPP, it is clear that not all Part D enrollees will benefit from participation in the program in a given year. Both the Part One and Part Two Guidances discuss the potential that an enrollee will not benefit if a high-cost medication is prescribed in the last quarter of the year.

The Part Two Guidance states that enrollees should *not* be notified that they are likely to benefit in the last month of the plan year. Komen supports this policy but thinks that more is needed to protect patients flagged for participation in the program in the last *quarter* of the year, not just the last month. Komen requests that CMS require plans to include greater detail for any enrollee flagged in the last quarter of a year regarding the specifics of how the MPPP works and why the timing of when an enrollee joins the program is so important. We encourage CMS to create an online calculator that enrollees could use to better understand what his/her costs will be under the MPPP. This calculator should be available via the CMS website in addition to Part D plan websites and the existence of such a resource should be promoted in MPPP materials. It should be made clear to the enrollee that while he/she may not benefit in this particular calendar year, if he/she is going to continue on this high-cost medication, the MPPP may be a good fit for them in the following year. Komen believes that the MPPP will help to reduce the financial burden currently faced by many in the Medicare Part D program but does not want the program to result in an enrollee actually paying more OOP than they would have outside of the MPPP.

Komen encourages CMS to collect data on the implementation of the MPPP particularly when it comes to better understanding when an enrollee will benefit from the program. For example, data collected on enrollees who are unlikely to benefit based either on when they join the program or because of the cost of the medication they took would be beneficial as the program moves forward in order to successfully be able to identify cohorts. Komen also encourages CMS to collect and track data related to demographics, most common drugs, median costs, and other elements related to the assessment of health equity, especially for those who are involuntarily disenrolled. This information will help CMS better tailor the program in future years.

### **Failure to Pay/Notice of Termination**

Komen wants to ensure that enrollees will have ample warning prior to being terminated from the program. Based on what is included in the Part One and Part Two Guidance, enrollees will receive an initial notice explaining that he/she has failed to pay the billed amount within 15 calendar days of that payment due date. This will be followed by a grace period of at least two months during which time the enrollee cannot be terminated from the program, even if that grace period carries over into a new year.

The notice of termination must be sent within three calendar days after the end the grace period. Komen does not believe it is sufficient to only provide one notice to the enrollee prior to the enrollee being terminated. We request that CMS require additional notices to be sent to the enrollee during the grace period explaining that failure to pay by a certain date will result in termination from the MPPP.

**Conclusion**

Komen looks forward to working with CMS to ensure smooth implementation of MPPP and is eager to partner with the agency to help educate the breast cancer community on this program. Please contact Valerie Nelson, Komen's Manager of Federal Policy and Advocacy, at [vnelson@komen.org](mailto:vnelson@komen.org) with any questions or if we can otherwise be helpful.

Sincerely,



Molly Guthrie  
Vice President, Policy & Advocacy  
Susan G. Komen

March 15, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW, Room 445-G  
Washington, DC 20201

Re: Medicare Prescription Payment Plan (MPPP) Draft Part Two Guidance on Select Topics

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the Medicare Prescription Payment Plan (MPPP) Draft Part Two Guidance on Select Topics. This guidance mostly describes the outreach and education, pharmacy processes and operational considerations for the program.

The Teachers' Retirement System of the State of Kentucky (TRS) has 38,000 retired Kentucky teachers on a self-funded stand-alone Medicare Part D EGWP. TRS pays a PBM to administer the Part D EGWP via a flat administration fee per covered lives per month and has paid the net cost of drugs (AWP + dispensing fee – discounts and – member cost share) directly to the PBM on a bimonthly basis for decades now. The net cost represents the TRS obligation for drug spend only after member cost share at retail and member cost share at mail have been secured directly by the retail pharmacy or the mail-order pharmacy. These personal consumer transactions at POS retail and POS mail are between that for-profit pharmacy and the purchasing consumer, which in the case of TRS's members are retired teachers. So, any financing of the members' cost share at mail or retail should be handled by the pharmacy filling the prescription. This transaction normally happens via a charge to a personal credit card or by involving the members' banking institution. TRS has never paid or advanced the TRS retirees' cost share using funds from the 115 trust because by state and federal law only the plan obligation can be paid as indicated in the TRS Draft Part 1 comments submitted in September 2023.

Inside the trust, funds are from retirees, active teachers, the state and the federal government — none of which legally can be used by responsible fiduciaries to pay the personal debt of a retiree — be that drug cost share or monthly utilities. This also does not happen in Medicare Advantage where the members' copayments, coinsurances and deductibles must be transmitted to the doctor or hospital at the time of service. Again, any financing of the medical cost-share transactions would be handled by the hospital or doctor's office and the patient, not TRS. On the TRS Medicare Advantage plan, TRS retirees must remit a \$150 annual medical deductible and a 4% coinsurance for all covered medical services, and a \$200 inpatient hospital copayment is paid by the patient at the time of admittance. The maximum annual out of pocket for medical services is \$1,200 and is financed solely between the hospital/doctor provider and the patient. TRS is not, and should not, be involved.



Unlike EGWPs, if an individual Part D policy has a high out-of-pocket maximum, CMS has already fixed that with the \$2,000 cap beginning in 2025. The easiest way to smooth the \$2,000 is through an actuarial analysis establishing minimum and maximum copayments for each drug utilized by retirees on the individual Part D open market plans. Of course, Part D plan sponsors on the open market will simply increase their monthly premiums to account for the smoothing, which the consumer will have to pay.

TRS is supplying the comments above to show concrete examples of concerns raised in the TRS September 2023 comments. Through this letter and that of September 2023, TRS requests a meeting with the appropriate personnel at HHS to discuss this further and the legal complications it presents at the next earliest convenience of HHS.

In addition to the legal issues of the trust fund and breaching fiduciary responsibility, TRS also is concerned about the potential reversal in drug utilization trends that TRS has worked so hard to achieve through benefit plan design and distribution channel design. These are industry best practices in running a cost-effective and valuable drug plan. For over 20 years, TRS has allowed retired teachers to use mail order where they have zero annual deductible and can get a 90-day supply of a preferred generic for \$10 and a 90-day supply of a preferred brand drug for \$20. The TRS benefit design at mail order is smoother and cheaper for the retiree than what HHS is proposing in the MPPP. TRS retirees have achieved a 54% day-supply utilization rate at mail order among approximately 2.3 million total annual prescriptions because of this plan design. The TRS contracts require much deeper discounts off AWP at mail order vs. retail, as mail order is a win for both the retiree and the plan. Mail order is a necessary distribution channel in terms of contactless access and cost, particularly given the experience of the recent pandemic with TRS's population being in higher risk groups.

TRS is concerned that the zero cost for the patient once the \$2,000 MOOP is reached, will result in a steep cost increase to TRS, and ultimately retired teachers, because retirees no longer have any incentive to continue to use mail order. TRS currently has almost a 90% generic fill rate and almost a 99% brand formulary compliance rate. The TRS plan design does cover Medicare-approved and required non-preferred drugs at a 50% coinsurance since 2014, known as tier 3. If a retiree reaches the \$2,000 MOOP and now has a zero-cost share, then no incentive would encourage the retiree to take the lower-cost, but equally effective formulary and generic drugs approved by Medicare, which erodes the whole reason for a formulary and the promotion of generic drugs, setting TRS and Medicare back almost three decades. Zero cost share at the retail POS and mail POS causes higher utilization because retirees will not understand the complicated MPPP calculations they're being forced to pay on their credit cards. If this proceeds, it would be helpful to allow TRS to use the formulary flexibilities already utilized and successful in commercial plans nationwide. This compromise would offset the valid utilization concerns being raised and allow EGWPs to remove all non-preferred brands and non-preferred generics from the formulary, placing the non-preferred drugs in a non-covered status. The Medicare approved formulary that TRS uses already has drugs representing all therapeutic categories in tier one and tier two.

The above represents huge paradigm shifts in the use of trust funds and cost containment methodologies through drug utilization patterns already accomplished by TRS and other EGWPs, and TRS would like for HHS/CMS to revisit these changes nationwide for EGWPs. As a final general comment, TRS is concerned this MPPP effort does not reduce the already soaring prices of prescription drugs, starting with the original list prices of drugs as established by the manufacturers. These MPPP efforts slice the drug-cost pie in different fractional pieces. They do not decrease the cost or original size of the pie.

Below are the more specific TRS comments to the sections in Part II Guidance relative to the outreach and education, pharmacy processes and operational considerations for the MPPP program.

- On page 10 (bottom) of the Part II Draft Guidance, HHS states the following:

*Section 60.2.1 of the draft part one guidance presented by CMS standardized framework for assessing “likely to benefit.” Specifically, we state that to be “likely to benefit” from the program, the Part D enrollee would have to incur some level of substantial OOP costs. Further, the Part D enrollee’s highest monthly OOP cost incurred would be more than the highest monthly paid amount under the Medicare Prescription Payment Plan (if the program had applied).*

The TRS benefit design at mail order for tier 1 and 2 is smoother and cheaper for the retiree than what HHS is proposing in the MPPP. Even if only for mail order tier 1 and 2, CMS using its waiver authority allowing TRS and other EGWPs not to require the MPPP would be helpful.

- On 30.2.2.1 Identifying Part D Enrollees Likely to Benefit Prior to the Plan Year, CMS states:

*...That is balanced, however, by a desire to limit notifications to Part D enrollees who are not likely to benefit from participation in the program.*

TRS shares the concerns about limiting notifications and the resulting confusion. Of TRS’s 38,000 retired teachers, the average age is 74. About 9,000 are older than 80 and 1,300 are older than 90.

- TRS would like to thank CMS for acknowledging that no proactive, specific notifications are required for those who may never benefit from MPPP.
- TRS is also supportive that retirees are not invited to participate in the MPPP when there is only one month left to smooth in the calendar year.
- TRS is also supportive that the MPPP not delay or change the prior authorization, coverage determination, and utilization management processes already in place, making sure that the retirees do not have to wait longer at mail or retail to pick up the prescription.

- TRS does not support inviting LIS retirees to participate in the MPPP when CMS acknowledges that LIS is more advantageous than participation in the MPPP, which also effectively acknowledges that it is a waste of time to invite a retiree who will not benefit. (See last sentence of 30.3.1 *Overview of Election Requirements*.) All LIS retirees nationwide should be completely exempted from MPPP.
- Limiting notifications supports CMS using its waiver authority to allow the TRS mail-order program tier 1 and tier 2 to be waived from the MPPP requirements, again, because the TRS mail-order program for preferred drugs is actuarially better than MPPP.
- On 30.3.5 *Notice of Voluntary Termination*, CMS provides that once a Part D enrollee voluntarily terminates from MPPP, the Part D sponsor must work with the enrollee to determine how they will pay their outstanding balance, which may include a lump sum payment; however, Part D sponsors cannot require full immediate repayment upon voluntary termination.

Whether a participant voluntarily terminates, loses Medicare eligibility or, as is frequently the case for a retirement system, dies, the proposal forces the trust to violate its legal, fiduciary duty by accepting an IOU that in many cases can never be repaid. Also, retroactive approval of an election at POS into the MPPP could force Part D plan sponsors to make spontaneous reimbursements. All of these scenarios force Part D plan sponsors – and by extension TRS’s retired teachers – to become financial institutions that are loaning funds interest free that belong to a trust and may never be repaid.

- On 60.1, *Part D Bidding Guidance for CY 2025*, CMS indicates that:

*Part D sponsors are required to treat any unsettled balances with respect to amounts owed by participants under the MPPP as plan losses. In addition, the statute requires that the HHS Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids. If a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells and unsettled balance as debt, it cannot treat the amount as a loss and cannot include it in its bid. Only uncompensated unsettled balances can be included in the bid.*

*Given the changes, the Part D bid pricing tool will be modified to reflect projected losses associated with the MPPP. Specifically, these losses must be reflected as administrative costs in the Part D bid pricing tool.*

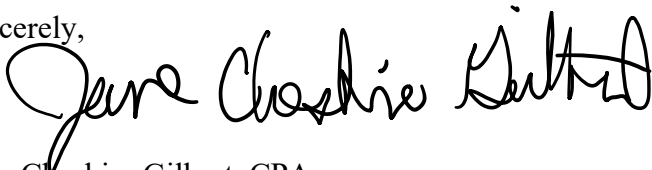
As CMS knows, EGWPs do not submit bids, but rely on the national bid average that will be unknown until July or August of this year. While CMS allows for projected bad debt in the

individual plan bids – and that gives some assurance that individual Part D plans will be made whole – this is not a guarantee for EGWPs. Self-funded EGWPs will still owe these uncollected amounts to the PBM whether it is called bad debt or administrative fees, forcing the 115 trust – and by extension the TRS Kentucky’s retired teachers – to pay for the personal debts of TRS Part D enrollees.

TRS is sure that the desire by CMS is to keep group customized Part D EGWPs as an option for large groups of retirees because, if EGWPs cease offering coverage to retirees and place retirees on the Medicare Part D open market, it was estimated to increase annual Medicare reinsurance liabilities by up to \$3 billion based on a study that was done before the recent Part D restructuring placing more obligations on plan sponsors and less on Medicare and drug manufacturers. (See Employer Group Waiver Plans Are at Risk, Help Retirees Keep Their Coverage at [https://d17f9hu9hnb3ar.cloudfront.net/s3fs-public/2021-08/Evernorth%20Policy%20Perspective\\_Part%20D%20Reforms%20Threaten%20EGWPs\\_August%202021.pdf](https://d17f9hu9hnb3ar.cloudfront.net/s3fs-public/2021-08/Evernorth%20Policy%20Perspective_Part%20D%20Reforms%20Threaten%20EGWPs_August%202021.pdf))

TRS desires to work with CMS to keep EGWPs affordable and sustainable. Specific consideration of EGWP plans as highlighted above is representative of the type of intentional EGWP-specific policy-making that TRS encourages CMS to adopt. It is TRS’s hope that TRS can serve as a resource to CMS to help achieve that end. Again, TRS would like to meet with HHS to discuss the concerns above at the next earliest convenience of HHS, and thank you.

Sincerely,

A handwritten signature in black ink, reading "Jane Cheshire Gilbert". The signature is fluid and cursive, with the first name "Jane" being the most prominent.

Jane Cheshire Gilbert, CPA  
Senior Federal Strategies Liaison  
Teachers’ Retirement System of Kentucky  
502-848-8512

# UNITEDHEALTH GROUP

9900 Bren Road East  
Minnetonka, MN 55343

March 15, 2024

Meena Seshamani, M.D., Ph.D.  
Deputy Administrator and Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Submitted via email to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

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

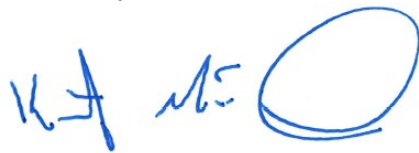
Dear Dr. Seshamani:

UnitedHealth Group (UHG) is pleased to respond to the Centers for Medicare and Medicaid Services' (CMS) request for comments regarding the *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*, dated February 15, 2024.

UHG is a mission-driven organization dedicated to helping people live healthier lives and helping make the health system work better for everyone through two distinct platforms - UnitedHealthcare, our health benefits business, and Optum, our health services business. We work with employers, providers, and governments to serve people and share a vision of a value-based system of care that provides compassionate and equitable care.

Thank you for your thoughtful consideration of our comments. Please do not hesitate to contact us if you have any questions.

Sincerely,



Kent Monical  
Medicare & Retirement West Region CEO / SVP Government Programs Pharmacy

## **UHG Technical Comments on 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**

UHG is committed to helping our enrollees spread the cost of their prescription drugs out over the plan year while providing the simplest experience and quality supported care. Part D enrollees who opt-into the Medicare Prescription Payment Plan (the “program”) will benefit from not having to pay their out-of-pocket (OOP) costs at the point-of-sale when filling their prescriptions. UHG appreciates how CMS is supporting Part D enrollee education and outreach and agrees that providing targeted education and decision tools to Part D enrollees who are considering whether to opt-in to the program will be critical, especially for the first year of the program.

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

While Part D sponsors must provide the option to elect the Medicare Prescription Payment Plan to all Part D enrollees, including Part D enrollees who are LIS-eligible,<sup>1</sup> UHG urges CMS to consider whether the program has any practical application to enrollees in plans with \$0 Part D cost sharing similar to CMS’s acknowledgement in the Draft Part Two guidance that the program has no practical application for PACE organizations and demonstration Medicare-Medicaid Plans (MMPs) that have no Part D cost sharing. While UHG understands that the program is applicable to enrollees in all Part D plans, we are concerned that proactively sending election request forms and educational materials to enrollees in plans without Part D cost sharing will lead to enrollee confusion. Therefore, UHG recommends that there be no requirement to proactively send program materials to enrollees in plans with \$0 Part D cost sharing, given that tailored information will still be available to all enrollees online, via phone, and in written format upon request. In the alternative, UHG requests CMS confirm that Part D sponsors have the flexibility to create different versions of all of the required educational material to provide appropriate context for enrollees in special needs plans (SNPs) or other plans with \$0 Part D cost sharing.

#### **30.1.1 – Required Mailings with Membership ID Card Issuance**

CMS proposes that when an individual signs up for a plan, Part D sponsors be required to include with the membership ID card hard copy mailing information regarding the program and a program election request form.

While UHG agrees that providing information regarding the program is important for new enrollees, we strongly encourage CMS consider not requiring Part D sponsors to include an election request form with the ID card mailing to limit enrollee confusion. UHG is concerned that if the election request form is sent with the ID card, some enrollees may sign-up when they may not be likely to benefit from the program and some enrollees may submit another election request submission after already opting into the program during the Annual Enrollment Period. Instead of proactively sending an election request form with the membership ID card hard copy mailing, UHG recommends that the informational materials direct enrollees to the appropriate

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<sup>1</sup> Section 1860D-2(b)(2)(E)(i) of the Act

telephone and online resources that can help them determine if they are likely to benefit from participating in the program.

If CMS finalizes the election form mailing requirement, UHG recommends that CMS allow Part D sponsors the flexibility to send the election request form as a part of another mailing or separately following the enrollee's preferred delivery method (i.e., mail or email) within the same time frame as the ID card mailing to align with enrollee expectations for health plan communications and to avoid enrollee confusion.

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

CMS proposes requiring outreach to Part D enrollees if the Part D sponsor has prior authorization (PA) or other utilization management (UM) edits in place for a drug that, based on the benefit structure, would result in out-of-pocket costs above the pharmacy point-of-sale notification threshold. While UHG agrees that pharmacies should provide program information to enrollees incurring out-of-pocket costs above the threshold at the pharmacy point-of sale, we request flexibility for Part D sponsors to determine when to outreach to enrollees who utilize high-cost drugs. Using PA and UM edits may not be the most effective approach because Part D sponsors do not have finalized pricing information at the time a PA or UM edit is put in place for a particular drug. UHG also has concerns that adding a cost review and program outreach requirement to the clinical process will not only require additional resources and complicate the process, but it could lead to a poor enrollee experience as enrollees will potentially be receiving duplicative outreach from the Part D sponsor and the pharmacy.

Further, UHG recommends that if CMS requires targeted outreach for high-cost drugs with PA or UM edits, that it only apply if an enrollee receives an approved coverage determination or on appeal and that it not tie to the UM review itself, as sending program information when the coverage request results in a denial will be confusing for enrollees. If CMS limits when the targeted outreach needs to occur, UHC requests CMS issue instructions for communicating program information for appeals that are approved at the Independent Review Entity (IRE) stage.

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

In 30.2.2.3, CMS notes that Part D sponsors must ensure that a pharmacy informs a Part D enrollee that they are likely to benefit from the program if the enrollee incurs out-of-pocket costs for a single prescription that exceeds the point-of-sale threshold. In Section 50 of the Draft Part Two Guidance, CMS notes that Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide likely to benefit notifications to Part D enrollees. UHG requests that CMS clarify in Section 30.2.2.3 that compliance with the contractual provision requirements set forth in Section 50 is sufficient for a Part D sponsor to demonstrate that the pharmacy provides notifications to Part D enrollees who are identified at the point of sale as likely to benefit from the program.

#### 30.2.3 – Communications with Contracted Providers and Pharmacies

UHG requests that in addition to the CMS-developed education product, CMS also develop standard notifications for pharmacies and providers. Because providers and pharmacies contract with multiple Part D sponsors, having a standard notification/communication will help

streamline the information sharing process and will help ensure enrollees are receiving consistent messaging.

#### 30.3.1 – Overview of Election Requirements

UHC requests CMS confirm whether the "effective date" of an enrollee's participation in the program is the date the enrollee's election request was received or when enrollee is approved to participate in the program. The Draft Part Two guidance outlines the election request dates for the various mechanisms an enrollee can use to submit a request (e.g., mail, telephone, website), but it does not indicate whether the election request date is also the effective date after program participation is approved.

#### 30.3.5 – Notice of Voluntary Termination

UHG requests clarification from CMS on whether it is consistent with Section 80.5 of the Part One guidance for enrollees who disenroll from either an MA-PDP or PDP plan (either voluntarily or involuntarily) to receive one termination letter as long as it includes language about termination from the program from the Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan.

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

#### 40.1 – Information on the Medicare Prescription Payment Plan

UHG understands that CMS intends to develop and provide an educational product for Part D enrollees on the Medicare.gov website and that Part D sponsors are encouraged to use the product to educate Part D enrollees. UHG requests confirmation that if it uses CMS's educational product (i.e., providing a link directing Part D enrollees to Medicare.gov), that it will satisfy all of the requirements set forth in section 30.1.5 that Part D sponsors are required to have on their website. Alternatively, if additional educational content is required on our website, UHG requests that CMS release the final materials as soon as possible to give Part D sponsors sufficient time to create this content.

#### 40.2 – Modifications to Existing Part D Resources

UHG appreciates that CMS will be making appropriate modifications to certain resources but asks that CMS provide Part D sponsors with information on how it plans to modify and/or use Medicare Plan Finder to provide information about the program. Specifically, it would be helpful to know if CMS plans to include static messaging or whether it will provide more specific detail on the program on Medicare Plan Finder.

### **Section 50 – Pharmacy Process**

#### 50.1 – Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount

UHG requests that CMS provide guidance to Part D sponsors on how to handle program billing for enrollees who opt-in to the program and have supplemental coverage. For example, in the event supplemental coverage changes the final patient liability amount (less than or greater than the applicable Part D copay), we would appreciate CMS providing additional information regarding



its expectations of both the Part D sponsor and pharmacy on how to advise the enrollee in that situation.

#### 50.2 – Pharmacy POS Notifications Late in the Plan Year

To avoid enrollee dissatisfaction with their Part D sponsor and/or pharmacy and consistent with the guidance in Section 30.2.2.2, UHG encourages CMS to allow Part D sponsors/pharmacies the ability to suppress the point-of-sale notification in the last month of the plan year and/or if enrollees have already opted into the program. In addition, if there are other scenarios where offering program information is not ideal from an enrollee perspective, UHG encourages CMS to allow Part D sponsors the ability to maintain rules to suppress the point-of-sale pharmacy notification.

#### Additional Issues

CMS indicated that auto re-election into the Medicare Prescription Payment Plan will be addressed in future guidance.<sup>2</sup> UHC recommends this guidance to be released as soon as possible to give plans time to implement the necessary functionality. Specifically, Part D sponsors need to understand if a renewing enrollee that is participating in the program and wants to continue participating in the program in the next plan year will have to opt-in to the program again or if their election will continue into the following year. Notification requirements will also need to be established for the transition from year to year. UHC recommends that CMS consider allowing Part D sponsors to use a single notice that addresses the transition between plan years rather than a disenrollment notice triggering at the end of the plan year, which may be confusing for program participants.

UHG also requests that CMS provide model notices for the Notification of Additional Information Required and Notice of Rejection required communications to program participants. Model notices or suggested text is requested by May 2024 to be incorporated by Part D sponsors into communications that will occur this fall.

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<sup>2</sup> Center for Medicare, Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments (2024).

March 15, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

Via [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov)

We are writing to provide comments on the [Medicare Prescription Payment Plan \(MPPP\) Draft Part Two Guidance](#), as published by the Centers for Medicare & Medicaid Services (CMS) on February 15, 2024. We are academics and health policy researchers with a keen interest in seeing the successful implementation of this “smoothing” of out-of-pocket (OOP) costs program given [our team was the first to recommend such a fix to Medicare Part D cost sharing based on our empirical research](#).

We were delighted to see that the MPPP draft guidance incorporates several of the [recommendations made by us in a Health Affairs Forefront article published in early 2023 and in our comment letter on the Part One Guidance](#). We offer below additional comments on key topics from the MPPP Draft Part Two Guidance in the hope that such feedback will aid CMS in maximizing the potential of this unique opportunity to improve medication affordability and access for Medicare beneficiaries.

Our feedback covers **three** overarching points for CMS’ consideration:

1. **Section 30: CMS should standardize the “who, what, when, where, and how” of the outreach, education, and communication requirements for Part D sponsors and make use of these standardize elements mandatory for all plans.**

While attention is naturally focused on the implementation of the MPPP, CMS should be aware that other changes in the Inflation Reduction Act (IRA) could have major consequences for the success of the MPPP program. The IRA has placed greater financial liability for Part D drug costs on plan sponsors (from 15% to 60% of drug costs in the catastrophic coverage phase). This 4-fold increase in financial liability creates strong incentives for Part D plans to avoid enrollment of high-cost beneficiaries who quickly enter catastrophic coverage during the benefit year. More importantly, as we have shown in [our prior work](#), the MPPP will make out-of-pocket (OOP) costs more manageable for beneficiaries requiring high-cost medications and they will be less likely to abandon or discontinue their expensive drug treatments during the year, leading to further increased financial liability for the Part D plan sponsor from these previously would-be non-initiators or discontinuers.

The increase in financial liability may increase Part D sponsor incentives to (a) discourage enrollment of high-cost beneficiaries in the Part D plan as well as enrollment in the MPPP, and/or (b) engage in “cream skimming” via increasing plan enrollment of low-cost beneficiaries. Given that current draft guidance provides too much leeway to Part D plan sponsors with respect to the “who, what, when, where, and how” of the outreach, education, and communication requirements for Part D sponsors, it may inadvertently create opportunities for such gaming of the system to occur. For instance, a plan may strategically advertise the MPPP in such a way that avoids attracting users of high-cost covered Part D drugs (such as by delaying outreach until

December) while using its advertising materials to present the MPPP as a plan benefit (rather than a free Medicare program open to all beneficiaries) to attract low-cost beneficiaries.

CMS should proactively take steps to **prevent such potential gaming by Part D plan sponsors** by standardizing the “who, what, when, where, and how” in the requirements for all sub-sections of Section 30 and making compliance with using these standardized elements mandatory for all Part D sponsors. Examples of elements in Section 30 that should be standardized and mandated include standardizing the format/content/timing of the required mailing with membership ID card issuance (Section 30.1.1), Part D sponsor websites (30.1.5), notice for Part D enrollees likely to benefit (30.2.1), and communications with contracted providers and pharmacies (Section 30.2.3). Such an approach would also **provide greater clarity to beneficiaries that the MPPP is not a product offered by select Part D plan sponsors but a universally available option to all beneficiaries under Part D**.

**While developing standardized outreach materials, CMS should also reconsider the current naming convention of the MPPP:** referring to the voluntary option of smoothing their OOP costs as a “plan” may still cause some beneficiaries to conflate it with their existing Part D plan (rather than as a separate program). Additionally, the current title fails to emphasize the monthly nature of the MPPP, which will be crucial to helping beneficiaries understand how the program will reduce their OOP costs. Since monthly payments are integral to MPPP operation, we recommend “Medicare *Monthly* Prescription Payment *Option*” as a possible alternative for consideration.

2. <b><u>Section 40:</u> CMS should <u>expand</u> their proposed educational and outreach efforts in such a way that no beneficiary falls through the cracks.</b>
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Because the **MPPP is set up as a voluntary program** and beneficiaries must reenroll each year, it is critical that its availability and benefits are clearly conveyed to all beneficiaries likely to benefit. We commend CMS for proposing development of an educational product on the MPPP (Section 40.1), considering modifications to existing Medicare resources (Section 40.2), and willingness to work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates have sufficient support and materials needed to effectively communicate the availability and nuances of MPPP to beneficiaries (Section 40.3). **However, the approach and details provided in these sections of the draft guidance are limited and fall short in many respects.**

**Careful and expanded efforts will be needed by CMS directly to ensure that beneficiaries most in need of the MPPP do not fall through the cracks for several reasons:**

- (1) Given the conflicting incentives for Part D sponsors described in #1 above, CMS should not rely on plan sponsor efforts and will need to ensure that its own education and outreach efforts are highly successful. Furthermore, promotion and education surrounding the MPPP program coming directly from CMS (as opposed to the plans) will have more credibility and validity.
- (2) Past experience has shown that voluntary enrollment programs for low-income individuals suffer from severe under enrollment among those eligible for such programs.
- (3) Given CMS’s proposed approach in the Final Part 1 guidance to identify patients likely to benefit (POS threshold of \$600 for a single prescription) will leave out large numbers of beneficiaries who may benefit from the MPPP. Examples of these groups include:
  - a. **Beneficiaries who use high-cost prescription drugs but do not meet the POS threshold (\$600 for a single prescription) proposed by CMS in the Final Draft 1 guidance.** CMS’ modeling exercise table in the draft Part 1 guidance shows that a higher POS threshold of \$600 for a single prescription will miss out on identifying

~1.4 million beneficiaries who actually would have benefited from MPPP enrollment if a lower POS threshold of \$400 for a single prescription was used.

- b. **Beneficiaries who use multiple moderate-to-high-cost prescription drugs but do not meet the POS threshold (\$600 for a single prescription) proposed by CMS in the Final Draft 1 guidance.** CMS' modeling exercise in the draft Part 1 guidance shows that a higher POS threshold of \$600 for a single prescription will miss out on identifying ~100,000 beneficiaries who actually would have benefited from MPPP enrollment if the same POS threshold of \$600 was used but for a single day (i.e. allowing multiple prescriptions) vs. a single prescription and ~1.6 million beneficiaries if a lower POS threshold of \$400 for a single day (i.e. allowing multiple prescriptions) vs. \$600 for a single prescription.
- c. **Beneficiaries who have previously foregone needed (but expensive) medications because of high out-of-pocket costs and hence did not incur high OOP costs (>\$2000) in the previous year and will neither meet the POS threshold of \$600 for a single prescription in 2025.** Consider a Medicare beneficiary with rheumatoid arthritis who was prescribed a Part D specialty drug (e.g., etanercept) that can be self-injected at home. Faced with high out-of-pocket costs at the pharmacy counter, this patient may have abandoned their Part D specialty drug treatment in favor of Part B specialty drugs (e.g., infliximab) that require visits for the infusion or even worse abandoned use of any specialty drug for their rheumatoid arthritis and continued to stay on older, less expensive Part D therapies such as oral DMARDs (e.g., methotrexate). Hence, such a patient would never get flagged as "likely to benefit" solely based on OOP costs since they are not filling (i.e. they had previously abandoned) the expensive Part D OOP specialty drug.

**CMS needs to develop a rigorous approach to directly educate Medicare beneficiaries and their family members/caregivers in an easy to understand and relatable way.**

- (a) CMS should embark on a national public advertising campaign (such a campaign was employed during the rollout of the Affordable Care Act's health insurance exchanges in 2014).
  - CMS should initiate a stepwise national advertising campaign several months in advance of the enrollment season so that patients have enough time to evaluate their personal situation and weigh the potential benefits of enrolling in the MPPP. For example, ads raising the awareness of the MPPP program availability should begin as early as summer of 2024.
  - A national CMS campaign would also make clear that the MPPP is a federal program open to all beneficiaries rather than a product being marketed by Part D plan sponsors.
- (b) CMS should integrate a visual tool in the Medicare Plan Finder to help beneficiaries understand the MPPP in addition to the resources that CMS will modify in Section 40.2. This is especially important given the complexity of the calculations that were presented in the Part One guidance document. Instead of hypothetical calculations requiring beneficiaries to think in the abstract about their own medication use and circumstances, CMS should consider developing a "calculator" that will allow beneficiaries to approximate their monthly OOP costs if they choose or not choose to participate in the MPPP (e.g., \$167 in the first month vs. \$2000 in the first month). More importantly, we suggest that the calculations be accompanied by easy-to-digest visual representations of what monthly costs would look like if they enrolled in MPPP vs. not ([for example, see this infographic that our team had prepared visualizing different cost sharing scenarios](#)) to aid beneficiaries and patient advocates. Integrating this calculator into the Medicare.gov Plan Finder tool would be ideal given this resource is typically used by beneficiaries to weigh plan options, assess annual costs, and choose a plan for enrollment.

In addition to projecting OOP costs in the **current** calendar year, the calculators and visual tools should also have the ability to project OOP costs for the **next** calendar year. This recommendation is particularly important for the newly-diagnosed and newly-prescribed patients receiving prescriptions for expensive medications during the calendar year. This group, [as we have pointed out previously](#), is particularly susceptible to making poor choices since the timing of when a beneficiary participates in the MPPP will have a large impact on the calculation of the monthly amount owed for the remainder of the calendar year. Consider a beneficiary who was newly diagnosed with a chronic condition and prescribed an expensive specialty medication at the beginning of November. The first prescription for this new specialty drug required \$2,000 in out-of-pocket costs. This patient's monthly OOP costs under the MPPP would then be \$1,000 in November and \$1,000 in December assuming they had no prior Part D OOP expenses in the calendar year. A patient may be discouraged by this amount and wrongly conclude that the MPPP is not worth enrolling in since this lower monthly amount (i.e., \$1,000) is still unaffordable for them. They may just [abandon the approved prescription at the pharmacy](#) and not pursue this treatment. However, the visual tool should show this patient that beginning in January of the following year, their OOP costs would be calculated out of 12 months and hence would only be \$167 per month. Given this information, the beneficiary may make other choices instead of abandoning their treatment. The patient may discuss with their physician and evaluate the pros and cons of delaying treatment or using a less expensive alternative treatment that "bridges" them until January of the following year. Alternatively, if immediate treatment is a must then the patient could seek financial help for those two months of the year with the potential relief that the following year their monthly payment would be capped at \$167.

**CMS should also actively engage with providers, pharmacists, and patient advocates in the development and dissemination of outreach and educational materials.**

We applaud CMS' acknowledgement that "health care providers and pharmacists play a key role in cost-of-care conversations with their patients that can include discussions about potential prescription drug costs". In fact, evidence suggests that [older adults trust physicians and pharmacists more than other sources to provide information on prescription drugs](#).

- (a) CMS should consider supporting development of continuing medical education (CME) programs for physicians, pharmacists, and nurse practitioners so that they are knowledgeable about the MPPP and able to encourage beneficiaries to enroll.
- (b) Developing materials specifically for these stakeholders—for instance, developing a notice or poster that could be displayed in all physician office waiting rooms about the program with a QR code—could ensure wider adoption among beneficiaries. Additionally, CMS should provide similar posters to display at pharmacies, including QR codes for patients to enroll/learn more and connecting them to plan finder visual tools website.

<p><b>3. Section 60: CMS should ensure there are ample opportunities to rigorously evaluate and improve the implementation of MPPP in the future.</b></p>
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We commend CMS' plans to "monitor and collect data about beneficiary complaints and grievances reported via the Medicare Complaints Tracking Module (CTM) to assess compliance with all MPPP requirements, beneficiary protections, and program integrity" (Section 60.3) as well as conduct audits of Part D plan sponsor's implementation of MPPP (Section 60.4).

We would also recommend [proactively reaching out to beneficiaries via regular surveys and focus groups during the first year of the program](#) rather than waiting for beneficiary complaints to trickle in. There may be easily identifiable, "low-hanging fruit" areas for improvement that could

be identified via surveys or beneficiary focus group that will not necessarily show up in beneficiary complaints about compliance or program integrity.

Given recent examples of Part D plan sponsors being non-compliant in several years, CMS should use available means to ensure that all plans are complying with MPPP program requirements. One approach for consideration for the future is to incorporate MPPP-related metrics into the Medicare Part D Star ratings program as a way to assess plans' success in implementing the program. Research has shown that Part D Star ratings and associated quality bonus payments, correlate with better patient experiences and increased delivery of services captured in the Star ratings metrics.

In addition to audits and oversight, CMS must also ensure that a rigorous quantitative evaluation of all aspects of the MPPP can be conducted by CMS or other researchers in the future using 100% Medicare claims data (as opposed to just relying on qualitative surveys). In fact, our team's prior work using Medicare claims data was instrumental in first identifying the "too much, too soon" problem which led to our recommendations for "smoothing" of OOP costs and necessitated the MPPP program. Not only will claims data analyses help identify beneficiary groups falling through the cracks and requiring further targeted outreach in future years of the MPPP program but will also be critical to evaluating the MPPP program in terms of its impact on monthly OOP costs and medication adherence, clinical outcomes, and health care costs. Hence, each PDE claim should have a field indicating whether or not that prescription was processed under the MPPP program. Additionally, data on the date of enrollment in the MPPP, date of termination under the MPPP (if any), reason for termination (voluntary vs. involuntary/penalty), and the monthly payments paid by the beneficiary for each month of enrollment should be made available since it will be critical for evaluating the success of the program.

Thank you for your consideration of our comments.

Sincerely,



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## CENTER FOR MEDICARE

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**DATE:** February 15, 2024

**TO:** Interested Parties

**FROM:** Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

**SUBJECT:** 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

### 10. Introduction

The purpose of this document is to provide interested parties with draft part two guidance on a select set of topics for the Medicare Prescription Payment Plan, which was established by section 11202 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) and signed into law on August 16, 2022.

The IRA makes Medicare stronger for current and future enrollees. It makes health care more accessible, equitable, and affordable. Section 1860D-2(b)(2)(E) of the Social Security Act (the Act), as added by section 11202 of the IRA, requires all Medicare prescription drug plans to offer their Part D enrollees the option to pay their out-of-pocket (OOP) Part D drug costs through monthly payments over the course of the plan year instead of as upfront payments at the pharmacy point of sale (POS) beginning January 1, 2025. This provision applies to all Part D sponsors,<sup>1,2</sup> including both stand-alone Medicare prescription drug plans (PDPs) and Medicare Advantage (MA) plans with prescription drug coverage (MA-PDs), as well as Employer Group Waiver Plans (EGWPs), cost plans, and demonstration plans.

Section 11202(c) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. In

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<sup>1</sup> This provision does not apply to the Limited Income Newly Eligible Transition (LI NET) coverage because participants in the LI NET program do not enroll in a PDP or MA-PD plan to receive transitional coverage under the program.

<sup>2</sup> Under section 1894(a) of the Act, PACE organizations must provide all medically necessary services including prescription drugs, without application of deductibles, copayments, coinsurance, or other cost-sharing that would otherwise apply under Medicare or Medicaid. While the Medicare Prescription Payment Plan is applicable to all Part D plans, it has no practical application for PACE organizations. In addition, the program has no application to those demonstration Medicare-Medicaid Plans (MMPs) that have no Part D cost-sharing.



accordance with the law, CMS is issuing this draft part two guidance for implementation of the Medicare Prescription Payment Plan (also referred to in this guidance as the “program”) for 2025. This draft part two guidance builds on the draft part one guidance that was issued on August 21, 2023 through a Health Plan Management System (HPMS) memo titled “Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments,” and the July 17, 2023, HPMS memo titled “Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans.”<sup>3</sup> In this draft part two guidance, CMS describes requirements for Part D sponsor obligations related to outreach and education, pharmacy processes, and operational considerations for the program.

CMS is voluntarily soliciting comment on this draft part two guidance. Please send comments pertaining to this draft guidance to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov) with the subject line “Medicare Prescription Payment Plan Guidance – Part Two.” Comments received by March 16, 2024 will be considered. CMS will issue final part two guidance in summer 2024 after considering the public comments received in response to this draft part two guidance. In the final guidance, CMS may make changes to any policies described in this draft guidance, including policies on which CMS has not expressly solicited comment, based on the agency’s further consideration of the relevant issues. This guidance, paired with the part one guidance, pertains to the first year of the program, contract year (CY) 2025, and the policies established in the final guidance will be subject to change in subsequent years. Additionally, CMS will issue model materials specific to the program in summer 2024 following an Information Collection Request (ICR) through the Office of Management and Budget (OMB).

If any provision in this guidance is held to be invalid or unenforceable, it shall be severable from the remainder of this guidance, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances.

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<sup>3</sup> Medicare Prescription Payment Plan publications, including the draft part one guidance and technical memorandum, can be accessed at: <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements>



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## **20. Overview of the Medicare Prescription Payment Plan**

Beginning in CY 2025, the statute requires Part D sponsors to provide all Part D enrollees the option to pay their OOP Part D prescription drug costs in monthly amounts over the course of the plan year, instead of paying OOP costs in full at the POS. As a result, Part D enrollees who opt into the Medicare Prescription Payment Plan will pay \$0 at the POS for a covered Part D drug,

instead of the OOP cost-sharing they would normally pay at the POS when filling a prescription. The Part D sponsor must pay the pharmacy the OOP cost-sharing amount that participants would have paid if they were not in the Medicare Prescription Payment Plan and then bill the program participants monthly for any OOP cost-sharing they incurred while in the program (according to calculations described in the draft part one guidance). The amount that the Part D sponsor bills the participant for a month under the program cannot exceed a maximum monthly cap. While this program is available to anyone with Medicare Part D drug costs, Part D enrollees incurring high OOP costs<sup>4</sup> earlier in the plan year are generally more likely to benefit, as discussed in the draft part one guidance.

In the draft part one guidance, CMS explained how Part D sponsors can satisfy statutory requirements for the Medicare Prescription Payment Plan, including how they must: provide all Part D enrollees with the option to elect into the Medicare Prescription Payment Plan prior to, and during, the plan year; determine a maximum monthly cap for each month's amount; bill the program participant for an amount that must not exceed the applicable monthly cap; and have in place a mechanism to notify a pharmacy during the plan year when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from the program.

This draft part two guidance builds on the draft part one guidance by primarily focusing on Part D sponsors' obligations for Part D enrollee education, outreach, and communications related to the Medicare Prescription Payment Plan. This includes how Part D sponsors must perform general and targeted education and outreach to Part D enrollees and provide communications to program participants, including instructions on using CMS-provided model materials that will be issued through the OMB ICR process. This guidance also includes a summary of how CMS is supporting Part D enrollee education and outreach, provides additional details related to pharmacy processes for operationalizing the program, and instructs Part D sponsors on how to prepare for contract year (CY) 2025 program implementation.

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

Under section 1860D-2(b)(2)(E)(v)(III) of the Act, Part D sponsors are required to provide Part D enrollees with promotional and educational materials on the Medicare Prescription Payment Plan both prior to, and during, the plan year. Specifically, section 1860D-2(b)(2)(E)(v)(III)(bb) of the Act requires Part D sponsors to notify prospective Part D enrollees of the option to make such an election in promotional materials prior to the plan year, and section 1860D-2(b)(2)(E)(v)(III)(cc) of the Act requires Part D sponsors to include information on the Medicare Prescription Payment Plan in Part D enrollee educational materials. Additionally, under section 1860D-2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism in place to notify a pharmacy when an enrollee incurs OOP costs for covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the Medicare Prescription Payment Plan. Finally, under section 1860D-2(b)(2)(E)(v)(III)(ee) of the Act, Part D sponsors must also ensure that a pharmacy, after receiving such notification, informs the Part D enrollee about the program.

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<sup>4</sup> For the definition of OOP costs used for the Medicare Prescription Payment Plan, see Appendix A of the draft part one guidance.

This section of the guidance outlines a list of materials that satisfy the requirements for Part D sponsors to provide enrollees with information about this program, including an overview of language access and accessibility requirements in section 30.4. In addition, this section includes guidance on how Part D sponsors can fulfill their statutory pharmacy notification requirements.

In this draft part two guidance, CMS describes how it will modify existing Part D materials to reflect implementation of the Medicare Prescription Payment Plan (see section 30.1). Additionally, CMS is developing model materials that will be made available for public comment through the OMB ICR process. Part D sponsors can use the model materials to communicate with Part D enrollees and program participants about the Medicare Prescription Payment Plan. Once the model materials are approved through the OMB ICR process, they will be released in summer 2024, ahead of the CY 2025 Annual Election Period.

For all materials provided to Part D enrollees, whether newly created or updated for this program, Part D sponsors should also reference existing Part D regulations at 42 CFR Part 423 subpart V, which set forth standards for Part D required materials, content, and delivery requirements. Part D sponsors should also refer to the Medicare Communications and Marketing Guidelines (MCMG) for CMS interpretation and examples of select subpart V provisions, as well as HPMS submission rules and processes for marketing materials. Finally, sponsors should also reference the Medicare Prescription Drug Benefit Manual and HPMS memoranda to ensure compliance with other Part D communications requirements.<sup>5</sup> Part D sponsors are also encouraged to review their plan materials including, but not limited to, those described in this guidance, and update these materials to include information about the Medicare Prescription Payment Plan, as appropriate.

Taken together, the education and outreach requirements included in this section aim to integrate the new Medicare Prescription Payment Plan into current Part D education, outreach, and enrollment processes to create a seamless experience for Part D enrollees. CMS requests public comment on the scope of included materials, including updated existing Part D materials and newly developed resources; their use, content, and distribution; ways to ensure all Part D enrollees receive information in an easy-to-understand manner, including at an appropriate literacy level and using language that allows all Part D enrollees, particularly those who may have language and accessibility barriers, to make an informed decision; and other potential materials that may be appropriate to modify or develop that are not currently included in this section.

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<sup>5</sup> These regulations and requirements outline specific requirements and prohibited practices, such as providing inaccurate or misleading information, for Part D sponsors' communications and marketing materials and activities. They also state specific requirements for submission, review, and distribution of materials, among other parameters for how Part D sponsors can contact Part D enrollees. Please note this summary is not exhaustive of the different requirements outlined in 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission through HPMS, and use of marketing materials. References to these regulations, requirements, and guidelines are meant to remind Part D sponsors that any materials used under the Medicare Prescription Payment Plan are subject to existing Part D requirements.

### 30.1 General Outreach and Education

Under section 1860D–2(b)(2)(E)(v)(III)(bb) of the Act, Part D sponsors must notify prospective Part D enrollees prior to the plan year through promotional materials of the option to participate in the Medicare Prescription Payment Plan. Additionally, under section 1860D–2(b)(2)(E)(v)(III)(cc), Part D sponsors must also provide educational materials to Part D enrollees. Because general outreach to and education of Part D enrollees are central to ensuring that all prospective and current Part D enrollees are aware of this program, CMS will require plans to use existing Part D materials that are required to be furnished to Part D enrollees under § 423.2267(e), as updated accordingly to include information about the program.

Further, Part D sponsors may include information on the Medicare Prescription Payment Plan in their marketing materials, so long as their marketing materials comply with existing Part D regulations at 42 CFR Part 423 subpart V, which sets forth standards for Part D required materials, content, and delivery requirements. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through HPMS, and use of marketing materials.

#### *30.1.1 Required Mailings with Membership ID Card Issuance*

Under § 423.2267(e)(32), the membership ID card is a model communications material that Part D plans must provide to Part D plan enrollees. It must be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment in the Part D plan or by the last day of the month prior to the plan effective date, whichever is later. The membership ID card must be provided in hard copy, and Part D plans may also provide a digital version, in accordance with § 423.2267(d).

For CY 2025, when an individual signs up for a plan, Part D sponsors will be required to include with the membership ID card hard copy mailing:

- information regarding the Medicare Prescription Payment Plan; and
- a Medicare Prescription Payment Plan election request form.

Requirements related to the election request form are outlined in section 30.3.1.1 of this guidance.

Part D sponsors are encouraged to provide the CMS-developed educational product, described in section 40.1 of this guidance, to satisfy the requirement to furnish information regarding the Medicare Prescription Payment Plan alongside the election request form in the membership ID card issuance packet. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed educational product to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of those marketing materials using HPMS, and use of marketing materials.

### *30.1.2 Evidence of Coverage (EOC)*

As required under § 423.2267(e)(1), the EOC is a standardized communications material that must be provided annually by Part D sponsors to all current Part D enrollees of a plan by October 15<sup>th</sup> prior to the year to which the EOC applies or, for new Part D enrollees, within 10 calendar days of the date the Part D sponsor receives confirmation of Medicare Part D enrollment from CMS or by the last day of the month prior to the Part D enrollment effective date, whichever is later. The EOC is a legal document that contains a detailed description of a Part D enrollee's plan benefits and rights, as required under § 423.128(b), and that explains the plan's rules for covered services and prescription drugs.<sup>6</sup>

CMS is updating the model EOC to include educational information about the Medicare Prescription Payment Plan, given the program's relevance to Part D plans' descriptions of their covered benefits and related cost-sharing responsibilities.

The updated model EOC will be released in spring 2024 as part of the general issuance of CY 2025 Model Materials (CMS-10260; OMB 0938-1051).<sup>7</sup>

### *30.1.3 Annual Notice of Change (ANOC)*

As required under § 423.2267(e)(3), the ANOC is a standardized marketing material that must be provided by Part D sponsors to current Part D enrollees annually and outlines changes in plan costs, coverage, and benefits that take effect on January 1 of the next plan year to help Part D enrollees decide whether to remain in their plan or choose a different plan.<sup>8</sup> In general, the document must be sent to Part D enrollees by September 30 of each year, and posted on the Part D sponsor's website by October 15, prior to the plan year.<sup>9</sup>

CMS has added educational language to the ANOC that describes the Medicare Prescription Payment Plan and provides instructions on how to opt into the program.

The updated model ANOC will be released in spring 2024 as part of the general issuance of CY 2025 Model Materials (CMS-10260; OMB 0938-1051).

### *30.1.4 Explanation of Benefits (EOB)*

Under section 1860D-4(a)(4) of the Act, Part D sponsors are required to furnish Part D enrollees with a written EOB when Part D benefits are provided. The EOB informs Part D enrollees about their prescription drug costs in relation to the Part D annual deductible, initial coverage limit, and annual OOP threshold. Part D EOB requirements are codified at § 423.128(e). Section 423.128(e)(7) requires that the EOB is furnished no later than the end of the month following

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<sup>6</sup> <https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf>.

<sup>7</sup> CY 2025 Model Materials will be posted at: <https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/models-standard-documents-educational-materials>.

<sup>8</sup> <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-V/section-423.2267>.

<sup>9</sup> <https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf>.

any month when Part D benefits are utilized. Part D EOBs must be written in the manner specified by CMS and in a form easily understandable to Part D enrollees.

As part of the most recent OMB ICR renewal for the Part D EOB, given the significant changes the IRA makes to the Part D benefit design and the launch of the Medicare Prescription Payment Plan in CY 2025, CMS requested comment on what information related to the Medicare Prescription Payment Plan should be included in the EOB. On June 6, 2023, CMS published in the Federal Register (88 FR 37066) notice of a 60-day comment period regarding the Part D model EOB (CMS-10453; OMB 0938-1228).<sup>10</sup>

CMS received a wide range of public comment regarding the EOB, including comments about inclusion of Medicare Prescription Payment Plan language.<sup>11</sup> Some commenters recommended CMS indicate whether the individual is participating in the program and include general education and the individual's previously paid and future costs under the program, as well as information as to whether the individual has met the annual OOP cap. CMS considered all comments received, and on December 8, 2023, published notice of an updated EOB with a 30-day comment period (88 FR 85622).<sup>12</sup> The revised EOB includes information about the Medicare Prescription Payment Plan and explains that enrollees who participate in the Medicare Prescription Payment Plan will receive a separate monthly Medicare Prescription Payment Plan billing statement. The EOB also explains that costs included in the EOB might differ from what a Medicare Prescription Payment Plan participant paid at POS. After considering comments received during the 30-day comment period, CMS expects to issue a final EOB for CY 2025 in spring 2024 as part of the general issuance of CY 2025 model materials.

### *30.1.5 Part D Sponsor Websites*

Under § 423.128(d)(2), Part D sponsors are required to have a publicly available website that includes a description of the Part D plan's coverage details, including information on the benefits offered, such as applicable conditions and limitations, premiums, and cost-sharing (including for subsidy-eligible individuals), and any other information associated with receipt or use of benefits. Websites must comply with anti-discrimination provisions, such as Section 508 of the Rehabilitation Act, with regard to providing access to websites and other materials, so that individuals can read sites and materials with screen reader technology.<sup>13</sup> Additionally, as stated in section 30.4 of this draft part two guidance, websites must comply with Medicare Part D language access and accessibility requirements.

As such, in addition to the required content under § 423.2265(b), Part D sponsors will be required to include information on the Medicare Prescription Payment Plan on their websites. **Section 70.3.1 of the Medicare Prescription Payment Plan draft part one guidance outlines the requirement for Part D sponsors to have available on their websites a Medicare Prescription**

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<sup>10</sup> <https://www.federalregister.gov/documents/2023/06/06/2023-11996/agency-information-collection-activities-proposed-collection-comment-request>.

<sup>11</sup> [https://www.reginfo.gov/public/do/PRAViewDocument?ref\\_nbr=202312-0938-004](https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202312-0938-004).

<sup>12</sup> <https://www.federalregister.gov/documents/2023/12/08/2023-27033/agency-information-collection-activities-submission-for-omb-review-comment-request>.

<sup>13</sup> For more specific website requirements, see 42 CFR 423.2265. Part D sponsors should also reference the MCMG.

Payment Plan election request mechanism that Part D enrollees can use to opt into the program and that provides the individual with evidence that the election request was received (e.g., a confirmation number). Section 30.3.1.4 of this draft part two guidance outlines requirements for this website election request mechanism.

In addition to offering an election request mechanism, Part D sponsors must provide on their websites:

- An overview of the program;
- Examples of how the program calculation works with easy-to-understand explanations. CMS encourages Part D sponsors to include a few examples of cost-sharing scenarios that demonstrate when the program would and would not benefit a Part D enrollee;
- A description of who is likely to benefit;
- The financial implications for the enrollee of participating in the program, including that the program is free to join, there are no fees or interest charged under the program, and the program does not reduce the amount of cost-sharing a participant owes for their Part D prescriptions. Part D sponsors are also encouraged to include information about the \$2,000 Medicare Part D OOP cap in 2025;
- The importance of paying monthly bills, including the implications of not paying monthly bills;
- A description of how to opt into and out of the program, including timing requirements around election effectuation;
- A description of the standards for urgent Medicare Prescription Payment Plan Election, as described in section 70.3.8 of the draft part one guidance;
- A description of how Part D enrollees can file complaints and grievances related to the program;
- Contact information that Part D enrollees can use to obtain further information; and
- General information about the Low-Income Subsidy (LIS) program, including information on recent the LIS expansion of eligibility, and how to apply and enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs), noting that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.

Part D sponsors are encouraged to use language from the CMS-developed educational product on the Medicare Prescription Payment Plan and other CMS-provided resources to meet these requirements. The CMS-developed educational product and other resources will be released at a later date and are discussed in more detail in section 40 below. Additionally, CMS encourages Part D sponsors to link to the CMS-developed educational products or CMS-developed resources, where applicable, to ensure the content is up to date.

### 30.2 Targeted Outreach and Education Requirements for Part D Sponsors

Under sections 1860D–2(b)(2)(E)(v)(III)(dd) and 1860D–2(b)(2)(E)(v)(III)(ee) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the enrollee may benefit from

participating in the program and must provide that the pharmacy, after receiving such a notification, informs the enrollee about the program.<sup>14</sup> CMS recognizes, however, that notification of Part D enrollees likely to benefit from the Medicare Prescription Payment Plan *prior* to reaching the pharmacy POS will be a critical component to program success. Early notification will streamline the election process and prevent drug dispensing delays, especially because, as discussed in section 70.3.9 of the draft part one guidance, a POS election option is not planned for 2025. As such, CMS is also requiring Part D sponsors to undertake targeted outreach, both prior to and during the plan year, directly to Part D enrollees likely to benefit from the program.

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

To support Part D sponsors in meeting this requirement, CMS is developing a standardized notice for Part D enrollees identified as likely to benefit from the Medicare Prescription Payment Plan, the “Medicare Prescription Payment Plan Likely to Benefit Notice.” Part D sponsors are required to use this standardized notice to satisfy their obligation to perform targeted outreach to Part D enrollees who are identified as likely to benefit prior to and during the plan year, including those identified through the pharmacy notification process. This outreach, when performed outside of the pharmacy POS notification process, may be done via mail or electronically (based on the Part D enrollee’s preferred and authorized communication methods). If the enrollee is identified through the pharmacy notification process, this outreach must be completed at the pharmacy POS (see section 30.2.2.3 below).

Specific parameters around how and when Part D sponsors must use the “Medicare Prescription Payment Plan Likely to Benefit Notice” to meet the targeted outreach requirements are outlined below. The “Medicare Prescription Payment Plan Likely to Benefit Notice” will be issued through the OMB ICR process, and once approved, will be released in summer 2024 ahead of the CY 2025 Annual Election Period. Additionally, CMS notes that the “Medicare Prescription Payment Plan Likely to Benefit Notice” is a standardized material that Part D sponsors are required to use in the form and manner provided by CMS. Part D sponsors can refer to 42 CR 423.2267(b) for requirements related to the use of standardized materials.

### *30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year*

Section 60.2.1 of the draft part one guidance presented the CMS standardized framework for assessing “likely to benefit.” Specifically, we stated that to be “likely to benefit” from the program, the Part D enrollee would have to incur some level of substantial OOP costs. Further, the Part D enrollee’s highest monthly OOP cost incurred would be more than the highest monthly paid amount under the Medicare Prescription Payment Plan (if the program had applied). In that draft guidance, CMS built upon the likely to benefit definition to define thresholds for targeted Part D enrollee notification at the pharmacy POS. The pharmacy POS notification, as required under sections 1860D–2(b)(2)(E)(v)(III)(dd) and (ee) of the Act, is a key

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<sup>14</sup> Additional information related to the notification of Part D enrollees who are likely to benefit at the POS is included in section 60.2.3 of the draft part one guidance. For information on the framework used to define “likely to benefit,” see section 60.2.1 of the draft part one guidance.



component of the Medicare Prescription Payment Plan. However, as noted above, CMS is aware that proactive notification of Part D enrollees likely to benefit (prior to their interaction at the pharmacy POS) will streamline the program election process and help to prevent drug dispensing delays.

To address this, CMS is requiring that Part D sponsors, prior to and during the plan year, identify Part D enrollees likely to benefit from the program and undertake targeted outreach to inform those Part D enrollees of the program. CMS recognizes that an individual Part D enrollee may find that they would personally benefit from the program even if they would not be identified as likely to benefit under this particular standardized framework. Those individuals are certainly permitted to opt into the program. The definition and framework for “likely to benefit” presented in the draft part one guidance are specifically for identifying Part D enrollees for targeted outreach and communication in the absence of any information regarding an individual’s specific financial circumstances.

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

As discussed in the draft part one guidance, while the Medicare Prescription Payment Plan is open to all Part D enrollees, Part D enrollees incurring high OOP costs earlier in the plan year are generally more likely to benefit. In setting criteria to identify Part D enrollees likely to benefit prior to the plan year, CMS strives to identify individuals who have persistently high costs for covered Part D prescription drugs. That is balanced, however, by a desire to limit notifications to Part D enrollees who are not likely to benefit from participation in the program (such as Part D enrollees for whom the program would initially provide substantial financial relief but later, due to timing constraints, would result in monthly payments that are higher than they would have been absent the program).<sup>15</sup>

With the goal of assessing the persistence of high OOP costs, and thus, the likelihood of a prior year’s OOP costs predicting future OOP burden, CMS analyzed historic Prescription Drug Event (PDE) records. CMS first identified Part D enrollees who had incurred total OOP costs of at least \$2,000<sup>16</sup> in the first three quarters of 2021, then examined their total OOP costs in the subsequent year, 2022. Of the 929,000 enrollees identified who reached \$2,000 in OOP costs in the first three quarters of 2021, 82 to 89 percent met CMS’s quantitative definition of “likely to benefit” in the subsequent year.<sup>17</sup> In addition, the majority (66 percent) of those 929,000 enrollees again had annual OOP costs of at least \$2,000 in the first three quarters of 2022.

CMS’s analysis was based on the patient payment amount for covered Part D claims only, reflecting the actual OOP financial burden for Part D enrollees.

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<sup>15</sup> Please refer to section 60.2.1 of the draft part one guidance for additional information related to identifying Part D enrollees likely to benefit from the Medicare Prescription Payment Plan.

<sup>16</sup> \$2,000 was used in this analysis because it is the Part D annual OOP threshold for CY 2025.

<sup>17</sup> The range of participants meeting the “likely to benefit” definition is based on two calculations—one using the full denominator of enrollees identified based on 2021 PDE data and the other using a denominator only including those who remained Part D enrollees in 2022.

To identify Part D enrollees likely to benefit in advance of the plan year, Part D sponsors are required to assess their current Part D enrollees' prescription drug costs from the current year and conduct outreach to Part D enrollees who incurred \$2,000 in OOP costs for covered drugs through September of that year. (More details on the process for conducting this analysis and outreach are below.)

Part D sponsors may develop supplemental strategies for identification of additional Part D enrollees likely to benefit prior to the plan year. The approach outlined in this section is a minimum requirement. If supplemental strategies are implemented, then Part D sponsors must apply any additional identification criteria to every enrollee of each plan equally.

Prior to the plan year, when a Part D sponsor identifies current Part D enrollees as likely to benefit using the above methods, it is then required to notify each such Part D enrollee in writing that they are likely to benefit from the Medicare Prescription Payment Plan, using the standardized "Medicare Prescription Payment Plan Likely to Benefit Notice" (as discussed above in section 30.2.1). This outreach may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods). The outreach must also include additional information about the Medicare Prescription Payment Plan; this additional information requirement may be fulfilled by including with the notice a CMS-developed educational product about the program (see section 40.1 for additional information about the product). If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed educational product to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through HPMS, and use of marketing material. Additionally, the initial notice may be provided via telephone, so long as the written notice and additional information are sent within three calendar days of the telephone notification.

To fulfill the requirements above, during the fourth quarter of the year, Part D sponsors must review their Part D claims history from the first three quarters of the year to identify Part D enrollees likely to benefit in the upcoming year. Based on this analysis and any additional analysis plan sponsors conduct to identify enrollees who may be likely to benefit from this program, the plan sponsor must send the "Medicare Prescription Payment Plan Likely to Benefit Notice" to identified enrollees no later than the end of the Annual Election Period (open enrollment), which is December 7 of each year. For CY 2025, Part D sponsors must assess claims for covered Part D drugs with dates of services from January through September 2024 and send the "Medicare Prescription Payment Plan Likely to Benefit Notice" in October, November, or early December 2024 (no later than December 7, 2024). If Part D sponsors develop supplemental strategies for identification of Part D enrollees likely to benefit prior to the plan year, these notifications must be provided during the same time frame.

While Part D sponsors are required to notify all Part D enrollees who meet the criteria outlined above, Part D sponsors should be aware that potential changes to a Part D enrollee's clinical condition, medication status, or cost-sharing (e.g., discontinuation of therapy or addition of

supplemental payers) could affect the likelihood that a Part D enrollee may benefit from the Medicare Prescription Payment Plan. Part D sponsors should be aware of potential status changes when contacted by an enrollee to discuss participation in the program and should counsel enrollees accordingly.

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

In addition to the criteria outlined above for identification of Part D enrollees likely to benefit from the program *in advance* of an upcoming plan year, CMS is also requiring that Part D sponsors put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit *during* the plan year. At minimum, Part D sponsors must undertake targeted outreach to Part D enrollees if they become aware in advance of a new high-cost prescription for a Part D enrollee that would trigger the pharmacy POS notification process.<sup>18</sup> Specifically, if Part D sponsors have prior authorization or other utilization management edits in place for a drug that, based on their benefit structure, would result in OOP costs above the pharmacy POS notification threshold, then the Part D sponsor must undertake outreach to the Part D enrollee, informing them of the Medicare Prescription Payment Plan and of the opportunity to opt into the program. (More details on this process are below.) A Part D enrollee is less likely to benefit from opting in during the last quarter of a year. For example, in December, the last month of the plan year, because OOP costs incurred in that month cannot be spread over more than one month. As such, a Part D enrollee should not be notified that they are likely to benefit in the last month of the plan year. Additionally, participants who have already opted into the Medicare Prescription Payment Plan should not be notified about opting into the program while their participation is in effect.

Part D sponsors may develop supplemental strategies for identification of additional Part D enrollees likely to benefit during the plan year. The approach outlined in this section is a minimum requirement. If supplemental strategies are implemented, then Part D sponsors must apply any additional identification criteria to every Part D enrollee equally.

During the plan year, when a Part D sponsor identifies current Part D enrollees using the above methods, it is required to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” (as discussed above in section 30.2.1) to the identified Part D enrollee within the same timeframe that applies to the coverage determination for the associated utilization management requirement.<sup>19</sup> For example, if the Part D sponsor receives a request for an expedited coverage determination for a covered Part D drug with OOP costs above the pharmacy POS notification threshold, they must provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee within 24 hours of receiving the request. This outreach must be performed in writing either by mail or electronically (based on the Part D enrollee’s preferred and authorized communication methods). The outreach must also include additional information about the Medicare Prescription Payment Plan, and this additional information requirement may



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<sup>18</sup> As discussed in section 60.2.4 of the draft part one guidance, CMS is requiring that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs that exceed a set threshold. The specific threshold amount will be published in the final part one guidance.

<sup>19</sup> Please refer to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for coverage determination processing requirements. <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev>.

be fulfilled by including with the notice a CMS-developed educational product about the program. See section 40.1 for additional information about the product. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed educational product to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through HPMS, and use of marketing materials. Additionally, the initial notice may be provided via telephone, so long as the written “Medicare Prescription Payment Plan Likely to Benefit Notice” and additional information are sent within three calendar days of the telephone notification. Part D sponsors are encouraged to inform the Part D enrollee that they are likely to benefit when contacting the Part D enrollee for other reasons, such as while communicating a prior authorization coverage determination.

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

Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program. Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that it is likely the Part D enrollee may benefit from the Medicare Prescription Payment Plan.

As discussed in section 60.2.4 of the draft part one guidance, CMS is requiring that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs that exceed a set threshold. The specific threshold amount will be published in the final part one guidance. To fulfill the requirement for pharmacies to then inform the Part D enrollee, the Part D sponsor must require the pharmacy to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” (discussed above in section 30.2.1) to the Part D enrollee. The Part D sponsor must ensure compliance with the language access and accessibility requirements outlined in section 30.4 in the delivery of the “Medicare Prescription Payment Plan Likely to Benefit Notice.” CMS encourages Part D sponsors to provide pharmacies with additional educational material on the Medicare Prescription Payment Plan, such as the CMS-developed educational product described in section 40.1, which could also be distributed to Part D enrollees along with the notice.

This requirement to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee. Pharmacies are encouraged, but not required, to provide educational material related to the Medicare Prescription Payment Plan at the time they provide an enrollee with the notice.

When a Part D enrollee opts into the Medicare Prescription Payment Plan after receiving the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, in addition to providing the notice of acceptance of election, as described in section 30.3.2 of this guidance, the Part D sponsor is responsible for clearly communicating additional necessary next steps to

the Part D enrollee. Next steps may include, but are not limited to, how to proceed with filling any outstanding prescriptions.

### *30.2.3 Communications with Contracted Providers and Pharmacies*

CMS is aware that health care providers and pharmacists play a key role in cost-of-care conversations with their patients that can include discussions about potential prescription drug costs. CMS encourages Part D sponsors to include information about the Medicare Prescription Payment Plan in their communications with contracted providers and network pharmacies. More specifically for contracted providers, CMS encourages Part D sponsors to target these communications to subgroups of providers based on provider specialty and likelihood of prescribing high-cost covered Part D drugs.

With regard to network pharmacies, CMS encourages Part D sponsors to provide pharmacies with education and resources related to the Medicare Prescription Payment Plan. While some pharmacies, such as specialty pharmacies, may be more likely to dispense high-cost drugs that trigger the POS notification, all pharmacy types would benefit from program resources and a thorough understanding of how the Medicare Prescription Payment Plan program works and how it can benefit participants.

The CMS-developed educational product described in section 40.1 of this guidance may serve as a useful tool for Part D sponsors to communicate information on the Medicare Prescription Payment Plan with both contracted providers and pharmacies.

## 30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors

This section provides an overview of the Medicare Prescription Payment Plan election and termination requirements. Additionally, this section introduces new model materials that CMS will develop to support Part D sponsors in meeting Part D enrollee communications requirements. These model materials and their content serve as an example of how to convey information on the Medicare Prescription Payment Plan to Part D enrollees and program participants, as applicable. Though Part D sponsors are not required to use the model materials and content verbatim, they must base their developed materials on CMS's model materials and must include the elements and information included in CMS's model materials in their developed materials. CMS notes that the "Medicare Prescription Payment Plan Likely to Benefit Notice," discussed above, is a standardized material that Part D sponsors are required to use in the form and manner provided by CMS. Part D sponsors can refer to §§ 423.2267(b) and 423.2267(c) for requirements related to the use of model and standardized materials.

The specific model materials that CMS is developing for the Medicare Prescription Payment Plan and that are outlined in this section will be issued through the OMB ICR process as one package. Once approved, the materials will be finalized by summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.



### *30.3.1 Overview of Election Requirements*

Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to elect into the Medicare Prescription Payment Plan to all Part D enrollees, including Part D enrollees who are LIS-eligible. Under section 1860D–2(b)(2)(E)(v)(II) of the Act, a Part D enrollee may opt into the Medicare Prescription Payment Plan prior to the beginning of the plan year or in any month during the plan year. Additionally, Part D sponsors must allow Part D enrollees to opt into the Medicare Prescription Payment Plan during Part D plan annual enrollment periods, initial Part D enrollment periods, and special Part D enrollment periods. Further, as noted in section 70.3.1 of the draft part one guidance, Part D sponsors must offer paper, telephone, and website program election options.

Part D sponsors are strongly encouraged to provide interested Part D enrollees with additional information about the Medicare Prescription Payment Plan, including offering a review of what their estimated monthly payments under the program may be, to ensure that potential participants understand the financial implications of participation. Part D sponsors are also encouraged to provide support tailored to the potential participant’s unique situation and clearly communicate to enrollees when it appears that they are less likely to benefit from the program (e.g., enrollees with low-to-moderate recurring OOP drug costs).

In addition to the requirements outlined below for requests made via different election mechanisms, Part D sponsors should also reference section 70.3 of the draft part one guidance for requirements related to election into the Medicare Prescription Payment Plan, including procedures for collecting missing information. In communications about the program with current and prospective program participants, Part D sponsors are also reminded that they must provide general information about applying for the LIS program and how to enroll (as an additional or alternative avenue for addressing prescription drug costs), noting that LIS enrollment, for those who qualify, is more advantageous than participation in the Medicare Prescription Payment Plan.

#### *30.3.1.1 Request to Participate in the Medicare Prescription Payment Plan*

CMS is developing a model “Medicare Prescription Payment Plan Participation Request Form” for Part D sponsors that Part D enrollees can use to initiate the request to opt into the program. As discussed above, the specific model language for the “Medicare Prescription Payment Plan Participation Request Form” will be published for public comment in the Federal Register and approved through the OMB ICR process.

As detailed above in section 30.1.1, an election request form, along with information on the Medicare Prescription Payment Plan, must be sent with the membership ID card issuance materials that are provided to new Part D enrollees upon enrollment in the Part D plan.

Part D sponsors must accept election requests they receive regardless of the format of the request (e.g., a letter or email). When a Part D sponsor receives an election request in an alternate format and required information is missing, they must contact the Part D enrollee telephonically or electronically to collect all necessary information and document the Part D enrollee’s and/or

their legal representative's agreement to the Part D sponsor's terms and conditions. Part D sponsors must follow the requirements and procedures related to collecting missing information outlined in section 70.3.3, 70.3.4, and 70.3.5 of the draft part one guidance.

### *30.3.1.2 Paper Election Requests*

When a paper election request is received (e.g., via mail) by the Part D sponsor, the Part D sponsor should ensure the request is complete, the information provided is accurate, and the Part D enrollee and/or their legal representative has agreed to the Part D sponsor's terms and conditions for the program. To expedite the election request process and streamline it for all parties, CMS encourages Part D sponsors to include their terms and conditions for participation in the election request form. This applies whether they use CMS's model "Medicare Prescription Payment Plan Participation Request Form" or develop their own election request form. If the election request is incomplete or inaccurate, or if the terms and conditions are not included in the election request form, then, upon receipt of a paper request, the Part D sponsor must promptly contact the Part D enrollee telephonically or electronically to finalize the election process and document the individual's and/or their legal representative's agreement to the Part D sponsor's terms and conditions (see sections 30.3.1.3 and 30.3.1.4 below for telephonic and electronic requirements and section 70.3.3 of the draft part one guidance for procedures related to collecting missing or incomplete information).

For requests sent to the Part D sponsor by mail, the election request date is the date the request is received by the Part D sponsor, regardless of the date of the postmark. Paper election requests are considered received on the date and time:

- The Part D sponsor initially stamps a document received by regular mail (i.e., U.S. Postal Service); or
- A delivery service that has the ability to track when a shipment is delivered (e.g., U.S. Postal Service, UPS, FedEx, or DHL) delivers the document.

Paper election requests can either be filled out electronically and printed or filled out by hand by a Part D enrollee or their representative. There will be an option for either a pen-and-ink or electronic signature.

### *30.3.1.3 Telephonic Election Requests*

For requests made by telephone, the election request date is the date of the call. A telephonic election request is considered received on the date and time:

- The verbal request is made by telephone with a customer service representative; or
- A message is left on the Part D sponsor's voicemail system if the Part D sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

The call must be recorded, follow a script previously approved by the Part D sponsor based on the content of the model "Medicare Prescription Payment Plan Participation Request Form," include a clear statement that the individual is requesting to participate in the Medicare Prescription Payment Plan, and record a confirmation that the individual understands the Part D

sponsor's terms and conditions. CMS expects Part D sponsors to complete the entirety of the Medicare Prescription Payment Plan election process in that single telephone interaction if the Part D enrollee wishes to participate in the program.

#### *30.3.1.4 Website Election Requests*

For electronic election requests made using the Part D sponsor's website, the election request date is the date the Part D enrollee completes the request through the Part D sponsor's secure electronic portal. An electronic election request is considered received on the date and time a request is received through the plan's website, provided the website and/or portal meets all applicable regulatory requirements. This is true regardless of when a Part D sponsor ultimately retrieves or downloads the request.

CMS expects Part D sponsors to complete the entirety of the Medicare Prescription Payment Plan election request process, including documenting the individual's agreement to the Part D sponsor's terms and conditions, in that single electronic election request. Election request systems must be based on the model "Medicare Prescription Payment Plan Participation Request Form" and include a distinct step that requires the Part D enrollee to activate an "Opt-In Now" or "I Agree" type of button or tool, along with documentation that the Part D enrollee understands the Part D sponsor's terms and conditions.

#### *30.3.2 Notice of Acceptance of Election*

Once the program election request is accepted by the Part D sponsor, the Part D sponsor must communicate that the request to participate in the Medicare Prescription Payment Plan has been accepted and effectuated via written notice. For Part D sponsor requirements related to response times for election requests, please reference the final part one guidance, to be issued in early 2024.

For requests received prior to the plan year, Part D sponsors are required to send a written notice of acceptance of election within the timeframes specified in the final part one guidance.

For requests received during the plan year, regardless of how the Part D enrollee submitted the election request (paper, telephone, or electronic), the Part D sponsor must deliver the notice of acceptance of election within the specified timeframe first telephonically and then via a written notice. Part D sponsors are encouraged to base the script used for the telephone notice on the language included in the "Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan." The Part D sponsor must then deliver a written notice of acceptance of election to the program participant either via mail or electronically, depending on the participant's preferred and authorized communication method, within three calendar days of delivering the initial telephone notice.

For all requests, in addition to the written notification of acceptance of election and effectuation, Part D sponsors must provide the new program participant with the information required in section 70.3 of the draft part one guidance. CMS also encourages Part D sponsors to provide



program participants with digital evidence of their election into the Medicare Prescription Payment Plan.

CMS is developing a model “Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan” to support Part D sponsors in meeting this notice requirement. As discussed above, the specific model language for the “Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan” will be published for public comment in the Federal Register and approved through the OMB ICR process. Once approved, the model notice will be finalized by summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.

### *30.3.3 Notice of Failure to Pay*

Section 1860D–2(b)(2)(E)(v)(IV)(aa) of the Act requires a Part D sponsor to terminate an individual’s Medicare Prescription Payment Plan participation if that individual fails to pay their monthly billed amount. As discussed in section 80.2.1 of the draft part one guidance, if a Part D sponsor determines that a Medicare Prescription Payment Plan participant has failed to pay a monthly billed amount, the Part D sponsor must send the individual an initial notice explaining that the individual has failed to pay the billed amount within 15 calendar days of the payment due date.

CMS is developing a model “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan” to support sponsors in meeting this notice requirement. The specific model language for the “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan” will be published for public comment in the Federal Register and approved through the OMB ICR process. Once approved, the model notice will be released in summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.

### *30.3.4 Notice of Termination of Election Following End of Grace Period*

Section 1860D–2(b)(2)(E)(v)(IV)(aa) of the Act requires a Part D sponsor to terminate an individual’s Medicare Prescription Payment Plan participation if that individual fails to pay their monthly billed amount. A participant will be considered to have failed to pay their monthly billed amount only after the conclusion of the required grace period, as described in section 80.2.2 of the draft part one guidance.

Part D sponsors must provide a notice of termination of participation to Part D enrollees who have failed to pay their outstanding balance within the required grace period. This notice must be sent within three calendar days after the end of the grace period.

CMS is developing a model “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan - Notification of Termination of Participation in the Medicare Prescription Payment Plan” to support sponsors in meeting this notice requirement. The specific model language for the “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan - Notification of Termination of Participation in the Medicare Prescription Payment Plan” will be published for public comment in the Federal

Register and approved through the OMB ICR process. Once approved, the model notice will be released in summer 2024 ahead of the CY 2025 Annual Election Period.

### *30.3.5 Notice of Voluntary Termination*

Part D sponsors must have a process in place to allow Part D enrollees participating in the Medicare Prescription Payment Plan to voluntarily terminate their participation in the program. After a participant voluntarily terminates their participation in the program, Part D sponsors must work with the enrollee to determine how they will pay their outstanding balance, which may include a lump sum payment; however, Part D sponsors cannot require full immediate repayment. If the enrollee chooses to continue paying in monthly amounts, Part D sponsors must continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year. After opting out, the individual will pay any new OOP costs directly to the pharmacy. The Part D sponsor must process the participant's voluntary termination request and send the individual a notification confirming the termination within 10 calendar days of receipt of the request. The Part D sponsor must also maintain a record of individuals who have been terminated from the program.

CMS is developing a model "Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan" to support Part D sponsors in meeting this notice requirement. The specific model language for the "Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan" will be published for public comment in the Federal Register and approved through the OMB ICR process. Once approved, the model notice will be released in summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.

As stated in section 80.5 of the draft part one guidance, when a Part D enrollee disenrolls from the Part D plan, such as when switching plans during the coverage year or for a subsequent coverage year, their participation in the Medicare Prescription Payment Plan, as administered by the Part D plan losing the enrollee, effectively ends. Part D sponsors are encouraged to use language from the "Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan" to communicate with these Part D enrollees, as well.

### 30.4 Language Access and Accessibility Requirements

Under section 1860D–2(b)(2)(E)(v) of the Act, both CMS and Part D sponsors are required to provide Medicare Prescription Payment Plan information and educational materials to Part D enrollees. CMS requires outreach materials and communications be provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds.

As required by § 423.2267 for all materials that CMS deems vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form to be translated and made available in markets with a significant population of persons with limited English proficiency. In

addition, for markets with a significant population of persons with limited English proficiency, the requirements finalized in the CY 2024 MA and Part D Final Rule (CMS–4201–F) apply to all Medicare Prescription Payment Plan educational and communications materials.<sup>20</sup> These requirements stipulate that Part D sponsors must provide translated materials to Part D enrollees on a standing basis in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area.

In addition, under § 423.2267, materials must be provided in a non-English language and an accessible format using auxiliary aids and services upon request or otherwise learning of the Part D enrollee’s primary language and/or need for an accessible format. As stated above in section 30.1.5, Part D sponsors’ websites must comply with anti-discrimination provisions, such as Section 508 of the Rehabilitation Act, with regard to providing access to websites and other materials, so that individuals can read sites and materials with screen reader technology.

The Part D regulation at § 423.2267(e)(33) also requires that Part D sponsors use a multi-language insert (MLI) that informs the reader, in several commonly spoken non-English languages used in the United States, as well as in any additional non-English language that is the primary language of at least five percent of the individuals in a PBP service area, that interpreter services are available for free.<sup>21</sup> Plans are required to include the MLI whenever a Medicare beneficiary is provided a CMS-required material.

The above requirements apply to information about the Medicare Prescription Payment Plan that is included in the following modified or newly created documents that Part D sponsors must use to educate on, or communicate about, the Medicare Prescription Payment Plan:<sup>22</sup>

- ANOC;
- EOC;
- EOB;
- Part D sponsor websites;
- Election request form;
- Notice of election approval;
- Notice of failure to pay;
- Notice of involuntary termination;
- Notice of voluntary termination; and
- The “Medicare Prescription Payment Plan Likely to Benefit Notice.”

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

Section 1860D-2(b)(2)(E)(v)(I) of the Act requires CMS to provide educational materials to Part D enrollees on the option to participate in the Medicare Prescription Payment Plan. To support

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<sup>20</sup> <https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf>.

<sup>21</sup> Under the 2023 MA and Part D Final Rule, the MLI must state “We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service.” <https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf>.

<sup>22</sup> <https://www.cms.gov/medicare/health-plans/managedcaremarketing/finalpartcmarketingguidelines>.

broad education of all Part D enrollees on the availability of the program, CMS will develop new Part D educational resources and will update existing Part D resources that provide individuals with information on Medicare Part D.

#### 40.1 Information on the Medicare Prescription Payment Plan

CMS will develop and provide an educational product for Part D enrollees on the Medicare.gov website and through other communication channels. Additionally, interested parties, such as Part D sponsors, pharmacies, providers, beneficiary advocates, and others, are encouraged to use this product to educate Part D enrollees.

Part D sponsors' use of this educational product will satisfy the Part D sponsor requirement to provide information on the Medicare Prescription Payment Plan:

- on their website (section 30.1.5);
- alongside the election request form included in the membership ID Card mailing (section 30.1.1); and
- alongside the “Medicare Prescription Payment Plan Likely to Benefit Notice” when sent prior to or during the plan year (section 30.2.2).

Additionally, Part D sponsors are encouraged to use this educational product to:

- provide additional information to pharmacies that pharmacists can furnish to Part D enrollees identified as likely to benefit at the POS alongside the “Medicare Prescription Payment Plan Likely to Benefit Notice” (section 30.2.2.3);
- communicate with contracted providers (section 30.2.3) and other interested parties; and
- describe the Medicare Prescription Payment Plan in other Part D enrollee education, communications, and marketing materials.

#### 40.2 Modifications to Existing Part D Resources

CMS will make appropriate modifications to CMS-provided Medicare Part D documents, web content, and tools to ensure that individuals have the resources needed to learn about the availability of the program before the plan year begins and understand how the program may benefit them based on their needs. Resources that CMS may modify include the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder, among others.

#### 40.3 National Outreach and Education Efforts

CMS will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates—including State Health Insurance Assistance Program (SHIP) counselors—have sufficient support and materials needed to effectively communicate the availability and nuances of this program to individuals.

## 50. Pharmacy Processes

Pharmacies play an important role in operationalizing the Medicare Prescription Payment Plan. Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program. Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Given this statutory requirement, Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees.

In this section, CMS provides additional information around pharmacy processes related to the Medicare Prescription Payment Plan. Except as otherwise required in this guidance or under other applicable requirements, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including but not limited to, mail order, home infusion, specialty, and long-term care pharmacies.

### 50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount

In the draft part one guidance for the Medicare Prescription Payment Plan, CMS stated that the likely to benefit notification required at the pharmacy POS will be based on the OOP costs incurred for a single prescription. Part D sponsors will be responsible for notifying the pharmacy when OOP prescription costs equal or exceed the determined threshold that will be finalized in the final part one guidance. This notification will be returned to the pharmacy on the primary Part D claim response from the Part D sponsor or pharmacy benefit manager (PBM). CMS is aware, however, that a small portion of Part D enrollees will have supplemental coverage, such as through a State Pharmaceutical Assistance Program (SPAP), charity, or other health insurance (OHI). In these cases, the final patient pay amount on a covered Part D prescription drug claim may then be reduced below the required notification threshold because of the contributions of a supplemental payer. CMS intends to provide language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” that recommends enrollees with supplemental coverage seek advice related to their specific situation prior to opting into the Medicare Prescription Payment Plan.

Part D sponsors should ensure that their customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election. When discussing a Part D enrollee’s prescription drug costs, customer service representatives may need to review records for Information Reporting (Nx) transactions, indicating supplemental coverage or OHI. As discussed in more detail in the draft part one guidance, all Part D enrollees are eligible for the Medicare Prescription Payment Plan, but those with low OOP costs are less likely to benefit.

## 50.2 Pharmacy POS Notifications Late in the Plan Year

As specified by section 1860D–2(b)(2)(E)(iv) of the Act, the number of months remaining in the plan year is an important component of the maximum monthly cap calculation.<sup>23</sup> As described in section 30.1 of the draft part one guidance, the maximum monthly cap in the first month of program participation is determined by calculating the annual OOP threshold minus any Part D costs the Part D enrollee incurred during the year before opting in, divided by the number of months remaining in the plan year. Given that the pharmacy POS threshold will be a static amount, this may result in scenarios late in the plan year in which Part D enrollees who receive the “Medicare Prescription Payment Plan Likely to Benefit Notice” at the pharmacy based on their OOP costs, but whose costs are below the maximum monthly cap, are then required to pay the full amount as part of their first month’s bill. For example, if a Part D enrollee has not yet opted into the Medicare Prescription Payment Plan and fills a new prescription with an OOP cost of \$650 in October 2025, their maximum monthly cap in the first month could be as high as \$666.67 (assuming \$0 in prior true out-of-pocket (TrOOP) accumulation). In this scenario, a Part D enrollee could receive the POS notification based on their OOP costs exceeding the threshold, but if they opted into the Medicare Prescription Payment Plan, because their OOP costs are below the maximum monthly cap, the Part D sponsor would bill them for the entire \$650 as part of their first month’s bill.<sup>24</sup> Part D sponsors should ensure that customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election.

## 50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies

As noted above, in general, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including, but not limited to, mail order, home infusion, specialty, and long-term care pharmacies. In pharmacy settings in which there is direct contact with enrollees (e.g., community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. This includes pharmacies with a drive-through or curbside pick-up option. However, CMS is aware that some pharmacy types may not have direct contact with Part D enrollees and/or may lack a practical means for providing a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” directly to the Part D enrollee. CMS is providing additional guidance below related to these settings.

In addition, CMS notes that regardless of the setting, if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the Part D sponsor must ensure that the pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee. For example, if a Part D enrollee visits a retail pharmacy to pick up their prescription but then declines to complete

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<sup>23</sup> See section 30 of the draft part one guidance for additional details on program calculations. The values there are illustrative; the POS threshold will be published as part of the final part one guidance.

<sup>24</sup> In comparison to the example described here, if a Part D enrollee had a prescription with OOP costs of \$650 in February instead of October (with no prior TrOOP accumulation), their maximum monthly cap in the first month would be \$181.82.

the transaction because of the cost, the Part D sponsor must still ensure that the pharmacy provides the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” to that Part D enrollee.

Pharmacies may also choose to develop additional strategies to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to enrollees identified as likely to benefit. For example, pharmacies with disease management or medication management programs may choose to include Medicare Prescription Payment Plan information as a component of those processes. In addition to providing a hard copy, pharmacies may also choose to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in other modes of communication with enrollees identified as likely to benefit, such as through a patient portal or secure email.

#### *50.3.1 Long-Term Care Pharmacies*

Long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident). In these cases, the pharmacy delivers medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee). As such, when the POS notification is received by a long-term care pharmacy, the plan sponsor is not required to ensure that the long-term care pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to dispensing the medication. Instead, the plan sponsor can require the long-term care pharmacy to provide the notice to the Part D enrollee at the time of its typical billing process.

#### *50.3.2 Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacies*

I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost-sharing, as defined by their plan’s benefit structure, is not collected at the POS. As such, if a high-cost prescription drug claim for an IHS-eligible Part D enrollee is submitted to a Part D sponsor from an I/T/U pharmacy, the Part D sponsor is not required to return the pharmacy notification indicating the enrollee is likely to benefit from the program.

#### *50.3.3 Other Pharmacy Types*

For other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. This requirement should not, however, be interpreted as a requirement to delay dispensing the medication. Pharmacies are encouraged to utilize existing touchpoints with Part D enrollees, such as outreach to review medication instructions or collect a method of payment, to convey the content of the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to processing payment for the prescription that triggered the notice. CMS encourages Part D sponsors to work with pharmacies to establish and maintain reasonable

procedures related to the timing and number of attempts for prompt notification of identified Part D enrollees.

#### 50.4 Readjudication of Prescription Drug Claims for New Program Participants

Part D enrollees who opt into the Medicare Prescription Payment Plan will pay \$0 at the POS for a covered Part D drug instead of the OOP cost-sharing they would normally pay when filling a prescription. For claims to be processed appropriately using the Medicare Prescription Payment Plan BIN/PCN methodology, the date of service on the primary Part D claim and the additional program-specific transaction must be on or after the date of program effectuation.

When a Part D enrollee receives the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription. As such, when the Part D enrollee returns to the pharmacy to pick up their prescription(s) after successfully opting into the program, all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary must be readjudicated to allow for appropriate processing by the Part D sponsor and/or PBM. This includes unpaid claims for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification.

For example, a Part D enrollee is prescribed a new medication with an OOP cost that is above the POS notification threshold. The plan would notify the pharmacy that the enrollee is likely to benefit from the Medicare Prescription Payment Plan. The pharmacy would then provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee. The enrollee decides to leave the pharmacy without paying for their high-cost prescription, so they can contact their plan and opt into the program. However, the pharmacy also has two other covered Part D prescriptions filled for the Part D enrollee from prior dates of service, for which the Part D enrollee also decided to leave the pharmacy without picking up and paying. When the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess all three claims, so the program participant pays \$0 at the pharmacy for all three drugs. Alternatively, the Part D enrollee could choose to pick up and pay for the two other covered Part D prescriptions at the initial pharmacy visit and only return for the high-cost prescription that triggered the notification once their election into the Medicare Prescription Payment Plan has been effectuated. The pharmacy must then reverse and reprocess only the claim for the high-cost prescription that is being billed under the program, so that the program participant pays \$0 at the pharmacy for that prescription. This same process applies when the Part D enrollee has prescriptions that have not yet been picked up and paid for at multiple pharmacies.

In the case of same-day program effectuation (when the Part D claim date of service is the same as the date of program effectuation), the pharmacy is not required to reverse and resubmit the Part D claim, provided that they otherwise obtain the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.

CMS notes that, in general, plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for



by the Part D enrollee. As noted in section 70.3.8 of the draft part one guidance, Part D sponsors must have processes in place to reimburse enrollee cost-sharing for urgent prescriptions when an enrollee has met the conditions for a retroactive election into the Medicare Prescription Payment Plan.

## 50.5 Processing of Covered Part D Claims for Program Participants in Special Settings

### *50.5.1 Long-Term Care Pharmacies*

CMS is aware that there are multiple types of payment arrangements between long-term care pharmacies and long-term care facilities and/or Part D enrollees. In some situations, long-term care pharmacies do not collect Part D cost-sharing from the enrollee but instead bill the long-term care facility for the final patient OOP responsibility. When such an arrangement is in place between a long-term care pharmacy and a long-term care facility, and an enrollee in a long-term care facility is participating in the Medicare Prescription Payment Plan, billing the participant's Part D plan's Medicare Prescription Payment Plan BIN/PCN for the participant's OOP costs (when the pharmacy would not have otherwise directly billed the enrollee) may result in additional financial burden on that participant. In such cases, CMS encourages Part D sponsors to take the participant's particular circumstances into account when considering Medicare Prescription Payment Plan billing practices and to work with the participant, their authorized representative, and the long-term care pharmacy to understand the best billing approach for the participant.

### *50.5.2 I/T/U Pharmacies*

As noted in section 50.3.2, I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost-sharing, as defined by their plan's benefit structure, is not collected at the POS. Given that, if an IHS-eligible Part D enrollee is also participating in the Medicare Prescription Payment Plan, the I/T/U pharmacy cannot bill the Part D plan's Medicare Prescription Payment Plan BIN/PCN. Instead, the I/T/U pharmacy must process the claim as if the IHS-eligible enrollee were not participating in the Medicare Prescription Payment Plan. If a Part D sponsor receives a claim from an I/T/U pharmacy for an IHS-eligible enrollee that was submitted to the Medicare Prescription Payment Plan-specific BIN/PCN, the Part D sponsor must reject the claim. To help prevent this situation from occurring, Part D sponsors must also put in place processes to prevent Medicare Prescription Payment Plan BIN/PCNs from being returned on paid claim responses to I/T/U pharmacies.

These requirements apply only with respect to I/T/U pharmacies that dispense prescriptions at no cost to the IHS enrollee. The plan sponsor must ensure other network pharmacies providing services to IHS-eligible Part D enrollees process claims in accordance with the Medicare Prescription Payment Plan requirements, as outlined in the draft part one guidance and elsewhere in this draft part two guidance.

Part D sponsors should also ensure that their customer service representatives are aware of this situation regarding I/T/U pharmacies when receiving inquiries from Part D enrollees regarding

program election. In discussing a Part D enrollee's prescription drug costs, customer service representatives may need to review the primary pharmacy type used by the Part D enrollee. Part D enrollees who use solely I/T/U pharmacies, and thus have \$0 in OOP costs for covered Part D drugs, may not benefit from participation in the Medicare Prescription Payment Plan.

## **60. Part D Sponsor Operational Requirements**

This section builds on the draft part one guidance and discusses the various operational requirements that Part D sponsors should be aware of and must comply with in implementing the program.

### **60.1 Part D Bidding Guidance for CY 2025**

Section 1860D-2(b)(2)(E)(v)(VI) of the Act requires Part D sponsors to treat any unsettled balances with respect to amounts owed by participants under the Medicare Prescription Payment Plan as plan losses. In addition, the statute requires that the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids. If a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells an unsettled balance as a debt, it cannot treat the amount as a loss and cannot include it in its bid. Only uncompensated unsettled balances can be included in the bid.

Given these changes, the Part D bid pricing tool (BPT) will be modified to reflect projected losses associated with the Medicare Prescription Payment Plan. Specifically, these losses must be reflected as administrative costs in the Part D BPT. The CY 2025 Part D BPT must be completed by following the applicable guidance for CY 2025 bidding, which will be made available at the following hyperlink: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions>.

### **60.2 Medical Loss Ratio (MLR) Instructions**

Sections 1857(e)(4) and 1860D-12(b)(3)(D) of the Act require that MA organizations and Part D sponsors be subject to financial and other penalties for a failure to have an MLR of at least 85 percent. The MLR is computed at the contract level and is expressed as a percentage of revenue used for patient care (for example, incurred claims for clinical services and prescription drug costs and quality improvement activities) rather than for such other items as administrative expenses or profit. The levels of sanctions for failure to meet the 85 percent minimum MLR requirement include remittance of funds to the Secretary, a prohibition on enrolling new members, and ultimately contract termination. To monitor this requirement and administer any of the penalties, CMS requires MA organizations and Part D sponsors to report MLR data to CMS on an annual basis, pursuant to the regulations at §§ 422.2460 and 423.2460.

Section 1860D-2(b)(2)(E)(v)(VI) of the Act specifies that any unsettled balances with respect to amounts owed under the Medicare Prescription Payment Plan “shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.” As Consistent with the inclusion of plan losses in the administrative expense portion of the Part D bid, unsettled balances from the Medicare Prescription Payment

Plan will be considered administrative costs for purposes of the MLR calculation and therefore be excluded from the MLR numerator.

### 60.3 Monitoring and Compliance

As discussed in section 100 of the draft part one guidance for the Medicare Prescription Payment Plan, CMS will require Part D sponsors to report information related to the program through PDE records and new reporting requirements.<sup>25</sup> Additional guidance on PDE reporting will be issued as part of the PDE reporting instructions, which will be published in spring 2024. Additional details related to other reporting requirements can be found in the draft part one guidance and associated OMB ICR packages:

- The MARx Medicare Prescription Payment Plan Beneficiary-Level Data Elements (CMS-10887; OMB 0938-New) ICR, which was published on January 26, 2024 for a 60-day public comment period, with comments due by March 26, 2024. It can be accessed here: <https://www.federalregister.gov/documents/2024/01/26/2024-01582/agency-information-collection-activities-proposed-collection-comment-request>
- The Medicare Part D Reporting Requirements (CMS-10185; (OMB 0938-0992) ICR, which was published on February 2, 2024 for a 60-day public comment period, with comments due by April 2, 2024. It can be accessed here: <https://www.federalregister.gov/documents/2024/02/02/2024-02095/agency-information-collection-activities-proposed-collection-comment-request>
- The Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments (CMS-10174; OMB: 0938-0982) ICR, which was published on December 18, 2023 for a 60-day public comment period, with comments due by February 16, 2024. It can be accessed here: <https://www.federalregister.gov/documents/2023/12/18/2023-27684/agency-information-collection-activities-proposed-collection-comment-request>

CMS will also monitor and collect data about beneficiary complaints and grievances reported via the Medicare Complaints Tracking Module (CTM) to assess compliance with all Medicare Prescription Payment Plan requirements, beneficiary protections, and program integrity. With respect to beneficiary complaints and grievances reported via the CTM, CMS will assess whether an additional CTM category or subcategory is needed for the Medicare Prescription Payment Plan in future years. Please refer to section 30 of the latest Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for details on grievance process requirements and section 40 for details on appeals requirements.<sup>26</sup>

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<sup>25</sup> Please see section 100 of the draft part one guidance for additional information: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>.

<sup>26</sup> <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev>.

In addition, CMS expects Part D sponsors to incorporate the Medicare Prescription Payment Plan into their compliance programs to ensure that they are meeting program requirements.<sup>27</sup> Part D sponsors are reminded that they must comply with the reporting requirements at §§ 423.505(f) and 423.514, and applicable final Medicare Part D Reporting Requirements<sup>28</sup> with respect to the Medicare Prescription Payment Plan.

#### 60.4 Audits

CMS and/or its contractors may conduct specific audits of Part D sponsors' implementation of the Medicare Prescription Payment Plan and may initiate audit activity that requires additional data collection or site visits.<sup>29</sup>

#### 60.5 Direct and Indirect Remuneration (DIR) Reporting Guidance

Section 1860D-15(f)(1)(A) of the Act requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of section 1860D-15 of the Act, including the calculation of reinsurance and risk-sharing. Therefore, each year, Part D sponsors are required to report to CMS drug costs and DIR associated with the Medicare Part D benefit.

CMS anticipates no changes to DIR calculations or reporting due to the Medicare Prescription Payment Plan. Part D sponsors should continue to report DIR in accordance with the explanatory guidance and instructions issued annually by CMS.

CMS encourages interested parties to submit comments on this draft part two guidance no later than March 16, 2024, as per the instruction in the Introduction section of this document.

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<sup>27</sup> 42 CFR § 423.504(b)(4)(vi) requires Part D sponsors to adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. Please refer to Chapter 9 of the Prescription Drug Benefit Manual for additional information regarding compliance program requirements.

<sup>28</sup> For the most recent Medicare Part D Reporting Requirements, see:

<https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements>.

<sup>29</sup> 42 CFR §§ 422.504(e) and 423.505(e).

Tony Evers  
Governor



DIVISION OF PUBLIC HEALTH

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Date: March 12, 2024

To the Centers for Medicare and Medicaid Services (CMS),

The Wisconsin Bureau of Aging and Disability Resources would like to share the below comments regarding [part two the draft guidance for the Medicare Prescription Payment Plan](#) shared in February 2024.

## Background on the Wisconsin Bureau of Aging and Disability Resources

The Wisconsin Department of Health Services (DHS) houses the Division of Medicaid Services (DMS), which administers the state Medicaid program, and the Division of Public Health, in which the Bureau of Aging and Disability Resources (BADR) is housed. BADR administers the State Health Insurance Assistance Program (SHIP) and Medicare Improvements for Patients and Providers Act (MIPPA) grants, whose purpose is to provide free and unbiased Medicare counseling to Wisconsin residents.

BADR develops and manages programs that serve persons who are elderly, persons with disabilities, persons in need of adult protective services, and persons who need or receive information about or access to community-based long-term support through an aging and disability resource center. BADR actively promotes individual choice, dignity, relationships, overall health, community participation, self-sufficiency, and respect.

## Comments

### 30.1 General Outreach and Education

BADR **supports** the plan to add information about the Medicare Prescription Payment Plan (MPPP) to existing Part D enrollment and educational materials.

BADR **does not support** the proposal to require all Part D sponsors to advertise the MPPP. This could make it seem like only select Part D sponsors offer the MPPP and cause beneficiary confusion. If CMS does allow sponsors to mention the MPPP in advertising materials, BADR strongly suggests that CMS require they use a CMS-determined script that makes it clear that the MPPP is available for all Part D plans.

BADR **recommends** that MPPP information and notices include information about the possibility of terminated participants' unpaid debt being sent to collections. This is a significant risk of which beneficiaries should be aware.

BADR **recommends** that MPPP information and notices include information about how to file appeals and grievances related to MPPP.

#### 30.1.1 Required Mailings with Membership ID Card Issuance

BADR **does not support** the proposal to require Part D sponsors to include an MPPP election form along with the Part D membership insurance card. BADR is concerned that beneficiaries will mistakenly think that they are required to complete the form. BADR believes the requirement for plans to provide general and targeted outreach for MPPP is sufficient instead.

#### 30.1.5 Part D Sponsor Websites

BADR **supports** the requirement that Part D sponsors list information about the MPPP and Low Income Subsidy on their websites **with the amendment that** CMS require Part D sponsors include a disclaimer on their websites stating the MPPP is an option for all Part D plans. This will help avoid the mistaken impression that the MPPP is a plan benefit.

## 30.2 Targeted Outreach and Education Requirements for Part D Sponsors

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

BADR **recommends** the "Medicare Prescription Payment Plan Likely to Benefit Notice" draft be posted for public comment. BADR **recommends** the notice be as concise as possible with plain language, emphasizing that the MPPP is optional and that the notice list referrals for assistance, including the Part D plan, 1-800-MEDICARE, and the State Health Insurance Assistance Program (SHIP)

### 30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year

BADR **recommends** that CMS update the Medicare.gov Plan Finder to:

- Notify beneficiaries when they may benefit from enrollment into the MPPP.
- Provide estimated costs under the MPPP compared to normal costs under the Part D structure.
- Enroll into the MPPP.

One of the best times to identify individuals likely to benefit from the MPPP is when they are conducting plan comparisons and enrolling into their Part D plan. Adapting the Plan Finder will help preemptively identify these individuals and facilitate enrollment.

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

BADR **supports** the plan to have Part D sponsors preemptively identify individuals likely to benefit from the MPPP by identifying who incurred \$2,000 in out-of-pocket costs through September of that year.

BADR **recommends** this targeting outreach include information about the opportunity to compare other prescription drug coverage options during the annual Open Enrollment Period (OEP) and the Low Income Subsidy.

BADR **does not support** the proposal to have plan sponsors send the “Medicare Prescription Payment Plan Likely to Benefit Notice” by December 7. BADR is concerned that sending this notice during the OEP can create confusion for beneficiaries, particularly if they have enrolled into a different plan between when the notice was sent and received. BADR **recommends** that sponsors be required to send this notice *prior to* the start of the OEP and that the notice include information about the opportunity to change Part D coverage during the OEP.

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

BADR **supports** the proposal to have Part D sponsors educate beneficiaries they know are about to take a high-cost drug plan.

BADR **recommends** that this targeted, mid-year education be limited to the **first three quarters of the year** rather than the first eleven months. BADR thinks that sending MPPP notices during the OEP will cause more confusion than benefit.

BADR **supports** the proposal to require Part D sponsors to apply any additional outreach identification criteria to all Part D members equally.

BADR **supports** the proposal to provide the MPPP notice within the same timeframe as the applied coverage determination.

### **30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors**

#### *30.3.1.2 Paper Election Requests*

BADR **does not support** the proposal to allow Part D sponsors to create their own version of the “MPPP Participation Request Form.” Standardizing the “MPPP Participation Request Form” would reduce confusion amongst beneficiaries and partners and facilitate enrollment requests, as the form could be downloadable and applicable to all beneficiaries. At the very least, BADR recommends that Part D sponsors be required to accept the CMS “MPPP Participation Request Form” in addition to their own version.

BADR **does not support** the proposal to have the election request date for mailed requests be the date of receipt. Beneficiaries should not be penalized for any delays in the mail service. BADR **recommends** using the postmark date as the election request date instead.

BADR **supports** the acceptance of electronic signatures.

#### *30.3.1.3 Telephonic Election Requests*

BADR **supports** the proposal to have the election request date be the date of a call or voicemail.

BADR **supports** the proposal to have the call be recorded and follow a script that includes “a clear statement that the individual is requesting to participate in the Medicare Prescription Payment Plan, and record a confirmation that the individual understands the Part D sponsor’s terms and conditions.”

#### *30.3.1.4 Website Election Requests*

BADR **supports** the proposal to have the election request date be the date of enrollment via a sponsor’s electronic portal.

BADR **recommends** that CMS develop an option for people to enroll in the MPPP via their Medicare.gov account on Medicare.gov as well.

BADR **recommends** that all electronic submission portals provide a confirmation page with the date and time listed.

### 30.3.2 Notice of Acceptance of Election

BADR **supports** the proposal to require Part D sponsors to provide confirmation of MPPP participation acceptance in writing.

BADR **recommends** CMS enhance Medicare.gov so that a copy of the participation confirmation is viewable in one's Medicare.gov account.

BADR **recommends** that CMS require, rather than encourage, sponsors to provide digital evidence of one's MPPP election.

### 30.3.5 Notice of Voluntary Termination

BADR **supports** the requirement for Part D sponsors to work with enrollees to determine how they will pay outstanding balances and the prohibition against allowing sponsors to request full immediate payment.

BADR **recommends** that CMS develop further guidelines dictating timelines and amounts for payment after termination from the MPPP.

## 30.4 Language Access and Accessibility Requirements

BADR **supports** the requirements for Part D sponsors to provide translated materials to Part D enrollees in the top five non-English languages spoken in their service area.

BADR **recommends** that CMS also develop videos explaining the MPPP program and its notices in American Sign Language with accessible closed captioning.

## 40. CMS Part D Enrollee Education and Outreach

### 40.3 National Outreach and Education Efforts

BADR thanks CMS for its commitment to working with and supporting SHIP counselors. The Wisconsin SHIP network is both eager to help beneficiaries who may benefit from the MPPP and concerned about potential strain on our already high caseloads, so we look forward to the materials that CMS plans to develop.

## 50. Pharmacy Processes

BADR **supports** uniformity of MPPP policy across all pharmacy types.

### 50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount

BADR appreciates CMS' consideration of how the MPPP will interact with supplemental prescription coverage. BADR **requests additional guidance** on how billing would work with State Pharmaceutical



Assistance Programs (SPAPs) in particular. Wisconsin's SPAP, [SeniorCare](#), coordinates with Part D, so we will need to provide training and resources on this subject.

## 50.5 Processing of Covered Part D Claims for Program Participants in Special Settings

### 50.5.2 I/T/U Pharmacies

BADR thanks CMS for its consideration of how the MPPP billing process will work with Indian Health Services claims.

## 60. Part D Sponsor Operational Requirements

### 60.3 Monitoring and Compliance

Though it is outside the scope of this proposal, BADR **requests** CMS seriously consider increasing the number of SHIP users allowed access to MARx. Currently, CMS only allows two SHIP state staff to access MARx. With the implementation of the MPPP, real-time access to enrollment status will be even more important to effectively assist beneficiaries who request assistance. Additionally, BADR requests CMS consider lifting the requirement that SHIP MARx users be state staff. Many SHIPs, including Wisconsin's SHIP, are decentralized, meaning most team members work at non-state agencies.

BADR **requests additional guidance** regarding how and when to submit Complaint Tracking Module (CTM) complaints related to MPPP prior to its implementation.

### Other Comments

BADR **suggests** CMS consider providing beneficiaries with an option to opt out of further reminders about the MPPP for the calendar year.

BADR **recommends** renaming the MPPP so "plan" is not in the title as this could be confused as another type of Part D plan. For example, CMS could call this the "Medicare Monthly Prescription Payment Option" instead.

BADR **requests additional guidance** related to MPPP appeals and grievance processes.

Thank you,

The Wisconsin Bureau of Aging and Disability Resources